CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Legislative Briefing Materials

Prepared for

Senate Health and Human Services Committee

August 14, 2014

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CPRIT's IMPLEMENTATION PLAN - STATE AUDITOR'S RECOMMENDATIONS

All SAO recommendations include the page number of the SAO report

Updated June 30, 2014

Rec.		Status	Date
Chapter 1A - CPRIT Should Ensure That All Grant Decisions Are Free from Real or Apparent Conflicts of Interest			
01 pg 8	**Recommendation:** Establish and implement rules that prohibit the CEO from discussing grant recommendations with individual members of the oversight committee before presenting those recommendations to the full Oversight Committee.	**Fully Implemented**	02/2014
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 prohibiting discussion between individual members of the Oversight Committee and the Program Integration Committee (PIC) until the PIC recommendations are presented to the full Oversight Committee. The process established by the adopted rule was followed for the training and MIRA grants recommended by the PIC and approved by the Oversight Committee in February 2014. *CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee.* **Documentation:** OC members sign a certification of non-communication following each award cycle.		
	Statute/Rule/Other: H&S Code § 102.251(d), 25 T.A.C. § 702.19(f), CPRIT Code of Conduct § V.F.(2)		
02 pg 2	**Recommendation:** Refrain from leasing office space from grantees and consider locating the offices of the chief commercialization officer, chief scientific officer, and director of scientific research in the same office location as CPRIT executive management.	**Fully implemented**	05/31/13
	Implementation: Leases were cancelled with Rice University and UTSW, effective November 30, 3012, and May 31, 2013, respectively. The Oversight Committee adopted a new administrative rule in January 2014 prohibiting an Oversight Committee member or a CPRIT employee from having an office in a facility owned by a grant applicant or grant recipient. The prohibition was included in the Code of Conduct adopted November 1, 2013.		
	Statute/Rule/Other: H&S Code § 102.057, 25 T.A.C. § 702.9(c)(15), CPRIT Code of Conduct § II.C.(3)		

Rec.		Status	Date
03 pg 8	**Recommendation:** Revise its rules to prohibit members of the oversight committee, peer reviewers, and employees from engaging in business activities with grant applicants and grantees.	**Fully implemented**	11/01/13
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 prohibiting an Oversight Committee member, CPRIT employee, or PIC member from being employed by or participating in the management of a business entity. A similar rule was adopted in January 2014 applicable to peer reviewers. The prohibition was included in the Code of Conduct adopted November 1, 2013. A change was also made to peer reviewer agreements effective September 1, 2013. **Documentation:** Code of Conduct, Peer Reviewer agreements		
	Statute/Rule/Other: H&S Code §§ 102.109 (b)(2), 102.156(c), 25 T.A.C. §§ 702.9(c)(8), 703.5 (g),(h), CPRIT Code of Conduct §§ II.B.(15), C.(1),(2)		
04 pg 9	**Recommendation:** Establish and implement a process to prevent CPRIT from awarding grants to applicants that made contributions to the CPRIT Foundation, as required by the General Appropriations Acts (81st and 82nd Legislatures).	**Fully implemented**	05/3/13 (awards and applications filed prior to 6/14/13) 02/19/14 (grants made following 6/14/13)
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 requiring grant applicants to certify that the grant applicant has not made and will not make a donation to CPRIT or to any foundation established to benefit CPRIT. The process was fully implemented in February 2014 for the first cycle of awards submitted following the end of the moratorium. For awards made based on applications submitted prior to the adoption of the administrative rule, CPRIT's Chief Compliance Officer cross-checked all grant awards against the list of CPRIT Foundation donors and reported the information to CPRIT's CEO. CPRIT's CEO sent a written request to the CPRIT Foundation Executive Director to return donations to five individuals. The CPRIT Foundation confirmed the return of the donations on May 3, 2013. **Documentation:** Grant Pedigree, List of donors to the CPRIT Foundation, CCO April 22, 2013 report, CEO April 23, 2013 letter to Foundation, May 3, 2013 confirmation from CPRIT Foundation that identified donations were returned.		
	Statute/Rule/Other: H&S Code § 102.251(e), 25 T.A.C. § 703.3(h)(1)		
05 pg 9	**Recommendation:** Upon receipt of grant applications, require its chief prevention officer, chief scientific officer, and chief commercialization officer to compare the list of grant applicants to the list of donors to the CPRIT Foundation. In addition, CPRIT should consider requiring the	**Fully implemented**	02/19/14

Rec.		Status	Date
	compliance officer to review the grant applications to ensure that there are no conflicts between the grant applicants and the CPRIT Foundation.		
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014, mandating that in order to be eligible to be considered for a CPRIT grant an applicant must certify that it has not made and will not make a donation to CPRIT or any foundation established to benefit CPRIT. Beginning with applications submitted for FY 2014 awards, the Chief Compliance Officer confirms the information as part of the grant pedigree for each grant application presented to the Oversight Committee for award consideration. *CPRIT notes that the 83rd Legislature amended Health and Safety Code, Chapter 102 to direct the Chief Compliance Officer, not the program officers, to perform this task.* **Documentation:** Application, List of donors to CPRIT and any supporting foundation, Grant pedigree for each application.		
	Statute/Rule/Other: H&S Code § 102.251(a)(3), 25 T.A.C. §§ 703.3(h)(5), 703.8(1)(C)		
06 pg 9	**Recommendation:** Establish and implement a policy that prohibits a peer reviewer with a conflict of interest from evaluating grant applications competing for the same grant funds as the applicant for which the peer reviewer has a conflict of interest.	**Fully Implemented**	02/2014
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 designating certain conflicts of interest that raise the presumption that the conflict may affect the reviewer's impartial review of other applications. The reviewer must be recused from participating in the review, discussion, scoring, deliberation and vote on all applications competing for the same grant mechanism in the entire cycle if a reviewer has one of these designated conflicts, unless a waiver has been granted. CPRIT notes that the rule applies to all individuals involved in the review/grant monitoring process, including Oversight Committee members, PIC members, CPRIT employees, and peer reviewers. This recommendation was fully implemented in February 2014 for the product development FY14 review cycle. **Documentation:** COI Policy Agreement, COI notification, Sign-out Sheets		
	Statute/Rule/Other: H&S Code §§ 102.1061(b),(c), 102.156, 25 T.A.C. §§ 702.11, 702.13(b),(c)		
07 pg 9	**Recommendation:** Consistently maintain documentation to show that it identifies and takes action to address its peer reviewers' conflicts of interests.	**Fully implemented**	02/01/14

Rec.		Status	Date
	Implementation: CPRIT and its third-party grant administrator implemented changes to the software system and grants database to maintain documentation related to conflicts of interest. This recommendation was fully implemented by February 2014 and used to create the grant pedigrees and CEO affidavits for the grant awards announced February 19, 2014. **Documentation:** Conflict of Interest Policy Agreement, Identification of Conflicts, Sign-Out Sheets, Third-Party Observer Reports, Post-Review Statements, Oversight Committee meeting minutes.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(4), 25 T.A.C. §§ 703.3(i), 703.4(1)(C)		
08 pg 9	**Recommendation:** Establish and implement a documented policy on residency requirements for members of its commercialization review council.	**Fully implemented**	12/01/12
	Implementation: As of December 2012, all members of the Product Development Review Council (formerly known as the Commercialization Review Council) and Product Development reviewers live and work outside of the state. The Oversight Committee adopted a new administrative rule in January 2014 establishing the policy that all reviewers must live and work outside of Texas, unless special circumstances justify using an in-state reviewer. **Documentation:** An explanation of the special needs justification must be recorded in the minutes of the Oversight Committee meeting when the reviewer's appointment is approved.		
	Statute/Rule/Other: H&S Code § 102.151(b), 25 T.A.C. § 701.17		
Chapter 1B - CPRIT Should Ensure the Transparency and Accountability of Its Peer Review Process			
09 pg 16	**Recommendation:** Update and consistently follow agency policies and procedures for reviewing grant applications.	**Fully Implemented**	02/2014
	Implementation: CPRIT has undertaken a comprehensive review and revision of the agency's administrative rules. A major project milestone was achieved with the adoption of the revised rules and new rules on January 24, 2014, affecting all stages of the grant application, review, award, and monitoring process. CPRIT's third party administrator has updated the electronic grant application receipt system and grant review scoring system to implement standardized procedures associated with reviewing grant applications. The processes specified by the new rules and rule changes were implemented for grant applications submitted in response to FY 2014 Cycle 1 requests for applications (RFAs). Grant pedigrees and, if applicable, CEO affidavits and the Chief Compliance Officer's certification of the awards document adherence		

Rec.		Status	Date
	to the agency's rules and statutory requirements for grant reviews. **Documentation:** Grant Review Process records, Grant Pedigrees, CEO Affidavits, Compliance Certification		
	Statute/Rule/Other: H&S Code § 102.051(d)(1), 25 T.A.C. § 703.8(1)(A)		
10 pg 16	**Recommendation:** Require the CEO to provide a written affidavit for each grant recommendation presented to the oversight committee certifying that the grant application was subject to the peer review process with the attached peer review score, including due diligence reviews and intellectual property reviews, when applicable.	**Fully Implemented**	02/12/14
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 specifying the information to be included in the CEO affidavit and the timing of the affidavits' submission to the Oversight Committee. CEO affidavits were used for the first time in February 2014 to support the grant award recommendations for FY14 training and MIRA continuation proposals. **Documentation:** The CEO affidavit presented for each grant award recommendation is part of the Grant Review Process records.		
	Statute/Rule/Other: H&S Code § 102.251(c), 25 T.A.C. § 703.7(h)		
11 pg 16	**Recommendation:** Ensure that reviews of all research grant applications, including recruitment grant applications, are subject to the same review process, including processes for documenting peer reviews in the Peer Review Management Information System.	**Fully Implemented**	01/24/14
	Implementation: The Oversight Committee adopted new administrative rules in January 2014 standardizing its grant review process among programs, including specifying variations applicable to a particular program and/or grant mechanism. These processes were implemented for the review of grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications. The CEO affidavits document the peer review process and scores for all grant applications submitted for a particular cycle. **Documentation:** Grant Review Process records, Grant Pedigrees, CEO Affidavit		
	Statute/Rule/Other: H&S Code § 102.251, 25 T.A.C. §§ 703.4(1)(A), 703.6		
12 pg 16	**Recommendation:** Maintain and secure data that supports why grant applications are withdrawn from the peer review process.	**Fully Implemented**	02/2014

Rec.		Status	Date
	Implementation: CPRIT has developed a process to document reasons for withdrawing applications from review. The process was implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications (RFAs) released 12/09/2013. **Documentation:** The reasons for withdrawing applications from review is maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system. Information about withdrawals is reported by the Chief Compliance Officer when the grant award slates are certified.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(1), 25 T.A.C. § 703.4(1)(B)		
13 pg 16	**Recommendation:** Require peer review councils to document how applications recommended for grants meet one or more of the recommendation standards.	**Fully Implemented**	02/06/14
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 requiring Review Councils to document reasons for recommending grants according to specified standards. The process was implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications. **Documentation:** The Review Council's reasons for recommending grants according to specified standards are reflected in the written recommendations submitted simultaneously to the CPRIT CEO and the Presiding Officer of the Oversight Committee. The information is maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.251(a)(1)(B), 25 T.A.C. §§ 703.4(1)(B), 703.6(d)(1) and (d)(2)(A)		
14 pg 16	**Recommendation:** Ensure that the [Program Integration Committee] documents the factors considered in deciding on grant recommendations and that those grant recommendations are substantially supported by the grant recommendations made by CPRIT's peer review councils.	**Fully Implemented**	02/12/14
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 specifying that the Program Integration Committee (PIC) document the factors considered when recommending grant awards, including demonstrating that the recommendations are substantially supported by the grant recommendations made by CPRIT's peer review councils. [CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee.] The changes were implemented by the PIC		

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	with its first grant recommendations submitted to the Oversight Committee in February 2014. **Documentation:** The factors considered by the PIC in deciding on grant recommendations are reflected in the letter submitted by the PIC Chair documenting the PIC's award recommendations. To the extent that the PIC recommendations vary from the Review Council recommendations (previously provided to the PIC and the Oversight Committee simultaneously), the PIC letter must document the reasons for the variance. All information is maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.251(a)(2)(A) and (B), 25 T.A.C. § 703.7(a)(3)		
15 pg 16	**Recommendation:** Maintain documentation that supports how recommended grant amounts are determined by the peer review councils and the [Program Integration Committee].	**Fully Implemented**	02/12/14
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 addressing the creation and maintenance of documentation that supports how recommended grant amounts are determined by the peer review councils and the Program Integration Committee. The process was implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications. **Documentation:** Written information reflecting the Review Council's and PIC's determination regarding grant award amounts is maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(1), 25 T.A.C. §§ 703.4(1)(B), 703.6(d)(2)(C) 703.7(d)(5), 703.4(1)(B)		
Chapter 1C- CPRIT Should Verify the Accuracy and Availability of Grantees' Matching Funds			
16 pg 20	**Recommendation:** Obtain documentation to verify the amount and availability of matching funds that grantees report.	**Fully implemented**	12/06/13
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 requiring grant recipients to submit documentation verifying the amount and availability of matching funds. In addition to the certification of available matching funds that the grantee must submit at the beginning of the grant award and each grant award year (if the grant recipient is demonstrating matching funds on a year-by-year basis), the grantee must submit supporting documentation that shows the actual expenditures of funds counted as match		

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	toward grants at the end of each award year. The grantee's failure to submit the required documentation will result in a suspension of grant funding by CPRIT until sufficient documentation is provided and may serve as a basis for terminating the grant contract. The matching funds certification and verification process was implemented in December 2013. **Documentation:** Matching funds certification, year-end information showing how grantee matching funds were used on the project; this information is maintained as part of the complete grant award records kept by CPRIT's electronic grants management system. If the grant recipient is an academic institution, the grant recipient may provide the letter from the government approving the federal indirect cost rate for the institutions.		
	Statute/Rule/Other: H&S Code §102.255(c)(3)(A)&(C),(d)(6), (d)(8) and (9), 25 T.A.C. §§ 703.4(1)(E), 703.10(c)(20), 703.11(a),(g),(j), 703.21(b)(3)(B)(x)		
17 pg 20	**Recommendation:** Require grantees to comply with matching fund requirements in statute and CPRIT rules.	**Fully implemented**	12/06/13
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 requiring grant recipients to submit documentation verifying the amount and availability of matching funds. Grantees must provide information and supporting documentation about the actual expenditures of funds counted as match toward grants at the end of each award year. Failure to provide verification documentation may serve as a basis for terminating the grant contract. The administrative rule establishes penalties, including suspension of grant fund disbursement, for the failure to expend matching funds as required. **Documentation:** Matching funds certification, year-end information showing how grantee matching funds were used on the project; this information is maintained as part of the complete grant award records kept by CPRIT's electronic grants management system. If the grant recipient is an academic institution, the grant recipient may provide the letter from the government approving the federal indirect cost rate for the institutions.		
	Statute/Rule/Other: H&S Code §§ 102.255(c)(2), 102.255(c)(3)(A) and (C), 102.260(d) and (f), 25 T.A.C. §§ 703.4(1)(E), 703.10(c)(21), 703.11 (g), 703.21(b)(3)(B)(i) and (x)		
Chapter 2A - CPRIT Should Establish Requirements for Advance Payments and Reimbursements It Makes to Grantees			
18	**Recommendation:** Adopt and implement a policy regarding advance payments to grantees.	**Fully**	05/2014

Rec.		Status	Date
pg 24	**Implementation:** The Oversight Committee adopted a new administrative rule in January 2014 requiring the CEO to seek approval by a simple majority of the Oversight Committee to disburse grant funds by advance payment. The rule directs the CEO to provide a list of applications recommended for advance payment at least three business days prior to the Oversight Committee meeting and include the reasons supporting the recommendation to advance funds. This process set by this rule was used in May to request advance authority for product development grant awards announced in February and May. **Documentation:** The CEO's letter requesting advance payment authority is included in the Oversight Committee Board Packet. The advance payment approval is reflected in the minutes of the Oversight Committee meeting. The grant contract must specify the amount, schedule, and requirements for advance payment of grant funds.	**implemented**	
	Statute/Rule/Other: H&S Code § 102.255(e), 25 T.A.C. §§ 701.19, 703.7(j), 703.10(c)(14)		
19 pg 24	**Recommendation:** Obtain sufficient documentation to support the appropriateness of all payments it makes to grantees.	**Fully implemented**	07/18/13
	Implementation: CPRIT requires grant recipients to submit quarterly financial status reports (FSR) and general ledger data supporting the FSR prior to releasing funds for reimbursement. The Oversight Committee adopted a new administrative rule in January 2014 that authorizes CPRIT to waive reimbursement for expenses incurred when the grantee fails to timely submit the quarterly FSR information. The waiver of expenses to be reimbursed will be effective for the FSR submitted for the June 1 – August 31 fiscal quarter. **Documentation:** CPRIT maintains quarterly FSRs and general ledger information submitted by grant recipients, as well documentation of the agency's review and approval of the FSRs in its electronic grants management system.		
	Statute/Rule/Other: H&S Code §§ 102.0535(a)(2), 102.260(a), 25 T.A.C. §§ 703.4(1)(E), 703.21(b)(1)		
Chapter 2B - CPRIT Should Improve Processes for Monitoring Grantee Expenditures and Research Progress			
20 pg 27	**Recommendation:** Retain documentation of all financial and progress reports received and all reviews of those reports.	**Fully implemented**	07/18/13
	Implementation: CPRIT has deployed a fully electronic grants management system that supports the agency's grant award compliance monitoring by maintaining complete grant award records, including the grant contract and matching funds certification, required grant		

Rec.		Status	Date
	award financial reports and grant progress reports, and CPRIT's review of those reports. Changes to the electronic grants management system were completed in July 2013 to retain documentation of financial reports and grant progress reports. **Documentation:** CPRIT maintains quarterly FSRs and general ledger information submitted by grant recipients, as well documentation of the agency's review and approval of the FSRs and annual progress reports in its electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(2), (3), (5), 25 T.A.C. § 703.4(1)(E)		
21 pg 27	**Recommendation:** Establish and implement a process to track the dates on which grantees' reports are due and received, and follow up on all missing reports.	**Fully Implemented**	02/2014
	Implementation: CPRIT has deployed a fully electronic grants management system that supports the agency's grant award compliance monitoring by tracking the due dates and submission status for required grant award reports; monitoring the status of past-due required financial reports and grant progress reports; sending automatic reminders and notifications to grant recipients of upcoming deadlines and past due reports. Functionalities such as tracking report due dates, reviewing the supporting financial reporting documentation, and generating compliance reports for follow up were possible via the electronic grants management system in early 2014. **Documentation:** Documentation of all progress and financial reports as well as any supporting documentation are maintained in the grants management system. The Chief Compliance Officer reports to the Oversight Committee quarterly regarding the status of grantee reports.		
	Statute/Rule/Other: H&S Code §§ 102.051(a)(5), 102.260(e), 25 T.A.C. § 703.4(1)(F)(G)		
22 pg 27	**Recommendation:** Follow the process established by CPRIT to perform desk reviews of financial reports that grantees submit.	**Fully Implemented**	03/01/14
	Implementation: CPRIT conducts desk reviews to assess and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the grant contract. CPRIT uses a risk-based methodology to perform desk reviews of financial reports for academic research and prevention grants. Desk reviews are performed for all financial reports submitted by company grantees. **Documentation:** Documentation of all progress and financial reports as well as any supporting documentation are maintained in the grants management system.		

Rec.		Status	Date
	Statute/Rule/Other: 25 T.A.C. § 703.21(b)(4)		
23 pg 27	**Recommendation:** Establish criteria for peer reviewers to follow when evaluating and documenting reviews of grantees' progress reports.	**Fully Implemented**	06/19/13
	Implementation: CPRIT uses standard evaluation criteria for the prevention, research and product development grantee progress reports and has been documenting the evaluation of grant progress against the particular grant goals or milestones and programmatic acceptance of the evaluation in the electronic grants management system. Peer reviewers complete the evaluations of prevention and product development progress reports and report those evaluations to the respective program managers who finalize the recommendations on continuing the grant or addressing weaknesses in the progress; however, due to the volume of research progress reports, CPRIT uses third-party contractors with scientific expertise to review and evaluate research grant progress. The research evaluations are sent to the research program officer who finalizes the recommendation, the same process in the other two programs. **Documentation:** CPRIT maintains the standard criteria and documentation of the agency's review and approval of the progress reports in its electronic grants management system.		
	Statute/Rule/Other: 25 T.A.C. § 703.21(b)(3)(D)		
24 pg 27	**Recommendation:** Ensure that public higher education institutions obtain and submit reports from required audits.	**Fully Implemented**	05/31/14
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 clarifying the methodology required for the annual audit of grants awards with expenditures of $500,000 or more. CPRIT also issued guidance instructing public higher education institutions to complete program specific audits by an institution's internal audit department to retrospectively address the audit requirements for fiscal years 2010, 2011, and 2012. These audits are due by June 30, 2014. The public higher education institutions must have independent auditors complete the required audit for fiscal year 2013. All organizations have nine months after the end of their fiscal year to have the independent audits completed and submitted. The public higher education institutions follow the state fiscal year, so any required audit report is due by May 31, 2014. **Documentation:** CPRIT maintains grantee audits and any corrective action plans in its electronic grants management system.		

Rec.		Status	Date
	Statute/Rule/Other: 25 T.A.C. § 703.13		
Chapter 2C - CPRIT Should Strengthen Certain Contract Management Processes			
25 pg 31	**Recommendation:** Develop, document, and implement a process for closing out grants and renewing grants, as well as develop, document, and implement procedures for extending grants.	**Fully Implemented**	06/01/14
	Implementation: The Oversight Committee adopted administrative rule changes in January 2014 specifying processes for closing out, renewing, and extending grants. CPRIT's electronic grant management system has been updated to reflect the changes required by the administrative rules. **Documentation:** CPRIT maintains requests to extend grants in its electronic grants management system. Processes for closing out and extending grants are described in the Process and Procedures manual.		
	Statute/Rule/Other: 25 T.A.C. § 703.14(c)		
26 pg 31	**Recommendation:** Ensure that all grant agreements include all reporting requirements.	**Fully Implemented**	03/01/14
	Implementation: All CPRIT grant award contracts include a list of required reports to be submitted by the grantee. The Oversight Committee adopted a new administrative rule in January 2014 addressing required reports. Grant award contracts effective on or after March 1, 2014 reflect the updated reporting requirements set forth in the new administrative rules. Grant award contracts that have an effective date prior to March 1, 2014 are subject to the updated reporting requirements pursuant to a contract term that specifies that the grantee is obligated to report any information covering its activities related to the grant award that is requested by CPRIT, the Legislature, or any other funding or regulatory bodies. **Documentation:** CPRIT Grant Contract		
	Statute/Rule/Other: H&S Code § 102.260(d), 25 T.A.C. § 703.10(c)(8), (9), (15)		
Chapter 3 - CPRIT Should Improve Its Management of the CTNeT Research Grant and Other Administrative Practices			
27 pg 35	**Recommendation:** Refrain from involvement in CTNeT's business decisions.	**Fully Implemented**	02/25/13
	Implementation: CPRIT began implementing the Chapter 3 recommendations related to the management of the CTNeT grant during the audit or immediately following the release of the audit report. While CPRIT believes it has fully implemented the recommendations within the		

Rec.		Status	Date
	scope of its overall grants management processes, CPRIT was unable to resolve some of the recommendations through management of the CTNeT grant itself because CTNeT ceased operations in February 2013. Going forward, CPRIT has clarified its administrative rules and adopted Code of Conduct and Ethics provisions to prohibit involvement in a grantee's business decision by an Oversight Committee member or CPRIT employee.		
	Statute/Rule/Other: H&S § Code 102.109(b)(2), 25 T.A.C. § 702.9(c)(2), (8), CPRIT Code of Conduct §§ II.B.(3) and (4), II.C.(1)		
28 pg 35	**Recommendation:** Prohibit CPRIT employees from serving on CTNeT's board of directors.	**Fully Implemented**	02/25/13
	Implementation: CTNeT ceased operations in February 2013. Going forward, CPRIT has clarified its administrative rules and adopted Code of Conduct and Ethics provisions to prohibit involvement in a grantee's business decision by an Oversight Committee member or CPRIT employee.		
	Statute/Rule/Other: H&S Code § 102.109(b)(8)(9), 25 T.A.C. § 702.9(c)(2),(8), (11), CPRIT Code of Conduct §§ II.B.(3) and (4) and (15), II.C.(1) and (2)		
29 pg 35	**Recommendation:** Prohibit CTNeT board members from serving on CPRIT's commercialization review council.	**Fully Implemented**	01/29/13
	Implementation: The member of the commercialization review council who also served on the CTNeT board resigned from the council on January 29, 2013, resolving the issue of having a member of the council on the CTNeT board. Going forward, CPRIT has clarified its administrative rules to prohibit a reviewer from serving on a grantee's board of directors.		
	Statute/Rule/Other: H&S Code § 102.156(c), 25 T.A.C. § 703.5(h)		
30 pg 35	**Recommendation:** Ensure that all payments to CTNeT comply with the terms of the grant.	**Fully Implemented**	12/01/12
	Implementation: CPRIT did not make any payments to CTNeT after November 2012. CTNeT ceased operations in February 2013 before the issues on matching funds and progress reports could be addressed. Going forward, CPRIT has clarified its administrative rules to suspend disbursement of funds if a grantee is not in compliance with contractual requirements regarding submission of progress reports and certification of matching funds.		
	Statute/Rule/Other: H&S Code §§ 102.260(b), 102.051(a)(5), 102.260(d), 25 T.A.C. § 703.21(b)(1) and (2)		

Rec.		Status	Date
31 pg 35	**Recommendation:** Withhold payments to CTNeT until after CPRIT has recovered the advanced funds that CTNeT spent on unallowable costs.	**Fully Implemented**	12/01/12
	Implementation: CPRIT did not make any payments to CTNeT after November 2012. CTNeT ceased operations in February 2013 before the organization could correct expenditures on unallowable costs. Going forward, CPRIT has clarified its administrative rules to prohibit disbursement of grant funds if a grantee is not in compliance with contractual requirements. The administrative rule changes make it clear that CPRIT can stop advance payments and may seek repayment of grant funds spent on unallowable costs.		
	Statute/Rule/Other: H&S Code § 102.260(b), 25 T.A.C. §§ 701.19(3),(4) and (5), 703.10(c)(14)		
32 pg 35	**Recommendation:** Require CTNeT to comply with requirements regarding matching funds and annual progress reporting.	**Fully Implemented**	12/06/13
	Implementation: CTNeT ceased operations in February 2013. Going forward, CPRIT has clarified its administrative rules to require all research award grantees to demonstrate the availability of matching funds for expenditures at the time of certification and comply with the annual progress reporting requirement that the grantee explain how matching funds were spent in the previous year. Failure to provide the matching fund documentation or to timely submit the annual progress report will result in the suspension of funding, and may make the grantee ineligible for future awards. Continued failure to submit the required reports will result in contract termination.		
	Statute/Rule/Other: H&S Code § 102.255(d), 25 T.A.C. §§ 703.10(c)(20) and (21), 703.11(g), (j), 703.21(b)(3)(B)(i), (x)		
Chapter 4A - CPRIT Should Ensure That Contracted Services and Related Costs Are Reasonable and Necessary			
33 pg 40	**Recommendation:** Ensure that it properly identifies and defines its services needs and the associated costs prior to executing service contracts.	**Fully Implemented**	03/01/14
	Implementation: CPRIT strives to procure contracted services competitively following the state procurement law as stated in the State of Texas Procurement Manual and other publications provided by the Comptroller of Public Accounts as well as the procurement practice guidelines documented in the agency's administrative policies and procedures. CPRIT documents the identification of its needs for contracted services and prohibits the awarding of contracts to parties that assist in the needs assessment for service contracts. In practice, CPRIT has issued a		

Rec.		Status	Date
	request for proposal for communication services that has defined needs and costs and was approved by the Oversight Committee's Governance Subcommittee on November 18, 2013. CPRIT also hired a procurement specialist with Contract Management certification effective June 2, 2014.		
	Statute/Rule/Other: State of Texas Procurement Manual		
34 pg 40	**Recommendation:** Prohibit the awarding of contracts to parties that assist in the needs assessment process for the contracted services.	**Fully Implemented**	03/01/14
	Implementation: CPRIT is documenting the practice of identifying and defining its needs for contracted services and prohibits the awarding of contracts to parties that assist in the needs assessment for service contracts, beginning March 1, 2013. In practice, CPRIT has issued a request for proposal for communication services that has defined needs and costs and was approved by the Oversight Committee's Governance Subcommittee on November 18, 2013.		
	Statute/Rule/Other: State of Texas Procurement Manual		
35 pg 40	**Recommendation:** Require vendor invoices to include specific information that clarifies the work products and services the vendors provided during the billing cycle.	**Fully Implemented**	04/10/13
	Implementation: CPRIT required the contractor to submit additional information to support the vendor's labor charges for identified invoices that contained insufficient detail. Once CPRIT received the additional information for the December 2012 invoice, payment was processed for the invoice on April 10, 2013. CPRIT continues to review the documentation for all of its vendors to ensure there is appropriate detail to support the invoices.		
	Statute/Rule/Other: State of Texas Procurement Manual		
36 pg 40	**Recommendation:** Competitively procure all contracted services, and require its contractors to competitively procure all subcontracted services.	**Fully Implemented**	06/28/12
	Implementation: CPRIT strives to procure contracted services competitively following state procurement law as stated in the State of Texas Procurement Manual and other publications provided by the Office of the Comptroller of Public Accounts. At this time, CPRIT has one contractor that procures subcontracted services. That contractor completed a competitive procurement of those subcontracted services in June 2012.		
	Statute/Rule/Other: State of Texas Procurement Manual		

Rec.		Status	Date
Chapter 4B - CPRIT Should Ensure That Its Honorarium Payments Are Appropriate			
37 pg 43	**Recommendation:** Establish minimum requirements for documentation that must be submitted for payments to reviewers for their services.	**Fully Implemented**	09/01/13
	Implementation: CPRIT's CEO adopted CPRIT's Honoraria Policy effective September 1, 2013. The written Honoraria Policy describes the expected duties and responsibilities for Review Council chairs, Review Council members, and peer review panel members, specifies the expected time commitment, and lists the hourly rate comparisons used to develop the honorarium amounts. The policy establishes minimum requirements for documentation that must be submitted for payments to reviewers for their services, as well as documents the process to support and justify all changes in the honorarium amount paid to reviewers. **Documentation:** CPRIT's Honoraria Policy		
	Statute/Rule/Other: H&S Code § 102.151(e), 25 T.A.C. § 701.15(4), *CPRIT's Honoraria Policy*		
38 pg 43	**Recommendation:** Implement a documented process to support and justify all changes in the amount of honorarium paid to reviewers.	**Fully Implemented**	09/01/13
	Implementation: CPRIT's CEO adopted CPRIT's Honoraria Policy effective September 1, 2013. The written Honoraria Policy describes the expected duties and responsibilities for Review Council chairs, Review Council members, and peer review panel members, specifies the expected time commitment, and lists the hourly rate comparisons used to develop the honorarium amounts. The policy establishes minimum requirements for documentation that must be submitted for payments to reviewers for their services, as well as documents the process to support and justify all changes in the honorarium amount paid to reviewers. **Documentation:** CPRIT's Honoraria Policy		
	Statute/Rule/Other: H&S Code § 102.151(e), 25 T.A.C. § 701.15(1), *CPRIT's Honoraria Policy*		
39 pg 43	**Recommendation:** Ensure that honorarium payment rates are reasonable and competitive for the value CPRIT receives.	**Fully Implemented**	09/01/13
	Implementation: CPRIT's CEO adopted CPRIT's Honoraria Policy effective September 1, 2013. The written Honoraria Policy designates other entities that also conduct peer review and pay honoraria and compares and contrasts the roles, responsibilities, and expected time commitment for CPRIT reviewers to these entities to document that CPRIT's honoraria payment rates are reasonable and competitive for the value CPRIT receives.		

Rec.		Status	Date
	Documentation: CPRIT's Honoraria Policy		
	Statute/Rule/Other: H&S Code § 102.151(e), 25 T.A.C. § 701.15(3), *CPRIT's Honoraria Policy*		
Chapter 5 - CPRIT Should Ensure That Its Outsourced Information Systems Maintain Valid and Reliable Grant Management Data			
40 pg 46	**Recommendation:** Obtain audits of the Peer Review Management Information System and CPRIT Application Receipt System and ensure that the grant management contractor corrects all weaknesses identified.	**Fully Implemented**	06/30/14
	Implementation: CPRIT procured an audit of the three electronic grant systems used by CPRIT's grants management contractor, SRA International: the CPRIT Application Receipt System (CARS), the Peer Review Management Information System (P^2RMIS), and CPRIT's Grant Management System (CGMS). CARS, P^2RMIS, and CGMS provide support for CPRIT, its peer reviewers and its grantees to manage grant applications, maintain grantee records, track grantee budget and expenditure information, and submit and track progress reports. The audit evaluated the SRA controls as they relate to AICPA Trust Service Principles, using the AICPA Guide: *Reporting on Controls at a Service Organization Relevant to Security, Availability, Processing Integrity, Confidentiality, or Privacy*. The audit report indicates that no findings or observations were noted that would significantly impact the processing capability of SRA's grant system applications, as related to the services provided to CPRIT. While no significant findings were noted, CPRIT will continue to require SRA to validate their control environment and be subject to periodic audits.		
	Statute/Rule/Other: H&S Code § 102.0535(b), 25 T.A.C. § 703.4(3)		
41 pg 46	**Recommendation:** Ensure that the Peer Review Management Information System maintains a complete record of all grant applications that receive a peer review and the scores associated with the review.	**Fully Implemented**	04/01/14
	Implementation: CPRIT's grants management contractor, SRA International, has incorporated recommendations identified in the audit into the three electronic systems managed by SRA: the CPRIT Application Receipt System (CARS), the Peer Review Management Information System (P^2RMIS) and the CPRIT Grants Management System. As part of the implementation of required processes, CPRIT has re-engineered its procedures and frequency that conflicts of interest have to be indicated by reviewers and stored. Requirements for these P^2RMIS changes		

Rec.		Status	Date
	were implemented sequentially over the course of three months with completion by April 1, 2014.		
	Statute/Rule/Other: H&S Code § 102.0535(a)(1), 25 T.A.C. § 703.4(1)(B), (C)		
The Legislature Should Consider Clarifying Certain Statutory Requirements to Increase Transparency and Accountability at CPRIT			
42 pg 49	**Recommendation:** Allow peer reviewers to provide their grant recommendations to the CEO and members of the CPRIT oversight committee at the same time.	**Fully Implemented**	02/06/14
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 requiring the review council's recommendations to be submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. *CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee.* This process was implemented for the first time with training and MIRA continuation grant awards announced in February 2014. **Documentation:** Review Council written list of recommendations and transmittal letter		
	Statute/Rule/Other: H&S Code § 102.251(a)(1), 25 T.A.C. § 703.6(d)(2)		
43 pg 49	**Recommendation:** Clarify what funds can be used and the intended use of matching funds reported by grantees.	**Fully Implemented**	06/01/14
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 specifying the process for crediting a public or private institution of higher education grantee's matching funds obligation with the dollar amount equivalent to the difference between the grantee's federal indirect cost rate and CPRIT's five percent indirect cost rate allowance. The matching certification form was revised to implement the change. **Documentation:** Matching Funds Certification		
	Statute/Rule/Other: H&S Code § 102.255(d)(2)(B),(d)(4), 25 T.A.C. § 703.11		
44 pg 49	**Recommendation:** Clarify whether contributions made by non-profit foundations affiliated with grantees are appropriate.	**Fully Implemented**	06/14/13
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 to make clear that a grant applicant that makes a contribution to CPRIT or a nonprofit foundation established to benefit CPRIT is ineligible to receive a CPRIT grant. As noted in response to SAO recommendation Nos. 4-5, CPRIT staff has reviewed all grant applications to		

Rec.		Status	Date
	ensure that no grantee has made a donation to CPRIT or to a nonprofit foundation established to benefit CPRIT. **Documentation:** Grant Pedigree		
	Statute/Rule/Other: H&S Code § 102.251(a)(3),(e), 25 T.A.C. § 703.3(h)(1)		
45 pg 49	**Recommendation:** Prohibit an interlocking directorate between CPRIT and the CPRIT Foundation.	**Fully Implemented**	02/25/13
	Implementation: The Oversight Committee adopted Bylaws prohibiting the presiding officer and vice presiding officer from holding a position on the board of directors of a foundation that was established to benefit CPRIT. The Oversight Committee adopted a new administrative rule in January 2014 prohibiting an interlocking directorate. **Documentation**: Oversight Committee Bylaws		
	Statute/Rule/Other: 25 T.A.C. § 701.5(1)(F), CPRIT Oversight Committee Bylaws § 5.3		
46 pg 49	**Recommendation:** Prohibit CPRIT employees from serving on grantee's board of directors and related foundations.	**Fully Implemented**	02/25/13
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 prohibiting CPRIT employees, Oversight Committee members, and PIC members from serving on a grantee's board of directors or the board of a related foundation. The Oversight Committee also adopted a Code of Conduct and Ethics reflecting the prohibition. **Documentation:** Code of Conduct and Ethics		
	Statute/Rule/Other: H&S Code § 102.109(b)(8)(9), 25 T.A.C. § 702.9(c)(2), (11), CPRIT Code of Conduct § II.B.(15)		
47 pg 49	**Recommendation:** Clarify the positions of the oversight committee's presiding officer and other officers, including the responsibilities and specific term of service for those positions.	**Fully Implemented**	02/25/13
	Implementation: The Oversight Committee adopted Bylaws specifying the term of office and specific responsibilities for the presiding officer and other officers. **Documentation**: Oversight Committee Bylaws		
	Statute/Rule/Other: H&S Code § 102.104(c)(1)(2), 25 T.A.C. § 701.5(1)(C)(D), CPRIT Oversight Committee Bylaws §§ 5.2, 5.3		
48 pg 49	**Recommendation:** Allow members of the oversight committee to affirmatively vote to approve the CEO's recommendations.	**Fully Implemented**	02/19/14

Rec.		Status	Date
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 establishing a process for the Oversight Committee to affirmatively vote to approve the grant awards recommended by the Program Integration Committee (PIC). The process was first used to approve the training and MIRA continuation grants announced in February 2014. *CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee.* **Documentation:** Oversight Committee meeting minutes		
	Statute/Rule/Other: H&S Code § 102.252, 25 T.A.C. § 703.8(2)		
49 pg 49	**Recommendation:** Remove the Attorney General and the Comptroller of Public Accounts from CPRIT's oversight committee so that their statutory duties and responsibilities would not be impaired.	**Fully Implemented**	6/14/13
	Statute/Rule/Other: H&S Code § 102.101(b)(4) and (5)		
50 pg 49	**Recommendation:** Allow the CEO to provide CPRIT's oversight committee, along with grant recommendations, documentation of the other factors that the CEO considered for making grant recommendations.	**Fully Implemented**	02/12/14
	Implementation: The Oversight Committee adopted a new administrative rule in January 2014 specifying the process for the Program Integration Committee (PIC) to document the factors considered in deciding grant recommendations. The rule and process changes implemented by CPRIT are applicable to the PIC and have been implemented for the grant applications submitted pursuant to FY 2014 Cycle 1 requests for applications (RFAs) released 12/09/2013. The first PIC meeting was held on 2/12/2014. *CPRIT notes that the 83rd legislative session amended Chapter 102 of the Texas Health and Safety Code to create the PIC and charge the PIC with the authority to make grant recommendations to the Oversight Committee.* **Documentation:** The factors considered by the PIC in deciding on grant recommendations are submitted to the Oversight Committee at the time that the awards are recommended; the information is maintained as part of the complete grant review process records kept by CPRIT's electronic grants management system.		
	Statute/Rule/Other: H&S Code § 102.251(a)(2)(A), (B), 25 T.A.C. §§ 7037.7(d)(3)(6) and (7), 703.7(h)		

Rec.		Status	Date
51 pg 49	**Recommendation:** Require the CPRIT Foundation to make its records, books, and reports available to the public.	**Fully Implemented**	06/14/13
	As of May, 2013, the CPRIT Foundation has ceased operations. The Oversight Committee adopted a new administrative rule in January 2014 requiring that the records, books, and reports of a nonprofit foundation established to benefit CPRIT will be made publicly available on CPRIT's website.		
	Statute/Rule/Other: H&S Code § 102.262(c) and (d), 25 T.A.C. § 701.27(13)		

CPRIT's Implementation of SB149

Texas voters overwhelmingly approved a constitutional amendment in 2007 to establish the Cancer Prevention and Research Institute of Texas (CPRIT) and authorized the state to issue bonds to fund groundbreaking cancer research and prevention programs and services in Texas.

Senator Jane Nelson (R-Flower Mound) introduced SB149 during the 83rd Legislative Session to clarify and strengthen conflict of interest provisions at CPRIT to ensure that all policies and regulations are strictly adhered to in order to allow CPRIT to focus on its goals of cancer research and prevention. The legislation made significant changes to CPRIT's structure and duties and established a Code of Conduct and additional conflict of interest rules. Representative Jim Keffer (R-Eastland) sponsored the legislation in the House. After approval by the Senate (31-0) and the House of Representatives (140-3), SB149 took immediate effect when it was signed by Governor Perry on June 14, 2013.

Statute	Description	Implementation	CPRIT Rule
Strengthening Conflict of Interest Disclosure and Prohibitions; Ensuring that Grant Decisions are Free From Real or Apparent Conflicts of Interest			
102.057	Directs CPRIT to refrain from leasing office space from grantees.	CPRIT cancelled leases with Rice University and University of Texas Southwestern Medical Center effective November 30, 2012, and May 31, 2013, respectively. This prohibition has been incorporated in CPRIT's administrative rules and Code of Conduct.	§ 702.9(c)(15), CPRIT Code of Conduct Sec. II.C.(3)
102.106	Mandates that the Oversight Committee adopt conflict of interest rules, based on the standards applicable to NIH reviewers, to govern Oversight Committee members, PIC members, and peer reviewers	CPRIT adopted changes to its existing administrative rules related to conflict of interest prohibitions, including establishing a process for requesting a waiver from CPRIT's conflict of interest requirements.	702.11
102.106(b)- (d), 102.1061	Requires that the conflict of interest rules address professional, financial, and personal conflicts of interest and specify the process for disclosing conflicts and recusal from the review process.	CPRIT adopted administrative rules requiring written disclosure of conflicts identified by peer reviewers, PIC members, CPRIT employees, and Oversight Committee members. A member of the peer review panel, the PIC, or the Oversight Committee with a conflict of interest related to one or more applications must recuse themselves from any discussion, deliberation, or vote on the application(s). This information is reflected in the grant pedigree. In addition, PIC members and Oversight Committee members must disclose the conflict in an	702.11(a)-(d), (f), 702.13(a)-(c)

Statute	Description	Implementation	CPRIT Rule
		open meeting of the Oversight Committee.	
102.1063, 102.1064	Establishes a process to investigate unreported conflicts.	CPRIT adopted administrative rules for the investigation, final report, and appropriate action related to unreported conflicts of interest. The rules direct an Oversight Committee or CPRIT employee to notify the CEO in the event the individual becomes aware of an unreported conflict of interest. A grant applicant may also request an investigation into an alleged conflict of interest that was not reported. CPRIT notifies grant applicants of the members of the review panel assigned to review applications in order to assist in the identification of any conflicts of interest.	702.15
102.1061(d), 102.1062	Authorizes creation of a process for requesting a waiver from the applicable conflict of interest rules when exceptional circumstances justify participation of the otherwise conflicted reviewer.	CPRIT adopted administrative rules regarding the waiver of its conflict of interest rules in the event that exceptional circumstances necessitate a conflicted reviewer's participation in the review process. The rule specifies reporting requirements. CPRIT's Oversight Committee approved conflict of interest waivers for Dr. Margaret Kripke and Dr. David Lakey at its November 22, 2013, meeting. The information was noted in CPRIT's annual report and the waivers are posted on CPRIT's website.	702.17
102.109(b)(2), 102.156(c)	Restricts Oversight Committee members, PIC members, and CPRIT employees from being employed by or participating in the management of a business entity, including serving on the grantee's board of directors.	This prohibition has been incorporated in CPRIT's administrative rules and Code of Conduct. CPRIT adopted a similar restriction applicable to its peer reviewers.	§ 702.9(c)(8), 703.5(g)(h), CPRIT Code of Conduct Sec. II.B.(15), (C)(1),(2)
102.151(b)	Requires CPRIT to adopt a written policy on in-state or out-of-state residency requirements for peer reviewers.	As of December 2012, all members of CPRIT's peer review committees live and work outside of Texas. CPRIT adopted an administrative rule formalizing the policy that all reviewers must live and work outside of the state unless special circumstances justify using in-	§ 701.17

Statute	Description	Implementation	CPRIT Rule
		state reviewers.	
102.251(e)	Prohibits awarding a grant to an applicant who has made a gift to CPRIT or to any foundation created to support CPRIT.	CPRIT requires a grant applicant to certify that it has not and will not make a donation to CPRIT or to any foundation established to benefit CPRIT. The certification was implemented for the first time in February 2014 for the initial round of applications submitted following the passage of SB149. For previous awards, CPRIT's Chief Compliance Officer cross-checked all grant awards against the list of the CPRIT Foundation donors and reported the information to CPRIT's CEO. CPRIT's CEO requested that the CPRIT Foundation return donations to five individuals. The CPRIT Foundation confirmed the return of these donations on May 3, 2013.	703.3(h)(1)
Increasing Transparency and Accountability of CPRIT's Review Process			
102.052	Directs CPRIT to post information on its website related to conflicts of interest and conflict of interest waivers.	Beginning with the information for the 2013 review cycles, CPRIT has included conflict of interest data and approved conflict of interest waivers in CPRIT's annual report and posted on CPRIT's website.	701.27(3)
102.0535(a)(4)	Obligates CPRIT to maintain documentation related to the identification and action taken to address peer reviewer conflicts of interest.	In early 2014 CPRIT and its third party grant administrator implemented changes to allow for the grants database to maintain documentation related to conflicts of interest and the review process.	703.3(i), 703.4(1)(C)
102.151(c)	Requires CPRIT to adopt rules regarding qualifications required for an individual trained as a cancer patient advocate to act as a member of the peer review committee.	CPRIT administrative rules specifying qualifications for trained patient advocates to serve as peer review committee members. Beginning with applications submitted to CPRIT following the enactment of SB149, trained patient advocates were added to the review panels for the scientific research and product development programs. The prevention program has been using patient advocates as part of its review process since 2010.	703.5(l)

Statute	Description	Implementation	CPRIT Rule
102.251(a), 102.0535(a)(1)	Ensures that reviews of all grant applications are subject to the same review process, including assessing a final score; document why grant applications are withdrawn from the peer review process and document Review Council standards of review.	CPRIT adopted administrative rules that standardized its grant review process among programs, including specifying variations applicable to a particular program and/or grant mechanism and documenting reasons for withdrawing applications from the review process. The revised processes were implemented for grant applications submitted for FY2014 grant awards.	703.4(1)(A), (B), 703.6(d)
102.251(a)(2)(A)	Specifies that the Program Integration Committee (PIC) documents the factors considered in deciding on grant recommendations and that those recommendations are substantially supported by the grant recommendations made by the peer review committees.	The Oversight Committee adopted administrative rules specifying the documentation requirements for PIC decisions, including that the recommendations are substantially supported by the grant recommendations made by the peer review committees. The PIC met for the first time in February 2014 to vote on grant recommendations that were approved by the Oversight Committee February 21, 2014.	703.7(a)(3)
102.251(a)(3)	Mandates that the Chief Compliance Officer review the grant applications to ensure that no applicants have made a donation to CPRIT or to a related foundation.	Each grant application submitted since September 2012 has a grant pedigree that relates information about the review process for the specific application. Beginning with the applications submitted for FY2014 grant awards, the Chief Compliance Officer has confirmed that no applicant has made a donation to CPRIT or a related foundation.	703.3(h)(5), 703.8(1)(C)
102.251(c)	Requires the CEO to submit a written affidavit for each grant application recommended for an award by the PIC. The affidavit must include all relevant information on the peer review process, the application score, and a summary of the due diligence review of the application.	Beginning in February 2014, the CEO has submitted affidavits to support the grant award recommendations for applications submitted after the passage of SB149. The CEO affidavits are publicly available following the announcement of the awards.	703.7(h)
102.251(d)	Prohibits a PIC member from discussing grant recommendations with individual members of the Oversight Committee	CPRIT's Code of Conduct requires Oversight Committee members to sign a certification of non-communication for each award cycle. This requirement was	§ 702.19(f), CPRIT Code of Conduct Sec. V.F(2)

Statute	Description	Implementation	CPRIT Rule
	before presenting those recommendations to the entire Oversight Committee.	implemented in February 2014, the first award cycle that was initiated following the adoption of SB149.	
102.262(d)	Directs CPRIT to post online records related to any gift, grant, or other consideration given to CPRIT, Oversight Committee member, or CPRIT employee.	CPRIT adopted administrative rules related to posting information about gifts and grants received by CPRIT, Oversight Committee members, or employees. Specific direction regarding gifts and grants is also incorporated in CPRIT's Code of Conduct. At its May 21, 2014, Oversight Committee meeting the Oversight Committee approved acceptance of a gift in accordance with the process established by CPRIT's administrative rules. The information has been posted on CPRIT's website.	701.27(15), 702.7(f), 702.9(17), Code of Conduct Section IV
Enhancing the Role of the Oversight Committee and the Chief Executive Officer			
102.0511	Authorizes the Oversight Committee to hire a Chief Executive Officer that has a demonstrated ability to lead and develop academic, commercial, and governmental partnerships and coalitions. Specifies the CEO's responsibility to hire chief program officers.	The Oversight Committee voted to hire Mr. Wayne R. Roberts as CPRIT's CEO on November 22, 2013. Mr. Roberts hired Dr. Tom Goodman as Chief Product Development Officer on April 14, 2014. Dr. Goodman joins Dr. Margaret Kripke (Chief Scientific Officer) and Dr. Becky Garcia (Chief Prevention Officer).	701.5(1)(G)
102.101(d)	Mandates that each appointing office must appoint at least one physician or scientist with experience in oncology or public health.	Dr. Bill Rice (Governor appointee), Dr. Craig Rosenfeld (Lt. Governor appointee), and Dr. Cynthia Mulrow (Speaker of the House appointee) were appointed to the Oversight Committee in 2013.	
102.101(f)	Requires each Oversight Committee member to annually report political contributions exceeding $1000 to state or federal candidates. CPRIT must make the information publicly available on its website.	CPRIT posted information related to Oversight Committee members' political contributions on its website in December 2013.	701.27(4)
102.104	Clarifies the process for electing a presiding officer and requires an assistant presiding officer; requires the Oversight Committee to establish duties and responsibilities for	The Oversight Committee amended its Bylaws to specify duties and responsibilities of the presiding officer and assistant presiding officer and specify an election process. Once all members were appointed to the	701.5, CPRIT Bylaws Sec. 5.2, 5.3

Statute	Description	Implementation	CPRIT Rule
	Oversight Committee officers that are distinguishable from the responsibilities of the CPRIT CEO and employees.	Oversight Committee, a vote was held at the November 22, 2013, Oversight Committee to elect Dr. Bill Rice presiding officer, Mr. Pete Geren assistant presiding officer, and Ms. Amy Mitchell secretary.	
102.107	Directs the Oversight Committee to annually set priorities for each grant program and consider the priorities in awarding grants.	The Oversight Committee initiated the Program Priorities Project, working initially through the board subcommittees. A working session will be held September 3, 2014, to discuss and establish policy priorities for each program and for CPRIT. A final decision is expected to be adopted at the November 19, 2014, Oversight Committee meeting.	701.27(5), 703.1(b)
102.109	Mandates that the Oversight Committee adopt a Code of Conduct applicable to the Oversight Committee members, PIC members, and CPRIT employees specifying the minimum requirements for the Code.	At its November 1, 2013, meeting, the Oversight Committee adopted revisions to the Code of Conduct originally approved February 25, 2013. The changes were made to specifically address the requirements specified in the statute.	702.9, CPRIT Bylaws, Article 9 (the Code of Conduct is adopted by reference in the CPRIT Bylaws.)
Augmenting the Review Process – Creation of the Program Integration Committee and Affirmative Approval by Oversight Committee of Grant Awards			
102.251(a)(2)	Establishes the Program Integration Committee (PIC) composed of the CEO, the Chief Scientific Officer, the Chief Product Development Officer, the Chief Prevention Officer, and the Commissioner of State Health Services. The PIC must submit grant recommendations to the Oversight Committee that fulfill statutory priorities. Mandates the attendance of the Chief Compliance Officer at PIC meetings to ensure compliance.	CPRIT established the PIC review process, including documentation of the factors considered by the PIC when recommending awards. The PIC submitted its first grant award recommendations to the Oversight Committee in February, 2014.	§ 703.7
102.252	Allows Oversight Committee members to affirmatively vote to approve the PIC's grant award recommendations.	The Oversight Committee voted to approve grant awards for the first time on February 19, 2014, for the initial cycle of grant applications submitted following the adoption of SB149.	703.8(2)

Statute	Description	Implementation	CPRIT Rule
Clarifying Matching Fund Requirements; Verifying Accuracy and Availability of Matching Funds			
102.255(c)(3)(A), (d)(6), (d)(8)-(9)	Requires CPRIT to verify the amount and availability of matching funds that grantees report.	In addition to the certification of available matching funds, CPRIT now requires the grantee to verify the expenditure of matching funds at the end of the project year by submitting supporting documentation that shows actual expenditure of funds counted as a match. The failure to submit required documentation will result in the suspension of grant funding and may serve as a basis for terminating the grant award.	703.10(c)(20),703.11(a),(g),(j), 703.21(b)(3)(B)(i) and (x)
102.255(d)(1)	Specifies new matching requirements for public or private institutions of higher education.	CPRIT adopted a change to its administrative rule establishing a process for public or private institutions of higher education to credit toward its matching fund requirement the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government and CPRIT's indirect cost rate.	703.11
Implementing a Compliance Program Under the Direction of the Chief Compliance Officer			
102.051(c), 102.263	Directs CPRIT to employ a Chief Compliance Officer who reports to the Oversight Committee. The CCO is responsible for establishing a compliance program to assure Oversight Committee member and employee compliance with statutory, administrative rule requirements, and policies related to ethics and standards of conduct, financial reporting, and internal audit controls.	Since August 2012, CPRIT has employed a Chief Compliance Officer that is accountable for apprising the Oversight Committee and the CEO regarding institutional compliance. The CCO presents his report to the Oversight Committee quarterly at an open meeting and may report to the Audit Subcommittee on issues occurring between quarterly Oversight Committee meetings.	701.7, 703.8(1)(A)
	Authorizes CPRIT to establish procedures for reporting compliance issues, such as a telephone hotline, to allow private access to the compliance program.		

Statute	Description	Implementation	CPRIT Rule
Improving Monitoring of Grantee Expenditures and Project Progress			
102.0535(a)(2)	Mandates that CPRIT obtain sufficient documentation to support the appropriateness of all payments it makes to grantees and to retain documentation of all financial and progress reports received and reviewed.	CPRIT requires grantees to submit quarterly financial status reports (FSR) and general ledger data supporting the FSR before releasing funds for reimbursement. CPRIT adopted an administrative rule that authorizes CPRIT to waive a quarterly reimbursement when a grantee fails to timely submit the quarterly FSR information. CPRIT's electronic grants management system maintains complete grant award records, including matching funds certification and verification, required financial reports and grant progress reports. Changes made to the electronic system in July 2013 allow CPRIT to retain all documentation.	703.4(1)(E), 703.21(b)
102.051(a)(5) – (7)	Requires CPRIT to continuously monitor grant contracts and ensure grantee compliance with the terms and conditions of the grant contract.	The Chief Compliance Officer is responsible for monitoring the timely submission of required grantee reports and notifying the Oversight Committee and General Counsel of a grantee's failure to comply with reporting deadlines. Since December 2012, the CCO has reported to the Oversight Committee at each quarterly meeting regarding submission of grantee reports. The CCO also issues a comprehensive annual report regarding grantees' compliance with the terms and conditions of the grant contracts. The CCO's report was included in the agency's 2013 Annual Report. CPRIT hired additional staff in June 2014 to monitor grant compliance and assist grantees in complying with administrative rules and contractual requirements.	701.7(c), 703.8(1)(C)(D)
102.051(d)	Directs the Chief Compliance Officer to ensure that all grant proposals are in compliance prior to the Oversight Committee's approval.	Beginning with the grant awards announced in December 2012, the Chief Compliance Officer certifies that the applications recommended for grant awards are in compliance prior to Oversight Committee approval.	703.8(1)(A)

Statute	Description	Implementation	CPRIT Rule
102.260(a)	Requires grantees, as a condition of the grant award, to submit to regular inspection reviews of the grant project to ensure compliance with the terms of the award and to ensure the scientific merit of the research. The CEO must report at least annually to the Oversight Committee on the progress and continued merit of each research program funded by CPRIT and is authorized to terminate grants that do not meet contractual obligations.	CPRIT adopted administrative rules specifying penalties for failing to timely submit required financial and project progress reports. The administrative rules also specify that the CEO will notify the Oversight Committee regarding the progress and continued merit of each CPRIT-funded project through the agency's Annual Report and in a presentation at the first Oversight Committee meeting following the publication of the annual report.	
102.260(f)	Obligates the Chief Compliance Officer to monitor the status of required reports not timely submitted to CPRIT.	The Chief Compliance Officer notifies the Oversight Committee and General Counsel of a grantee's failure to comply with reporting deadlines. Since December 2012, the CCO has reported to the Oversight Committee at each quarterly meeting regarding submission of grantee reports. The CCO also issues a comprehensive annual report regarding grantees' compliance with the terms and conditions of the grant contracts. The CCO's report was included in the agency's 2013 Annual Report.	
Increasing Transparency in Relationship with Foundations Created to Support CPRIT			
102.056	Prohibits the salary supplementation of CPRIT employee salaries with gifts or grants given to CPRIT.	CPRIT ended the salary supplementation of the Executive Director when the Oversight Committee hired Wayne R. Roberts as interim Executive Director on December 21, 2012. The salary supplementation for the Chief Scientific Officer ended August 31, 2013. All employee salaries are paid only with general appropriations.	
102.262(c)	Determines that the records of a nonprofit organization created to support CPRIT are public information.	CPRIT adopted administrative rules to carry out this requirement. The CPRIT Foundation shut down in May 2013. Currently there are no organizations that were created to support CPRIT in operation.	701.27(13), 701.29(f)(6)

Figure VII - Research Peer Review Process

Cancer Prevention & Research Institute of Texas

STEP 1 Request for Application (RFA)	CPRIT releases a Request for Application (RFA) via the website, subscribers to CPRIT's email newsletter and the Texas Register.
STEP 2 Applying Online	Applicants submit proposals using CPRIT's online application receipt system (www.cpritgrants.org). Applicants must include information about all sources of funding, including private investors. Only applications submitted via the designated electronic portal are eligible for consideration of a grant award and applications are eligible only for the grant mechanism under which the grant application was submitted.
STEP 3 Administrative Review	Applications submitted by the deadline are checked for compliance against the application's administrative requirements and may be withdrawn at this step.
STEP 4 Reviewer Conflict of Interest (COI) Identification	Experts and advocates in cancer research are recruited by panel chairs, provisionally appointed by CPRIT's CEO and approved by the Oversight Committee. The reviewers access a non-confidential summary, a list of key personnel and sources of funding for every application. Reviewers flag potential COI. Some categories of COI may excuse a reviewer from reviewing any application submitted under the same grant mechanism.
STEP 5 Reviewer Assignment	Peer reviewers are assigned to panels in their area of expertise. Panel chairs assign applications to primary reviewers (usually 3 per application). At least one advocate reviewer is assigned to each panel. All reviewers live and work outside of the state. A list of members by panel can be found on CPRIT's website. A reviewer with a conflict does not participate in the discussion, presentation, or scoring of the application at any point in the process. Due to volume, research applications may undergo a preliminary evaluation using the process and criteria specified in the RFA.
STEP 6 Initial Scoring	An eligible application undergoes a rigorous peer review; the proposal is evaluated by (usually three) primary reviewers who provide an individual overall score. Individual overall scores are averaged to produce a single initial overall score for the application.
STEP 7 Panel Discussion	The full peer review panel (12-15 reviewers) discusses the applications. If there is insufficient time to discuss all grant applications, the Review Panel chair determines applications to be discussed, based on initial scores. After discussion, each panel member provides individual overall scores that are averaged to provide a final overall score.
STEP 8 Final Scoring	Based upon the discussion and the scores, the peer review panel develops a rank ordered list of applications it recommends for grant awards. A final overall score and a summary statement of the reviewers' comments are provided to each applicant.
STEP 9 Review Council Recommendation	The Scientific Review Council, consisting of the Chair and panel chairs, considers the panels' recommendations and conducts a programmatic review. Criteria considered during programmatic review are spelled out in the RFA. The Council assigns a numerical ranking score to each application. The Council specifies and explains changes, if any, to the applications' goals, objectives, budget or timeline and these are provided to both the CEO and the Oversight Committee (OC). Once the review process is complete, all reviewers sign a statement that they have followed the CPRIT COI agreement terms.
STEP 10 Program Integration Committee (PIC) Review	The Program Integration Committee (PIC) considers the prioritized list of applications submitted by the Program Review Councils and approves by a majority vote a final list of applications to be recommended to the OC. The PIC includes an explanation for its recommendations.
STEP 11 Oversight Committee Action	The CPRIT CEO forwards the PIC's recommendations and provides an affidavit that each application complied with CPRIT's submission and review process. Two-thirds of the Oversight Committee members present and voting must approve each grant award recommendation submitted by the PIC. The CPRIT Compliance Officer also certifies each recommended award.
STEP 12 Grant Award Contract	All CPRIT grants are awarded through a contract that specifies the responsibilities and obligations of the award recipient and reflects certain reporting and legal requirements.

Note: Recruitment Award Process. Applications for recruitment awards follow steps 1 through 3 above, but they are reviewed by members of the Scientific Review Council (SRC). Reviewers flag potential COI, and the SRC Chair assigns applications to primary reviewers (usually 3). Primary reviewers evaluate and score applications based on criteria specified in the RFA. Applications then follow steps 6-12 above, with SRC members acting as panel members and the SRC Chair serving as Review Panel Chair.

Figure VIII - Product Development Peer Review Process

Cancer Prevention & Research Institute of Texas

STEP 1 Request for Application (RFA)	CPRIT releases a Request for Application (RFA) via the website, subscribers to CPRIT's email newsletter and the Texas Register.
STEP 2 Applying Online	Applicants submit proposals using CPRIT's online application receipt system (www.cpritgrants.org). Applicants must include information about all sources of funding, including private investors. Only applications submitted via the designated electronic portal are eligible for consideration of a grant award and only for the grant mechanism under which the grant application was submitted.
STEP 3 Administrative Review	Applications submitted by the deadline are checked for compliance against the application's administrative requirements and may be withdrawn at this step.
STEP 4 Reviewer Conflict of Interest (COI) Identification	Experts and advocates in development of products related to cancer research are recruited by panel chairs, provisionally appointed by CPRIT's CEO and approved by the Oversight Committee. The reviewers access a non-confidential summary, a list of key personnel and sources of funding for every application. Reviewers identify which applications match their area of expertise and flag potential COI. Some categories of COI may excuse a reviewer from reviewing any application submitted under the same grant mechanism.
STEP 5 Reviewer Assignment	Peer reviewers are assigned to panels in their area of expertise. At least one advocate reviewer is assigned to each panel. All reviewers live and work outside of the state. A list of members by panel can be found on CPRIT's website. A reviewer with a conflict does not participate in the discussion, presentation, or scoring of the application at any point in the process.
STEP 6 Individual Evaluation and Scoring	An eligible application undergoes a rigorous peer review; the proposal is evaluated by (usually three or four) primary reviewers who provide an individual overall score. Individual overall scores are averaged to produce a single initial overall score for the application.
STEP 7 Panel Discussion	The full peer review panel (12-15 reviewers) meets by teleconference and discusses the applications. After discussion, the primary reviewers may adjust their initial scores. The primary reviewers' individual overall scores are then averaged to provide an overall evaluation score for the application; the score and a summary statement of the reviewers' comments are generated for each application that does not move forward for further review. A reviewer with a conflict of interest for an application recuses themself from the discussion and scoring of that application.
STEP 8 In Person Presentations	Applicants with sufficiently positive scores after the panel discussion are invited to present their proposal to the full review panel and answer reviewer questions. Following the presentation, the reviewers discuss the application and all reviewers individually submit an overall score for the application. The individual overall scores are then averaged to provide a final overall evaluation score for the application; the score and a summary statement of the reviewers' comments are provided to each applicant. A reviewer with a conflict of interest for an application recuses themself from the discussion and scoring of that application.
STEP 9 Due Diligence Review	The applications that score sufficiently well after the in-person presentation undergo due diligence review conducted by outside contractors hired by CPRIT and overseen by the Chief Product Development Officer. Due diligence involves an in-depth evaluation of the proposal's underlying intellectual property, clinical trial design, regulatory affairs, manufacturability of product, marketing, etc. The due diligence reports are provided to the primary reviewers and the Product Development Review Council for their consideration.
STEP 10 Review Council Recommendation	Following a discussion of the due diligence reports, the Review Council conducts a programmatic review and decides which applications should be recommended for CPRIT grant funding. Criteria considered during programmatic review are spelled out in the RFA. All Product Development applications recommended for grant funding are numerically ranked by the Review Council and submitted to the Program Integration Committee. The Council specifies and explains changes, if any, to the applications' goals, objectives, budget or timeline and these are provided to both the CEO (as Chair of the Program Integration Committee) and the Oversight Committee (OC). Once the review process is complete, all reviewers sign a statement that they have followed the CPRIT COI agreement terms.
STEP 11 Program Integration Committee (PIC) Review	The Program Integration Committee (PIC) considers the prioritized list of applications submitted by the Program Review Councils and approves by a majority vote a final list of applications to be recommended to the OC. The PIC includes an explanation for its recommendations.
STEP 12 Oversight Committee Action	The CPRIT CEO forwards the PIC's recommendations and provides an affidavit that each application complied with CPRIT's submission and review process. Two-thirds of the Oversight Committee members present and voting must approve each grant award recommendation submitted by the PIC. The CPRIT Compliance Officer also certifies each recommended award.
STEP 13 Grant Award Contract	All CPRIT grants are awarded through a contract that specifies the responsibilities and obligations of the award recipient and reflects certain reporting and legal requirements, including revenue sharing terms and agreed upon milestones.

Figure IX - Prevention Peer Review Process

Cancer Prevention & Research Institute of Texas

STEP 1 Request for Application (RFA)	CPRIT releases a Request for Application (RFA) via the website, subscribers to CPRIT's email newsletter and the Texas Register.
STEP 2 Applying Online	Applicants submit proposals using CPRIT's online application receipt system (www.cpritgrants.org). Applicants must include information about all sources of funding, including private investors. Only applications submitted via the designated electronic portal are eligible for consideration of a grant award and only for the grant mechanism under which the grant application was submitted.
STEP 3 Administrative Review	Applications submitted by the deadline are checked for compliance against the application's administrative requirements and may be withdrawn at this step.
STEP 4 Reviewer Conflict of Interest (COI) Identification	Experts and advocates in cancer prevention are recruited by panel chairs, provisionally appointed by CPRIT's CEO and approved by the Oversight Committee. The reviewers access a non-confidential summary, a list of key personnel and sources of funding for every application. Reviewers identify which applications match their area of expertise and flag potential COI. Some categories of COI may excuse a reviewer from reviewing any application submitted under the same grant mechanism.
STEP 5 Reviewer Assignment	Peer reviewers are assigned to panels in their area of expertise. At least one advocate reviewer is assigned to each panel. All reviewers live and work outside of the state. A list of members by panel can be found on CPRIT's website. A reviewer with a conflict does not participate in the discussion, presentation, or scoring of the application at any point in the process.
STEP 6 Initial Scoring	An eligible application undergoes a rigorous peer review; the proposal is evaluated by (usually three) primary reviewers who provide an individual overall score. Individual overall scores are averaged to produce a single initial overall score for the application.
STEP 7 Panel Discussion	The full peer review panel (12-15 reviewers) discusses the applications. If there is insufficient time to discuss all grant applications, the Review Panel chair determines applications to be discussed. After discussion, each panel member provides individual overall scores that are averaged to provide a final overall score. A reviewer with a conflict of interest for an application recuses themself from the discussion and scoring of that application.
STEP 8 Final Scoring	Based upon the discussion and the scores, the peer review panel develops a rank ordered list of applications it recommends for grant awards. A final overall score and a summary statement of the reviewers' comments are provided to each applicant.
STEP 9 Review Council Recommendation	The Prevention Review Council, consisting of the Chair and panel chairs, considers the panels' recommendations and conducts a programmatic review. Criteria considered during programmatic review are spelled out in the RFA. The Council assigns a numerical ranking score to each application. The Council specifies and explains changes, if any, to the applications' goals, objectives, budget or timeline and these are provided to both the CEO and the Oversight Committee (OC). Once the review process is complete, all reviewers sign a statement that they have followed the CPRIT COI agreement terms.
STEP 10 Program Integration Committee (PIC) Review	The Program Integration Committee (PIC) considers the prioritized list of applications submitted by the Program Review Councils and approves by a majority vote a final list of applications to be recommended to the OC. The PIC includes an explanation for its recommendations.
STEP 11 Oversight Committee Action	The CPRIT CEO forwards the PIC's recommendations and provides an affidavit that each application complied with CPRIT's submission and review process. Two-thirds of the Oversight Committee members present and voting must approve each grant award recommendation submitted by the PIC. The CPRIT Compliance Officer also certifies each recommended award.
STEP 12 Grant Award Contract	All CPRIT grants are awarded through a contract that specifies the responsibilities and obligations of the award recipient and reflects certain reporting and legal requirements.

Peer Reviewer Scoring Guidance

The Overall Evaluation score reflects the reviewers' overall impression of the application based on scored and unscored evaluation criteria described in the RFA

OVERALL EVALUATION	
Score	**Evaluation** (Guidance on Merit and Fundability ratings)
1	Exceptionally strong with essentially no weaknesses Exceptional responsiveness to RFA *Highly recommended for funding*
2	Extremely strong with at least one minor weaknesses Strongly responsive to RFA *Strong recommendation for funding*
3	Very strong with only some minor weaknesses Very responsive to RFA *Strong recommendation for funding*
4	Very good but with numerous minor weaknesses Responsive to RFA *Moderate recommendation for funding, resubmission strongly encouraged*
5	Good but with at least one moderate weakness *Reservations toward funding, resubmission is encouraged*
6	Some strengths but also some moderate weaknesses *Significant reservations toward funding, significant improvements for resubmission*
7	Some strengths but with at least one major weakness *Recommendation not to fund*
8	A few strengths and a few major weaknesses *Strong recommendation not to fund*
9	Very few strengths and numerous major weaknesses *Very strong recommendation not to fund*

Peer Reviewer Scoring guidance for scoring each criterion listed in the RFA

CRITERIA EVALUATION	
Score	**Evaluation** (Guidance on Criterion Ratings)
1	Exceptionally strong with essentially no weaknesses
2	Extremely strong with at least one minor weakness
3	Very strong with only a few minor weaknesses
4	Very good but with numerous minor weaknesses
5	Good but with at least one moderate weakness
6	Some strengths but also some moderate weaknesses
7	Some strengths but with at least one major weakness
8	A few strengths and a few major weaknesses
9	Very few strengths and numerous major weaknesses

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CPRIT Prevention Program Reviewers

Prevention Program Reviewers

Lawrence Green, Chair

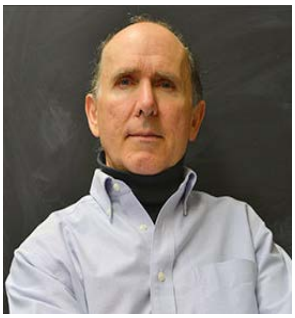
Lawrence (Larry) Green, Dr. P.H., is the Chair of Panel A. He is a Professor at the University of California at San Francisco. His professional interests include social and behavioral aspects of public health, policy and program implications of health research and evaluation, and health education of the public. Dr. Green has a distinguished career with numerous awards including the Lifetime Achievement Award from the American Academy of Health Behavior, an elected member of the Institute of Medicine, National Academy of Science, and the Health Education Hall of Fame Award. He was appointed by President Carter as the first Director of the Office of Health Information, Health Promotion, Physical Fitness and Sports Medicine. Dr. Green has authored over 250 journal articles, monographs, reports, and books. Dr. Green developed the Precede-Proceed model of health program planning and evaluation; use of this model has led to over 1000 publications. He is a graduate of the University of California, Berkeley.

Barbara Berman

Barbara Berman, Ph.D., is an Adjunct Professor Emeritus at the University of California, Los Angeles. Her research interests are tobacco prevention and cancer prevention and control programs. She is particularly interested in tobacco prevention among high risk adolescents and young adults, low-income multi-ethnic populations, and deaf and hard of hearing youth, as well as breast cancer prevention programs for deaf and hard of hearing women and health professionals. Dr. Berman has authored numerous publications, received several grant awards, and served on numerous federal and state grant review panels. She has been involved in training of pre and post-doctoral fellows in cancer prevention and control research. She is a graduate of the University of Michigan.

Heather Brandt

Heather M. Brandt, Ph.D., CHES, is an Associate Professor in the Department of Health Promotion, Education, and Behavior and core faculty in the Cancer Prevention and Control Program in the Arnold School of Public Health at the University of South Carolina (USC). She is also a faculty affiliate in the Women's and Gender Studies Program at USC. She is a social and behavioral scientist whose research interests focus on cancer disparities in cancer prevention and control, HPV-associated cancers (especially cervical cancer), colorectal cancer, and prostate cancer. Her approach to research utilizes community-engaged and community-based participatory strategies. Since 1997, Dr. Brandt has conducted cancer educational programs and research in South Carolina in partnership with other researchers and community partners. She is dedicated to examining, describing, and intervening upon cancer disparities by using innovative approaches in partnership with the community to develop and implement community solutions to community problems to improve health. Dr. Brandt has authored over 40 publications, received over 25 grant awards, served on over 30 federal and state grant review panels, and trained more than 25 graduate students. Currently, Dr. Brandt leads and serves as a team member on several community-based cancer prevention and control research projects working with interdisciplinary research teams and community partners. This research addresses cancer disparities in underserved communities across South Carolina and the United States. She also holds leadership positions in national and state organizations, including the Public Health Education and Health Promotion Section of the American Public Health Association, American Cancer Society, South Carolina Cancer Alliance, and South Carolina Coalition for Healthy Families. She is the recipient of numerous awards in areas including leadership, teaching excellence, and a documentary film. She lives in Columbia, South Carolina with her husband, Forrest Alton.



Richard Crosby

Richard (Rick) Crosby, Ph.D., is the Good Samaritan Endowed Professor and the Senior Director of the Rural Cancer Prevention Center at the University of Kentucky. His research interests are cancer prevention in rural areas, HIV prevention, and sexual behavior. Dr. Crosby has published over 280 journal articles, more than 50 chapters in textbooks, and authored a textbook entitled *Research Methods for Health Promotion*. He has received over 30 grant awards, served on national and international grant review panels, and is the recipient of numerous awards and honors. He is a graduate of Indiana University.

Louise Galaska

Louise Galaska, M.P.A., is a Consultant in the areas of public health program development and policy. She has over 30 years of experience in public health service delivery, program development, and policy. In 2010, she retired from the Centers for Disease Control and Prevention (CDC) where she served as the Chief Management Officer for the Coordinating Center for Environmental Health and Injury Prevention. Her career at CDC also included positions as the Deputy Director for the National Center for Injury Prevention and Control and eight years as the Deputy Director of the Division of Cancer Prevention and Control, as well as 15 years managing infectious disease control programs in state and city health departments. She is a graduate of the University of North Carolina-Chapel Hill.

Charles Given

Charles (Bill) Given, Ph.D., is a Professor at Michigan State University (MSU) in the Department of Family Medicine in the College of Human Medicine and a Senior Research Scientist at the Walther Cancer Foundation. He is also the Director of Research Institute for Health Care Policy at MSU. His research interests are the impact of behavioral interventions on chronic disease – especially cancer, disparities in the delivery and quality of cancer care, and quality and costs of cancer care. He has authored over 240 publications, more than 15 books and book chapters, and over 50 policy statements. Dr. Given is the recipient of several honors and awards and more than 80 funded grants. He has served on numerous state and federal grant review panels. He is a graduate of Michigan State University.

Lauren Jenks

Lauren Jenks, M.P.H., CHES, is Health Statistics Manager at the Center for Health Statistics at the Washington State Department of Health. Her previous positions at the Washington State Department of Health include Epidemiologist for the Healthy Housing and Childhood Lead Poisoning Prevention Program and Director of the Cancer Prevention and Control Unit. She currently serves as the Vice Chair of the Washington State Institutional Review Board. Ms. Jenks began her career as a Public Health Prevention Specialist with the US Centers for Disease Control and Prevention. She is a graduate of Temple University.

Ellen Jones

Ellen Jones, Ph.D., is a Health Policy, Chronic Disease and Health Promotion Consultant at the University of Mississippi Medical Center. She was previously the Associate Director of the Mississippi Health Policy Research Center and the Associate Editor of *Health Promotion Practice*. Dr. Jones' interests are public health policy, program evaluation, and leveraging of resources. She has authored several publications and has received several awards from the Centers for Disease Control Directors of Health Promotion and Education and the National Association of Chronic Disease Directors. She is a graduate of the University of Mississippi Medical Center.

Anne McTiernan

Anne McTiernan, M.D., Ph.D., is a Member at the Fred Hutchinson Cancer Research Center (FCHRC). She previously was the Director of the FCHRC Prevention Center. Her research interests are prevention of cancer through physical activity, diet, and chemoprevention; epidemiology; and cancer survivorship. Dr. McTiernan has authored over 350 publications, written and edited 4 books, and received over 45 grant awards. She has been featured in national publications such as Time Magazine, USA Today, the New York Times, Parade Magazine, and U.S. News and World Report. Dr. McTiernan has served on numerous state, national, and international grant review panels, editorial boards, and advisory committees, including the Department of Health and Human Services Physical Activity Guidelines Advisory Committee and the American Association for Cancer Research (AACR) Cancer Prevention Committee. She is a graduate of New York Medical College and the University of Washington.

Donald Morisky

Donald (Don) Morisky, Sc.D., M.S.P.H., is a Professor of Public Health at the University of California at Los Angeles. His research interests are behavioral health, social and behavioral determinants of HIV/AIDS prevention, and chronic and infectious disease control. Dr. Morisky has authored over 180 publications, has given nearly 600 presentations at national and international scientific meetings, and written over 30 books and book chapters. He has received over 40 grant awards and served on numerous grant review panels and advisory boards. Dr. Morisky is the recipient of numerous honors and awards, including the Distinguished Career Award from the American Public Health Association, the Mentor of the Year Award from the Society of Public Health Education, and the Elizabeth Fries Prize for Excellence in Health Education. He is a graduate of the Johns Hopkins School of Hygiene and Public Health and the University of Hawaii School of Public Health.

Marcus Plescia

Marcus Plescia, M.D., M.P.H., is the Director of the Mecklenburg County Health Department in North Carolina. He previously was the Director, Division of Cancer Prevention and Control at the Centers for Disease Control and Prevention (CDC). His interests are cancer screening programs and program policy, planning, and evaluation. Dr. Plescia has authored over 35 publications, 10 surveillance reports, 12 commentaries, and 2 book chapters. He has received several grants from national and local agencies and has served on several advisory committees and boards of directors, including C-Change and the National Institute of Environmental Health Sciences Federal Advisory Committee on Breast Cancer and the Environment. Dr. Plescia is also the past President of the National Association of Chronic Disease Directors. He is a graduate of the University of North Carolina at Chapel Hill.

Robin Vanderpool

Robin Vanderpool, Dr.P.H., CHES, is an Assistant Professor in the Department of Health Behavior at the University of Kentucky (UK) College of Public Health and the Deputy Director of the UK Rural Cancer Prevention Center. She previously served as a Senior Research Coordinator for the National Cancer Institute's Cancer Information Service. Her professional interests include cancer disparities among rural and Appalachian populations, implementation and dissemination research, qualitative research, and the impact of cancer on employment and treatment outcomes. Dr. Vanderpool has authored over 30 publications, contributed to 2 textbooks, and collaborated on 10 public health reports at local and state levels. She has received several grant awards and has served on state, national, and international grant review panels. She is a graduate of UK, Western Kentucky University, and Centre College.

Charlotte Naschinski

Charlotte Naschinski, RN, M.S., is an advocate reviewer representing the Ovarian and Gynecological Cancer Coalition of Greater Washington, where she has served on the Board of Directors and as Medical Program Chair. She is also actively engaged with the Ovarian Cancer National Alliance. Ms. Naschinski is a long-term ovarian cancer survivor. She has served on numerous national and state peer review panels in subject areas including health care, nursing and ovarian cancer and cancer prevention and control. Before Ms. Naschinski's retirement from her professional career, she was the Director, Continuing Education for Health Professionals at the Uniformed Services University of the Health Sciences. She has an M.S. in nursing education and administration and has numerous publications, presentations, and awards in this area. She is a graduate of the University of Maryland at Baltimore.

Jane Segelken

Jane Segelken, M.A., LMSW, is a 17-year breast cancer survivor and an advocate reviewer representing the Cancer Resource Center of the Finger Lakes. She is the previous President of the Ithaca Breast Cancer Alliance Board of Directors. Ms. Segelken has served on numerous national and state peer review panels in subject areas including breast cancer, prostate cancer, neurofibromatosis, clinical trials, and cancer prevention and control. In her professional life, she is a Service Coordinator at McGraw House (an independent-living apartment for senior citizens). Ms. Segelken has master's degrees in social work and health advocacy. She is a graduate of Syracuse University and Sarah Lawrence College.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CPRIT Scientific Review Council

Biographies and Research Interests

Scientific Peer Review Panel Members

Richard Kolodner, Ph.D., Chair, Scientific Review Council

Head, Academic Affairs, Ludwig Institute for Cancer Research, New York Offices
Member, Ludwig Institute for Cancer Research San Diego Branch and Head of the Laboratory of Cancer Genetics
Distinguished Professor of Medicine and of Cellular and Molecular Medicine, UCSD School of Medicine

Research Focus

The major research interest of Dr. Kolodner's laboratory is using *Saccharomyces cerevisiae* as a model organism to study the molecular mechanisms by which cells maintain the stability of their genome and prevent the accumulation of mutations and genome rearrangements. The laboratory also works on inherited defects in human recombination and repair genes to understand how such defects cause cancer susceptibility and to understand the basic human genetics of these genes. These studies have involved the routine use of techniques in *S. cerevisiae* genetics, protein purification, genomics and human genetics.

Research in Dr. Kolodner's laboratory is focused on two major projects. In the first project, the laboratory is using *S. cerevisiae* to study the genes and proteins that function in DNA Mismatch Repair (MMR), a pathway that prevents mutations from accumulating as a result of errors during DNA Replication. The majority of ongoing work on this project is directed at the purification and study of MMR proteins, the reconstitution of MMR using purified proteins and the biochemical analysis of the mechanism of MMR. As part of Dr. Kolodner's work on MMR, his laboratory has made a number of important contributions to the discovery that a common cancer susceptibility syndrome, hereditary non-polyposis colon cancer (HNPCC) sometimes called Lynch Syndrome, is caused by inherited defects in MMR genes. The laboratory also discovered that the majority of sporadic MMR defective cancers occur as the result of epigenetic silencing of MMR genes. In a second project on DNA repair in *S. cerevisiae*, Dr. Kolodner's laboratory identified a new class of genes that prevent the accumulation of deletion mutations and chromosomal translocations like the chromosomal rearrangements seen in human cancer cells. The majority of onging work on this project is directed at identifying the genes and pathways that suppress genome rearrangements, identifying the mechanisms by which genome rearrangement are formed and prevented, and determining if defects in genome rearrangement suppressing pathways play a role in the development of cancer.

Education

University of California, Irvine, B.S.
University of California, Irvine, Ph.D., Biological Sciences
Postdoctoral Fellow at Harvard Medical School

Other Experience

Member, American Society for Microbiology
Member, American Society of Biochemistry and Molecular Biology
Member, Genetics Society of America
Member, American Association for Cancer Research
Co-editor-in-chief of PLASMID
Associate Editor, Cancer Research
Associate Editor, Cell
Editorial Board Member, Molecular and Cellular Biology
Editorial Board Member, Journal of Biological Chemistry
Advisory Committee, NIH consortium of Familial Colon Cancer Registries

Selected Honors

ACS Junior Faculty Research Award
ACS Faculty Research Award
NIH MERIT Award
Sandoz Pharmaceuticals Inc. Special Scientific Achievement Award
Dana-Farber Cancer Institute Morse Research Award
Dana-Farber Cancer Institute Charles A. Dana Senior Investigator Chair
Charles S. Mott Prize of the General Motors Cancer Research Foundation
Kirk A. Landon-American Association for Cancer Research Award for Basic Cancer Research
Fellow, American Academy of Arts and Sciences
Member, National Academy of Sciences (USA)
Member, Institute of Medicine (USA)

Tom Curran, Ph.D., FRS, Chair, Basic Cancer Research Peer Review Panel

Mai and Harry F. West Chair in Pediatric Research
Deputy Scientific Director, The Children's Hospital of Philadelphia Research Institute
Professor of Pathology and Laboratory Medicine, Cell & Developmental Biology, Perelman School of Medicine
Associate Director Translational Genomics, University of Pennsylvania

Research Focus

Dr. Curran discovered the Fos oncogene and its binding partner, p39, which he later showed was the product of the Jun oncogene. His laboratory demonstrated that Fos and Jun function as inducible transcription factors that regulate gene expression in response to extracellular stimuli associated with proliferation, differentiation, cell death and neuronal activation. This work elucidated the signal transduction pathways that go awry in cancer cells and has initiated the use of Fos as a marker for activity-dependent changes in the nervous system.

His laboratory also uncovered redox regulation of mammalian transcription factors by Ref-1, which also functions as a DNA repair protein. In addition, he identified the gene Reelin and elaborated a signaling pathway that controls neuronal positioning in the developing brain.

Dr. Curran recently developed a high-incidence model of pediatric medulloblastoma with which he demonstrated that orally-bioavailable, small molecule inhibitors of Hedgehog signaling rapidly eliminate even large tumors in mice. This work led to clinical development of inhibitors for the treatment of basal cell carcinoma and medulloblastoma.

Education

University of Edinburgh (Scotland), B.Sc. (Honors), Biological Sciences
Imperial Cancer Research Fund & University College (London), Ph.D., Zoology and Anatomy
Salk Institute, Postdoctoral, Molecular Oncology

Other Experience

Member, NIH Study Section Cellular Biology and Physiology 2
Member, Scientific Review Board, Hoffmann La Roche, Inc.
Member, NCI Initial Review Group Committee Subcommittee C
President, American Association for Cancer Research
National Cancer Institute Board of Scientific Advisors

Selected Honors

Passano Foundation Young Scientist Award
Rita Levi Montalcini Award in Neurosciences
Tenovus-Scotland Medal, Glasgow University, Scotland
American Association for Cancer Research, for Outstanding Achievement in Cancer Research Award
Golgi Award, Italian Academi of Neuroscience and the Camillo Golgi Foundation, Brescia, Italy
Fellow of the American Association for the Advancement of Science
Fellow of the American Society of Microbiology
Highly Cited Scientist by Institute for Scientific Information (ISI) in three categories; Neuroscience, Molecular Biology & Genetics, and Microbiology
Javitz Neuroscience Investigator Award, National Institute of Neurological Disorders and Stroke, NIH
Peter M. Steck Memorial Award for Brain Tumor research
LIMA International Award for Excellence in Pediatric Brain Tumor Research, Pediatric Brain Tumor FD
Fellow of the Royal Society
Member, Institute of Medicine of the National Academies
American Association for Cancer Research Academy

Basic Cancer Research, Panel 1 Peer Review Panel Members

Suzanne Baker, Ph.D.
Dept of Developmental Neurobiology
St. Jude Children's Research Hospital Comprehensive Cancer Center
Memphis, TN

Allan Balmain, Ph.D., FRSE
Institute for Human Genetics
University of California, San Francisco
San Francisco, CA

Steve Fiering, Ph.D.
Dept of Microbiology and Immunology, and Genetics
Dartmouth University Geisel School of Medicine
Lebanon, NH

Kevin M. Haigis, Ph.D.
Dept of Pathology
Harvard Medical School
Boston, MA

Lin He, Ph.D.
Dept of Molecular and Cell Biology
University of California, Berkeley
Berkeley, CA

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Dept of Molecular Oncology
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Kent Hunter, Ph.D.
Center for Cancer Research
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Dept of Anatomy
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San Francisco, CA

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Gene Expression and Regulation Program
Tumor Microenvironment and Metastasis Program
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Dept of Pathology
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Detroit, MI

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Joshua Schiffman, M.D.
Division of Pediatric Hematology/Oncology, Dept of Pediatrics,
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Depts of Pharmacology and Cancer Biology
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Robert Wechsler-Reya, Ph.D.
Tumor Initiation and Maintenance Program
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Bart Williams, Ph.D.
Center for Skeletal Disease and Tumor Metastasis
Van Andel Research Institute
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Dept of Biochemistry
Case Western Reserve University
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Advocate Reviewers
David Houchens, Ph.D.
Us TOO International, Inc.
Columbus, OH

Roxana Bellia, Ph.D.
USC Norris Comprehensive Cancer Center
Long Beach, CA

Carol Prives, Ph.D., Chair, Basic Cancer Research Peer Review Panel

Professor, Dept of Biological Sciences, Columbia University

Research Focus

Dr. Prives's research has focused on the p53 tumor suppressor since the late 1980's when she established conditions for purifying and characterizing the p53 protein biochemically and was among the first to show that p53 is a sequence specific transcriptional activator. Her research found that tumor derived mutant forms of p53, especially those that are mutated with high frequency, are defective in such transactivation. Dr. Prives continued to study p53 as a DNA binding transactivator, with special focus on mechanisms by which p53 selects its target genes; and she also provided the first model for stabilization of p53 by genotoxic stress when her group showed that p53 becomes phosphorylated after DNA damage at sites that weaken its interaction with its negative regulator Mdm2. They have continued to study the structure and functional regulation of Mdm2 and its relationship to p53. After the p53 homologues, p63 and p73, were identified, she developed and tested the hypothesis that one of the modes by which some tumor derived mutant forms of p53 elicit pro-oncogenic activities is through down-regulation of the apoptotic functions of p63/p73. Since then, her work has focused on many aspects of the p53 family and on mutant p53. Recently, she has examined mutant p53 pro-oncogenic activities in breast cancer cell lines using the "3D" culture protocol.

Education

McGill University, B.S., Biochemistry
McGill University, Ph.D., Biochemistry
Albert Einstein College of Medicine, Postdoc Fellow, Biochemistry
Weizmann Institute, Senior Postdoc, Biochemistry

Other Experience

NIH Virology Study Section
Chair, NIH Experimental Virology Study Section
Damon Runyon Advisory Committee
NICHD Scientific Advisory Board
Damon Runyon Scholars Panel
Alberta Heritage Foundation SAC
Howard Hughes Medical Institute Review
NCI Board of Scientific Councilors
MGH Cancer Center Advisory Board
Dana Farber Cancer Center Advisory Board
Memorial Sloan Kettering Scientific Advisory Board
General Motors Awards Council
AACR Board of Directors
Chair, CAMP Study Section

Selected Honors

NIH MERIT Award
American Cancer Society Research Professor
American Academy of Arts and Sciences
American Academy of Microbiology
Member, Institute of Medicine of the National Academies
Member, National Academy of Sciences
NCI Rosalind E Franklin Award for Women in Science
Paul Jansen Prize in Advanced Biotechnology and Medicine
AACR-Women in Cancer Research Charlotte Friend Memorial Lectureship Award

Basic Cancer Research, Panel 2 Peer Review Panel Members

Nabeel Bardeesy, Ph.D.
Dept of Medicine
Harvard Medical School
Boston, MA

Shelly Berger, Ph.D.
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Nina Bhardwaj, M.D., Ph.D.
Depts of Medicine, Pathology and Dermatology
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New York, NY

Walter Chazin, Ph.D.
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Nashville, TN

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Davis, CA

Winfried Edelmann, Ph.D.
Dept of Cell Biology and Physiology
Albert Einstein College of Medicine
New York, NY

Jan Karlseder, Ph.D.
Glenn Center for Research on Aging
The Salk Institute for Biological Studies
La Jolla, CA

James Manfredi, Ph.D.
Dept of Oncological Sciences
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John Petrini, Ph.D.
Weill Graduate School of Medical Sciences
Cornell University
Ithaca, New York

Ellen Puré, Ph.D.
Perelman School of Medicine
University of Pennsylvania
Philadelphia, PA

Ali Shilatifard, Ph.D.
Stowers Institute for Medical Research
Kansas City, MO

Nahum Sonenberg, Ph.D.
Dept of Biochemistry & Goodman Cancer Research Centre
McGill University
Montreal, QC

Alan Tomkinson, Ph.D.
Depts of Internal Medicine and Molecular Genetics and Immunobiology
University of New Mexico
Albuquerque, NM

Matthew Weitzman, Ph.D.
Children's Hospital of Philadelphia
Dept of Pathology and Laboratory Medicine
Philadelphia, PA

Jeffrey Wrana, Ph.D.
Lunenfeld-Tanenbaum Research Institute
Mount Sinai Hospital
Toronto, Ontario

Junying Yuan, Ph.D.
Dept of Cell Biology
Harvard Medical School
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Advocate Reviewers
Margerie Manning, D.D.S.
San Luis Obispo Young Survivors
San Luis Obispo, CA

Sarah Wise Miller, M.B.A.
Kidney Cancer Association
Rye, NY

Peter Jones, Ph.D., Chair, Cancer Biology Peer Review Panel

Mark A., J. Ruth, and Stillman F. Sawyer Chair in Cancer Research, Keck School of Medicine of USC, USC Norris Comprehensive Cancer Center
Professor of Biochemistry & Molecular Biology and Urology, Keck School of Medicine USC

Research Focus

A pioneer in the field of epigenetics, Dr. Jones has uncovered basic mechanisms of DNA methylation and its role in cancer. He discovered that 5-azacytidine can induce changes in gene expression and act as a powerful DNA methylation inhibitor, which led to the isolation of the first mammalian determination gene and to the discovery of tumor suppressor genes that are epigenetically silenced in human cancer. The drug 5-azacytadine has been approved for use in treatment of myelodysplastic syndrome.

Dr. Jones' collaborative research has led to delineating molecular pathways in the development of bladder cancer and to the realization that DNA methylation sites are hotspots for cancer-causing mutations and that epigenetic silencing plays a major role in carcinogenesis. He helped establish the International Human Epigenome consortium and co-directs a Stand-Up-to-Cancer dream team developing new cancer treatments.

Education

University College of Rhodesia, B.Sc., Biochemistry
University of London, Ph.D., Biochemistry

Other Experience

Member, Cellular Biology and Physiology Study Section
Member, Cancer Center Support Review Committee, NCI
Member, Integration Panel, US Army Medical Research and Development Command Breast Cancer Research
Co-Chair, NCI Progress Review Group, Kidney and Bladder Cancers
President, American Association for Cancer Research

Selected Honors

Outstanding Investigator Grant, National Cancer Institute
Distinguished Professor of Biochemistry and Molecular Biology at USC
Greenfield Lecturer, University of Nebraska Medical Center
Nakahara Memorial Lecture, Tokyo, Japan
Simon M. Shubitz Award, University of Chicago
Willet Whitmore Lecture, American Urological Association
Distinguished Speaker, American Society of Human Genetics
Firkin Oratory, Australian Society for Medical Research
William Wallace Scott Memorial Lecture, The Johns Hopkins University
Donald S. Coffey Lecture, Society for Basic Urologic Research
Oettlé Award, Cancer Association of South Africa
Workman Award, Samuel Waxman Foundation, New York, NY (shared with S. Baylin)
Kirk A. Landon Prize for Basic Cancer Research (shared with S. Baylin)
Meyenburg Lecturer, German Cancer Research Center
MERIT Award, National Cancer Institute
Fellow, American Association for the Advancement of Science
Distinguished Service Award, University of Miami, Winter Symposium
American Cancer Society, Medal of Honor for Basic Research (shared with S. Baylin)
Lattimer Lecturer, American Urological Association
Fellow, American Association for Cancer Research Academy

Cancer Biology Peer Review Panel Members

Steven Belinsky, Ph.D.
Population Sciences Program, New Mexico Cancer Center
University of New Mexico
Albuquerque, New Mexico

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Boston Medical Center
Boston, MA

Carol Vallett, Ed.D.
Cancer Patient Support Program
Fairfax, VT

Thomas A. Sellers, Ph.D., M.P.H., Chair, Cancer Prevention Research Peer Review Panel

Executive Vice President and Center Director, H. Lee Moffitt Cancer Center & Research Institute
Adjunct Professor, Dept of Epidemiology and Biostatistics, College of PH, University of South Florida
Adjunct Professor, Dept of Oncologic Sciences, College of Medicine, University of South Florida
Adjunct Professor, Dept of Epidemiology and Health Policy Research, University of Florida

Research Focus

Dr. Sellers' research program seeks to integrate a basic science background in nutrition and genetics with observational research methods to try to understand questions such as, why do less than 20% of cigarette smokers develop lung cancer and why is a proven effective cancer treatment beneficial to only a subset of patients? His studies are based on genetic analysis of germline DNA and the increasing incorporation of acquired (somatic) events. The primary focus of his research is ovarian cancer, which is a devastating disease with no clear warning signs and high mortality rates. Dr. Sellers also has active collaborations that involve cancers of the breast, lung and prostate. The underlying theme is identifying individual differences in cancer susceptibility and using that information to facilitate approaches to cancer prevention, early detection and precision medicine to enhance outcomes after diagnosis. Critical to the success of this effort is team science, necessitating collaborations with geneticists, pathologists, biostatisticians, biomedical informaticists and clinicians.

Education

American River College, A.A., Physical Science
University of California at Davis, B.S., Community Nutrition
Tulane University, School of Public Health and Tropical Medicine, M.P.H., Epidemiology
Tulane University, Ph.D., Epidemiology
Louisiana State University Medical Center, Post-doc, Genetic epidemiology

Other Experience

National Cancer Institute, Board of Scientific Advisors
American Association for Cancer Research, Member, Board of Directors
International Genetic Epidemiology Society
American Society for Preventive Oncology, Executive Committee

Selected Honors

Delta Omega Honorary Society of Public Health, Eta Chapter
Sigma Xi Scientific Research Society
Postdoctoral Prize, Sigma Xi/LSUMC Research Day
Bush Foundation Excellence in Teaching Program
Paul N. Larson Memorial Lecture - University of Minnesota
Alpha Theta Lecture - University of Mississippi Medical Center
Elected member, American Epidemiological Society
James B. Knight Memorial Lecture

Cancer Prevention Research Peer Review Panel Members

William Barlow, Ph.D.
Dept of Biostatistics
University of Washington
Seattle, WA

Thomas Brandon, Ph.D.
Dept of Health Outcomes and Behavior
Moffitt Cancer Center
Tampa, FL

Zigang Dong, M.D., Dr.P.H.
The Hormel Institute
University of Minnesota
Austin, MN

Brooke Fridley, Ph.D.
Dept of Biostatics
University of Kansas Medical Center
Kansas City, KS

Christopher Haiman, Sc.D.
Dept of Preventive Medicine
University of Southern California
Los Angeles, CA

Alan Kristal, Dr.P.H.
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Lawrence Kushi, Sc.D.
Dept of Internal Medicine
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Dept of Epidemiology
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Elena Martinez. M.P.H., Ph.D.
College of Public Health and Arizona Cancer Center
University of Arizona
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Susan Mayne, Ph.D., F.A.C.E.
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Andrew Olshan, Ph.D.
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Chapel Hill, NC

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Fazlul Sarkar, Ph.D.
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Wayne State University School of Medicine
Detroit, MI

Advocate Reviewers
Michal-Judith Gillman
San Luis Obispo Young Survivors
Central Coast Survive Oars
Atascadero, CA

Brian Booher
Ann's Place, Inc.
Brookfield, CT

Margaret A. Tempero, M.D., Chair, Clinical and Translational Cancer Research Peer Review Panel

Director, UCSF Pancreas Center
Rombauer Family Distinguished Professorship in Pancreas Cancer Clinical and Translational Science

Research Focus

Dr. Tempero's research career has focused on pancreatic ductal adenocarcinoma, especially in the area of investigational therapeutics. She was a pioneer in the use of antibody-based therapies and helped develop the fixed dose rate concept for gemcitabine. Her group has developed effective gemcitabine combinations and provided a foundation for using CA19-9 as a surrogate for survival in clinical trials, and currently is assessing molecular subtypes and molecular enrichment for selecting new drugs for clinical evaluation.

Education

Creighton University, B.S., Medical Technology
University of Nebraska Medical Center, M.S., Clinical Pathology
University of Nebraska Medical Center, M.D., Medicine
University of Nebraska Medical Center, Residency, Internal Medicine
University of Nebraska Medical Center, Fellowship, Oncology

Other Experience

President, American Society of Clinical Oncology
Member, Board of Directors, American Society of Clinical Oncology
Organizer, Pancreas Cancer Think Tank
Co-Lead, NCI sponsored Progress Review Group on Pancreatic Cancer
Chair, NCCN Guidelines Panel on Pancreatic Cancer
Co-Chair, NCI Pancreas Task Force Tissue Acquisition Working Group
Co-Director, AACR/ASCO Methods in Clinical Cancer Research
Chair, NCI Clinical Oncology Study Section (CONC)
Member and Chair, NCI Board of Scientific Counselors
External Advisory Board, Pancreas SPORE, University of Alabama-Birmingham/University of Minnesota/Mayo Clinic
Scientific Advisory Board, Lustgarten Foundation; Pancreatic Cancer Action Network; The V Foundation; The Alberta Canada Cancer Board; EORTC
Oncology Drug Advisory Committee, FDA
Member, Clinical Advisory Board and Scientific Advisory Board, Raven Biotechnologies, Inc.
Member, Scientific Advisory Board at Ras Therapeutics, Inc.
Chairperson, Oncology Scientific Advisory Board at Rexahn Pharmaceuticals, Inc.
Member, Clinical Trial Advisory Board of Oxigene Inc.

Selected Honors

Doris & Donald Fisher Distinguished Professor in Clinical Cancer Research; University of California, San Francisco

Clinical and Translational Cancer Research Peer Review Panel Members

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Walter J. Curran Jr., M.D.
Dept of Radiation Oncology
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Division of Pulmonary and Critical Care Medicine
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Fred Hirsch, M.D., Ph.D.
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Clifford A. Hudis, M.D.
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Memorial Sloan-Kettering Cancer Center
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Fadlo Khuri, M.D.
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Patricia LoRusso, D.O.
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Karmanos Cancer Institute
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Stanford University School of Medicine
Palo Alto, CA

Pamela Munster, Ph.D.
Dept of Medicine, Hematology/Oncology
University of California, San Francisco
San Francisco, CA

Donna Niedzwiecki, Ph.D.
Dept of Biostatistics and Bioinformatics
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Kenneth Pienta, M.D.
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University of Michigan Medical School
Ann Arbor, MI

Oliver Press, M.D., Ph.D.
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Antoni Ribas, M.D., Ph.D.
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University of California Los Angeles Jonsson
Comprehensive Cancer Center
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Neil Shah, M.D., Ph.D.
Dept of Medicine, Hematology/Oncology
University of California, San Francisco
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Walter Stadler, M.D., F.A.C.P.
Dept of Medicine
University of Chicago School of Medicine
Chicago, IL

Sarah Thayer, M.D., Ph.D.
Dept of Surgery
Harvard Medical School
Boston, MA

Eric Winer, M.D.
Dept of Medicine
Dana-Farber Cancer Institute
Boston, MA

Advocate Reviewers
Laura Porter, M.D.
Colon Cancer Alliance
Cheverly, MD

Robert Mesloh
Lymphoma Research Foundation
NJ

Sanjiv "Sam" Gambhir, M.D., Ph.D., Chair, Imaging Technology and Informatics Peer Review Panel

Chair, Dept of Radiology, Stanford University School of Medicine
Director, Canary Center at Stanford for Cancer Early Detection
Director, Molecular Imaging Program at Stanford (MIPS)
Professor, Dept of Radiology and Bio-X Program, Stanford University
Professor, Dept of Bioengineering, Stanford University

Research Focus

Dr. Gambhir's research focuses on imaging assays to monitor fundamental cellular/molecular events in living subjects with an emphasis on cancer. Technologies being utilized include micro-positron emission tomography (microPET), bioluminescence imaging, fluorescence optical imaging, Raman optical imaging, ultrasound, and photoacoustics in small animal models. Particular interest of his research and lab is early cancer detection including combining *in vivo* and *in vitro* diagnostics.

Education

Arizona State University, B.S., Physics
University of California Los Angeles, M.D. (MSTP)
University of California Los Angeles, Ph.D., Biomathematics (MSTP)

Selected Honors

Distinguished Basic Scientist of the Year Award, Academy of Molecular Imaging
Doris Duke Distinguished Clinical Scientist Award
Scientific Achievement Award, Society of Molecular Imaging
Fellow of the American Institute for Medical and Biological Engineering
Hounsfield Medal, Imperial College London
Paul C. Aebersold Award, Society of Nuclear Medicine
Nobel Conference – Organized and co-chaired Nobel symposium, "Watching Life Through Molecular Imaging," Stockholm, Sweden
Tesla Medal, United Kingdom Royal College of Radiologists
American Society of Clinical Investigation
Member, Institute of Medicine of the National Academies
Virginia and D.K. Ludwig Endowed Professorship
George Charles de Hevesy Nuclear Pioneer Award, Society of Nuclear Medicine

Imagining Technology and Informatics Peer Review Panel Members

Carolyn Anderson, Ph.D.
Depts of Radiology, Pharmacology and Chemical Biology, and Bioengineering
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James Basilion, Ph.D.
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Ross Berbico, Ph.D.
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Weibo Cai, Ph.D.
Depts of Radiology and Medical Physics
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John Gore, Ph.D.
Center for Imaging Science
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Martin Pomper, M.D., Ph.D.
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Mark L. Stolowitz, Ph.D.
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Julie Sutcliffe, Ph.D.
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Warren Warren, Ph.D.
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Durham, NC

Shimon Weiss, Sc.D.
Dept of Chemistry & Biochemistry
University of California, Los Angeles
Los Angeles, CA

Anna M. Wu, Ph.D.
Dept of Molecular and Medical Pharmacology
University of California, Los Angeles
Los Angeles, CA

Kurt Zinn, Ph.D.
Dept of Computer and Electrical Engineering
University of Alabama – Birmingham
Birmingham, AL

Advocate Reviewers

Stephanie Dunn Haney
American Lung Association, National Headquarters
Bloomsburg, PA

Jilda Nettleton, M.D., Ph.D.
Young Survival Coalition
Seattle, WA

Richard J. O'Reilly, M.D., Chair, Translational Cancer Research Peer Review Panel

Chair, Dept of Pediatrics and Director of the Bone Marrow Transplantation Program, Memorial Sloan-Kettering Cancer Center

Research Focus

Dr. Richard J. O'Reilly has been engaged in clinical research and experimental therapeutics focused on allogeneic hematopoietic cell transplantation. He pioneered the development of curative marrow transplantation approaches for the treatment of children with severe combined immune deficiency who lack an HLA matched sibling donor. He introduced the use of matched unrelated donors and T-cell depleted transplants from HLA half matched donors in order to provide a normal blood system without graft vs host disease (GvHD) to patients afflicted with lethal immune deficiencies and leukemia, and subsequently performed the first successful transplants of unrelated marrow for the treatment of leukemia. He and his colleagues developed an approach employing soy bean lectin agglutination and E-rosette depletion for elimination of T lymphocytes from bone marrow allografts. Thereafter, they verified the potential of allogeneic T cell-depleted transplants to prevent GvHD in primate models. Beginning in 1980, they introduced trials of transplants from haplotype matched parents depleted of T-cells by this technique as a treatment for children with severe combined immune deficiency. This experience, which is now one of the world's largest, clearly demonstrates that such transplants can reconstitute immunity and abrogate GvHD. Indeed, 70% of the patients in the entire series are surviving with immune reconstitution and without GvHD.

Over subsequent years, his research focused on the application of T-cell depleted transplants in patients with leukemia and demonstrated that adequately depleted bone marrow or cytokine mobilized blood progenitor cells can be transplanted both in matched and HLA disparate recipients without GvHD. In 1994, he introduced the use of adoptive T-cell therapy for treatment of EBV+ lymphomas. Currently, he is developing new approaches for adoptive cell therapy for leukemias and conducting Phase I and II trials testing adoptive transfer of virus-specific and tumor-specific T-cells as a therapeutic approach for EBV+ lymphoproliferative disease, drug resistant CMV infections, and leukemic relapse in post-transplant patients.

Education

College of the Holy Cross, B.S., Pre-Medicine
University of Rochester School of Medicine, M.D.

Other Experience

Member, Sloan-Kettering Institute for Cancer Research
Professor of Pediatrics, Cornell University Medical Center
Lila Acheson Wallace Professor of Pediatric Research, Cornell University Medical Center
Associate Professor of Pediatrics, Cornell University Medical Center
Assistant Professor of Biology, Sloan-Kettering Division of Graduate School of Medical Science, Cornell University
Associate, Sloan-Kettering Institute for Cancer Research
Head, Laboratory of Microbial Immunology, Sloan-Kettering Institute
Instructor of Pediatrics, Harvard Medical School

Selected Honors

John P. McGovern Compleat Physician Award, Houston Academy of Medicine
Bob Pinedo Cancer Care Prize, Society of Translational Oncology
Sanctae Crucis Award, Holy Cross College
Lifetime Achievement Award, American Society for Blood and Marrow Transplantation
Pediatric Oncology Award, American Society of Clinical Oncology
Distinguished Alumnus Award, Memorial Sloan-Kettering Cancer Center
Pediatric Oncology Award, American Society of Clinical Oncology
Lifetime Achievement Award – Society for Blood and Marrow Transplantation
Timothy Gee Humanity in Medicine Award – Lauri Strauss Leukemia Foundation
Claire L. Tow Chair in Pediatric Oncology Research
Herman Boerhaave Medal, Leiden University
Board of Scientific Counselors, National Cancer Institute
Mary Jane Keller Visiting Professorship, Yale University
Vincent Astor Chair in Clinical Research, Memorial Sloan Kettering Cancer Center
Visiting Woodruff Professor, Emory University School of Medicine
Louise and Allston Boyer-Young Investigator Award - Clinical Research

Translational Cancer Research Peer Review Panel Members

Steven P. Balk, M.D., Ph.D.
Hematology-Oncology Division
Beth Israel Deaconess Medical Center
Boston, MA

Stephen Baylin, M.D.
Sidney Kimmel Comprehensive Cancer Center
Johns Hopkins University School of Medicine
Baltimore, MD

Riccardo Dalla-Favera, M.D.
Institute for Cancer Genetics
Columbia University Medical Center
New York, New York

John F. DiPersio, M.D., Ph.D.
Dept of Medicine, Oncology Division
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St. Louis, MO

Victor Engelhard, Ph.D.
Dept of Microbiology, Immunology and Cancer Biology
University of Virginia School of Medicine
Charlottesville, VA

Stephen Fesik, Ph.D.
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Nashville, TN

Olivera Finn, Ph.D.
Dept of Immunology
University of Pittsburgh School of Medicine
Pittsburgh, PA

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Dept of Medicine, Division of Hematology/Oncology
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San Francisco, CA

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Elizabeth Jaffee, M.D.
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Charles Mullighan, M.D.
Dept of Pathology
St. Jude Children's Research Hospital
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Dept of Pediatrics, Molecular Microbiology, and Immunology
Children's Hospital Los Angeles
Los Angeles, CA

Simon Powell, M.D., Ph.D.
Dept of Radiation Oncology
Memorial Sloan Kettering Cancer Center
New York, New York

Stan Riddell, M.D.
Program in Immunology
Fred Hutchinson Cancer Research Center
Seattle, WA

Jerome Ritz, M.D.
Dept of Medicine
Harvard Medical School
Boston, MA

Neal Rosen, M.D., Ph.D.
Dept of Medicine
Memorial Sloan-Kettering Cancer Center
New York, NY

Alessandro Sette, Dr. Biol.Sc.
Center for Infectious Disease
La Jolla Institute for Allergy and Immunology
San Diego, CA

Terry Van Dyke, PhD
Center for Advanced Preclinical Research
National Cancer Institute Frederick
Frederick, MD

Advocate Reviewers

Samantha Guild, J.D.
AIM at Melanoma
Richmond, CA

Donna Nichols Threlkeld, J.D.
Susan G. Komen for the Cure, Central Indiana Affiliate
Indianapolis, IN

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

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CPRIT Product Development Review Council

Biographies

Product Development Peer Review Panel Members

Product Development Review Panel Members

Jack Geltosky, Ph.D., Chair of the Product Development Review Council
Managing Director, JEG and Associates, LLC

Jack has over 30 years of experience in the pharmaceutical industry, evenly split between R&D and licensing.

Jack was the Senior Vice President of Business Development for Arizona Technology Enterprises (AZTE), the technology transfer arm of Arizona State University, from 2007 to June of 2011. He now serves as a Senior Consultant to AZTE.

Jack served on the Board of Directors of Enzon Pharmaceuticals from 2008-2009 and is currently on the Board of Protox Therapeutics.

From 2002-2007, Jack was Vice President of External Science, Technology and Licensing at Bristol Myers Squibb. There he was responsible for the acquisition and licensing of compounds, R&D technologies and intellectual property to support the company's drug discovery and development efforts. In this role, Jack and his team identified, evaluated, and coordinated due diligence activities on potential in- and out-licensing candidates in pre-clinical and clinical development, across all therapeutic areas. Jack's team consisted of 15 licensing professionals.

Prior to joining BMS, Jack was President and Chief Executive Officer of Message Pharmaceuticals, a privately held biotechnology company focused on the discovery of drugs active on RNA. Previously he worked for SmithKline Beecham as Vice President, Scientific Licensing. He also held several other research and development roles of increasing responsibility with Johnson & Johnson, including Senior Director of Research for the Robert Wood Johnson Pharmaceutical Research Institute. Jack began his career as a research scientist at E.I. DuPont.

Jack holds a B.S. in chemistry from Memphis State University and a Ph.D. in biochemistry from the California Institute of Technology.

David Shoemaker, Ph.D., Member - Product Development Review Council
Senior Vice President, Research and Development, Rho, Inc.

David is currently responsible for developing integrated product development strategies for products ranging from discovery through market approval. David serves as an advisor to multidisciplinary program teams, contributing regulatory perspectives on clinical, preclinical, and chemistry, manufacturing and controls development decisions.

David has participated in the development of the regulatory strategy for programs involving central nervous system products, blood products, oncology therapeutics and vaccines, gene and stem cell products, immunomodulators, cardiovascular therapeutics, and metabolic and endocrine therapeutics. He has experience in the preparation and filing of all types of regulatory submissions, from regulatory authority meeting briefing packages to INDs, IMPDs, CTAs, NDAs/BLAs and MAAs. He has moderated dozens of regulatory authority meetings and negotiated the release of several products from regulatory clinical hold.

David's primary areas of expertise include the design of preclinical and clinical study protocols and the integrated regulatory strategy for the development of novel drug and biological products; however, he is also well-versed in the development of products for 505(b)(2) and biosimilar marketing applications.

Kapil Dhingra, M.D., Member - Product Development Review Council
Consultant, KAPital Consulting, LLC

Dr. Dhingra founded KAPital Consulting, LLC, in 2008, a company dedicated to helping biotechnology, pharmaceutical and diagnostic companies realize the clinical and commercial advances in oncology. From 1999 to 2008, Dr. Dhingra served in positions of increasing responsibility at Hoffmann-La Roche, including Vice President, Head, Oncology Disease Biology Leadership Team, and Head, Oncology Clinical Development. Prior to joining Roche, he worked in the oncology clinical development group at Eli Lilly and Company. From 1989 to 1996, he was a faculty member at The University of Texas M.D. Anderson Cancer Center where he led a successful laboratory as well as clinical research program. Throughout his industry career, Dr. Dhingra maintained an active faculty appointment, at Indiana University School of Medicine from 1997 to 1999, and, more recently, at Memorial Sloan Kettering Cancer Center in New York from 2000 to 2008. Dr. Dhingra holds an M.B.,B.S. (equivalent to US M.D.) degree from the All India Institute of Medical Sciences (AIIMS), and has performed postgraduate work at the AIIMS, the Lincoln Medical and Mental Health Center (New York Medical College), Bronx NY and Emory University School of Medicine, Atlanta GA. He is Board-certified in Internal Medicine and Medical Oncology. Dr. Dhingra is currently Chairman of Board of Exosome Diagnostics and a member of Board of Directors of Epitherapeutics as well as Advanced Accelerator Applications. In addition, he is an advisor to several biotechnology and pharmaceutical companies and healthcare organizations. He is also a member of the NCI Experimental Therapeutics panel and a member of the New Drug Advisory Committee of the EORTC. He has previously served on the Boards of several successful biotech companies, including Biovex, Micromet, Algeta, and YM Biosciences, which were acquired by major pharmaceutical companies.

Roy Cosan, B.B.A. ., Member - Product Development Review Council
Managing Director, Fjord Ventures

Roy Cosan is a Managing Director of Fjord Ventures. Roy's experience includes 32 years with Johnson and Johnson. He was Vice President of New Product Development at Janssen Pharmaceutica where he launched Risperdal and Reminly. Roy was also a Vice President with the Johnson & Johnson Development Corp., the venture capital arm of J&J where he invested in 19 companies and held 11 board of director seats. Roy helped build a virtual R&D capability within J&J Pharma.

Product Review Panel Members

Alex Adjei, M.D., Ph.D.
Senior Vice President of Clinical Research Professor and Chair, Department of Medicine
The Katherine Anne Gioia Chair in Cancer Medicine Roswell Park Cancer Institute

Alex joined the faculty of Roswell Park Cancer Institute (RPCI) in 2006 as Senior Vice President of Clinical Research and Chair of the Department of Medicine.

Alex is responsible for expanding the Department's phase I and Thoracic Oncology programs and strives to enhance existing programs and establish new clinical and research initiatives.

Alex is a distinguished national leader in translational research, drug development and thoracic oncology. He comes to RPCI from the Mayo College of Medicine, Rochester, MN, where he served as Professor of Oncology and led highly successful thoracic oncology and Phase I clinical research programs.

Alex earned his medical degree from the University of Ghana Medical School in Legon. He obtained a doctorate degree in pharmacology at the University of Alberta in Edmonton, Canada. Alex completed residency training at Howard University, Washington, DC, and clinical and research fellowships in oncology at Johns Hopkins School of Medicine, Baltimore, MD. He is a Diplomate of the American Board of Internal Medicine.

Alex's research is focused on assessing the toxicity, pharmacology and initial activity of novel agents for the therapy of solid tumors and developing biomarkers of drug effects. His laboratory studies focus on elucidating mechanisms of action and resistance of novel agents that inhibit cell signaling. He also conducts phase II clinical trials of novel agents in lung cancer.

Alex is an active member of numerous professional organizations. As a member of the American Association for Cancer Research (AACR), he has served as Chair of the Minorities in Cancer Research Council; Co-Chair of the AACR's 2005 Annual Meeting and currently is Co-Chair of the 2007 AACR Annual Meeting.

Alex also has served on many committees for the National Cancer Institute. He is Group Vice-Chair of the North Central Cancer Treatment Group (NCCTG) and Chair of the NCCTG Lung Cancer Committee. He was a member of the Lung Cancer Progress Review Group in 2000 and the Lung Cancer Concept Evaluating Panel from 1999-2002. He is a member of the Clinical Research Review Committee Study Section of the National Center for Research Resources for the National Institutes of Health, and the Investigational Drug Steering Committee, for which he co-chairs the Clinical Trials Design Task Force.

Alex has authored or co-authored more than 200 journal articles, abstracts and book chapters. He is a Senior Editor of Molecular Cancer Therapeutics; Associate Editor of the American Journal of Clinical Oncology and Current Drug Targets, and a member of the editorial boards for Investigational New Drugs, Journal of Clinical Oncology, Cancer Chemotherapy and Pharmacology, Clinical Lung Cancer, Medicinal Chemistry Reviews and Update on Cancer Therapeutics.

Michelle Arkin, Ph.D.
Associate Adjunct Professor, University of California, San Francisco
Pharmaceutical Chemistry

Michelle Arkin is an Associate Professor in Pharmaceutical Chemistry and the Associate Director of Biology at the Small Molecule Discovery Center at UCSF. Michelle's research interests include developing biological tools and drug leads for orphan and neglected diseases and designing compounds to modulate the function of allosterically regulated enzymes and protein-protein interactions (PPI). As associate director of the SMDC, Michelle oversees the high-throughput screening operation and collaborates with many academic and pharmaceutical laboratories to tackle challenging problems in drug discovery. Michelle earned her PhD in chemistry at Caltech and then held a Daymon Runyon postdoctoral fellowship at Genentech. She was among the first scientists at Sunesis Pharmaceuticals, where she developed inhibitors of PPI, including SAR1118, currently in phase 3 trials for dry-eye at SARcode. From 2005 to 2007, she was the Associate Director of Cell Biology at Sunesis and led the translational science team for Vosaroxin, an anti-cancer agent in phase 3 clinical trials.

Gabriel Cipau, Ph.D., M.B.A., M.S.
President, Key Healthcare Partners, Inc.

Gabriel has spent 42 years in the pharmaceutical and biotechnology industry. He joined Burroughs Wellcome Co. as a research scientist in 1970 and held positions of increasing responsibility in R&D and manufacturing, including Director of Technical R&D and Senior Vice president of Operations. In these capacities, Gabriel was involved in the development and production of 23 new cardiovascular, antibacterial and antiviral pharmaceutical products.

In 1993 he was appointed President and CEO of Wellcome Japan and a member of the Board of Directors of Wellcome PLC and of Wellcome Foundation Ltd based in UK.

Gabriel joined Copley Pharmaceuticals as President and CEO in 1995 and later on was a founder, CEO and President of Catalytica Pharmaceuticals, Biolex and PhaseBio Pharmaceuticals.

Following his retirement in 2006, Gabriel established Key Heathcare Inc. a consulting company providing services for investors and companies involved in the pharmaceutical and biotechnology areas. He is a member of the Board of Directors of several companies operating in this field.

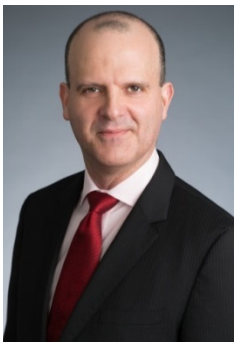
Neil J Clendeninn M.D., Ph.D.
President, CANAID, Inc.

Dr. Clendeninn has over 20 years experience in the pharmaceutical/biotech industry. He was recently the VP of Clinical for Agouron Pharmaceuticals, of La Jolla, CA. He developed the AIDS protease inhibitor Viracept, which was approved in record time of 36 months. He previously worked for Burroughs Wellcome, Research Triangle Park, NC where he was head of Clinical Oncology.

Dr. Clendeninn received his BA (Biology and Chemistry) from Wesleyan University, Middletown, CT and his MD and PhD (Pharmacology) from New York University, NY. He trained at NCI in Oncology and specialized in new drug development.

He has served on a number of Boards including Oncogenex Technologies, Vancouver, Canada, and the Board of Scientific Advisors for NCI. He also consults for a number of biotech companies, CROs and investor companies. He is the author of over 150 papers, abstracts and textbooks.

He is currently heading a medical practice team developing early palliative care on Kauai, HI.



Adam R. Craig, M.D., Ph.D., M.B.A

Executive Vice President, Development and Chief Medical Officer

Adam R. Craig, M.D., Ph.D., M.B.A., was appointed Chief Medical Officer of Sunesis in February 2012. Prior to Sunesis, Dr. Craig served as Chief Medical Officer at ChemGenex Pharmaceuticals, where he led the development program for omacetaxine, an investigational treatment for chronic myeloid leukemia, including serving as the lead presenter and moderator for a 2011 Oncologic Drug Advisory Committee (ODAC) presentation. ChemGenex was acquired by Cephalon/Teva for $225M in 2011. Before joining ChemGenex in 2007, he was founding Chief Medical Officer at Innovive Pharmaceuticals, Inc., a hematology-focused company. Prior to joining Innovive, Dr. Craig held positions of increasing responsibility at ArQule Inc., Ilex Oncology Inc., and Antisoma plc. Dr. Craig received his medical qualifications from the University of London, a Ph.D. in molecular medicine from the University of Leeds, and an M.B.A. from the Open Business School in the United Kingdom. Dr. Craig is a member of the Royal College of Pediatrics and Child Health Physicians (UK) and undertook post-graduate training in pediatrics and pediatric oncology. He also currently serves as a member of the Commercialization Review Council for the Cancer Prevention Research Institute of Texas, a $3 billion fund for groundbreaking cancer research and prevention programs and services.

Raymond DuBois, M.D., Ph.D.

Executive Director, The Biodesign Institute at Arizona State University

Raymond DuBois, MD, PhD, is the executive director of the Biodesign Institute at Arizona State University. Biodesign is a research institute engaged in addressing critical global challenges in health care, sustainability and security. In addition to his role at Biodesign, DuBois has joint ASU appointments as the Dalton Chair, School of Health Solutions; and Professor, Department of Chemistry and Biochemistry.

DuBois began his Biodesign Institute leadership role in December 2012. In addition to his ASU responsibilities, his appointment includes co-leadership of the Cancer Prevention Program at the Mayo Clinic, which has a hospital and clinic, and is developing a medical school campus in the Phoenix area.

An internationally renowned expert in the molecular and genetic basis for colorectal cancer, DuBois maintains his own laboratory at Biodesign to examine the molecular mechanisms by which inflammatory mediators affect epithelial biology, the tumor microenvironment, carcinogenesis and development.

Prior to coming to ASU, DuBois was provost and executive vice president and professor of cancer medicine and cancer biology at the University of Texas MD Anderson Cancer Center in Houston. From 1998 to 2004, DuBois directed Vanderbilt's Division of Gastroenterology, Hepatology and Nutrition.

In the 1990s, DuBois and colleagues reported that colorectal tumors contained high levels of the enzyme cyclo-oxygenase-2 (COX-2). This enzyme is a key step in the production of pro-inflammatory mediators such as prostaglandin E2. The DuBois team was the first to show that colorectal cancers over-expressed COX-2 and their research defined a series of critical molecular pathways involved in COX-2 expression – namely, that blocking or

inhibiting the COX-2 enzyme would cause colorectal tumors to shrink. This work led to clinical trials and the treatment of precancerous polyps with Celebrex, an arthritis drug that selectively inhibits COX-2.

During his career as a physician-scientist, DuBois has published 137 peer reviewed journal articles, 62 article reviews, 25 book chapters, and three books, the latest of which is entitled “Progress in Experimental Tumor Research.” DuBois is a co-inventor of a method to identify and prevent cellular genes necessary for viral growth and cellular genes that function as tumor suppressors in mammals.

DuBois’ first two degrees were in biochemistry. He earned a bachelor’s degree from Texas A&M University and a doctoral degree from the University of Texas Southwestern Medical Center at Dallas. DuBois obtained a medical degree from the University of Texas Health Science Center at San Antonio, followed by an Osler Medicine internship and residency, and a gastroenterology fellowship at the Johns Hopkins Hospital in Baltimore.

James (Jim) E. Foley, Ph.D.
Managing Director, Aqua Partners LLC

Jim’s career in the pharmaceutical industry began in 1977 at the Squibb Institute of Medical Research (E. R. Squibb and Sons). In 1989, he joined the Department of Licensing and Business Analysis at Squibb and relocated to Tokyo to further establish the company's worldwide pharmaceutical licensing activities in Japan and relationships with Japanese R&D-based pharmaceutical companies. Jim joined SmithKline Beecham's Worldwide Business Development Team in 1991 as Vice President and Director, Business Development- Japan/Asia, and remained based in Tokyo, representing the company's worldwide licensing interests in Japan, Asia, and Australia/New Zealand. He returned to the United States in 1995, where he continued his responsibilities based in Philadelphia. In 2002, Jim re-joined Bristol-Myers Squibb as Vice President, Business Development- Japan/International, focused on the identification of strategic R&D collaboration and product licensing opportunities from the Japan, Asia and Australia/New Zealand region. From April 2006 to February 2008, Jim was President and CEO of SMART Biosciences, an early-stage discovery biotechnology company focused on neurodegenerative diseases, particularly Alzheimer’s disease. Jim joined Aqua Partners, a corporate and business development advisory firm focused on strategy development, licensing, M&A and finance for biotechnology and mid-tier pharma companies worldwide, with a special expertise in cross-border relationships and deal making.

Jim serves or has served on the Board of Trustees of St. Peter's School, Philadelphia, the Boards of Directors of SFJ Pharmaceuticals,), Traxion (Baltimore), Sosei and Company (Tokyo), the Japan-America Society of Greater Philadelphia and New York Pharma Forum, and the Advisory Boards of the Haub School of Business (St. Joseph's University, Philadelphia), the Marshall School of Business Global BioBusiness Initiative (University of Southern California, Los Angeles), and Sc Capital I (University City Science Center, Philadelphia). Jim co-chairs the US-Japan Health Sciences Dialogue, an annual meeting held in Philadelphia addressing healthcare issues/solutions in the U.S. and Japan. A member of the Licensing Executives Society (LES), Jim was honored by the organization with the Frank Barnes Mentorship Award. He was designated a Certified Licensing Professional (CLP™) by LES in 2008. Jim holds a Ph.D. in Physiology from Thomas Jefferson University College of Graduate Studies. He received a B.A. in Biology and Chemistry from Rutgers University. He was a NIH Post-Doctoral Fellow from 1975 to 1977 in the Department of Pharmacology, Tulane University School of Medicine.

Judy Fox
Consultant, FoxBiopharma, LLC

Judith A. Fox, Ph.D. is a consultant for the research and development of large and small molecule oncology therapeutics as founder of FoxBiopharma LLC, and also serves as Senior Vice President, Research & Development for Amphivena Therapeutics. Most recently, Dr.

Fox was Vice President, Product & Preclinical Development at Sunesis Pharmaceuticals, where she led the vosaroxin program in acute myeloid leukemia through early to late stage clinical development. Previously, she was Senior Director in Translational Sciences at Chiron Corporation (now Novartis AG), supporting the development of the company's novel oncology compounds, and she established the Pharmacological Sciences Department at Genencor International. Dr. Fox's industry career began at Genentech, Inc. where she contributed to the development of products such as Herceptin®, Xolair®, Raptiva® and Avastin®. Her career has focused on the translation of basic mechanistic understanding of promising drugs into coherent, evidence-based clinical development. Dr. Fox received her Ph.D. in Biological Chemistry from the Massachusetts Institute of Technology, where she serves on the Chemistry Visiting Committee, and an A.B. in Chemistry from Bryn Mawr College. She conducted postdoctoral research at The Rockefeller University.

Darrick Fu

Director of Business Operations, The Dermatology Center

Darrick Fu is currently Director of Business Operations at The Dermatology Center of Raleigh P.A., where he is has profit and loss responsibility for a private medical practice. In this role, Mr. Fu has been implementing strategies that position a small business to meet the challenges of tomorrow's complicated healthcare environment.

Previously, Mr. Fu was Chief Product Development Officer at the Duke Human Vaccine Institute in Durham NC where he worked to translate discovery research into early, proof of concept, human trials in the field of HIV/AIDS vaccine discovery for a novel academic consortium by applying a virtual quasi-biotech model.

Prior to joining Duke, Mr. Fu was Vice President Scientific & Regulatory Affairs at the Pharmaceutical Research and Manufacturers of America (PhRMA). At PhRMA, he led several industry wide strategic initiatives to improve the biopharmaceutical R&D business model in order to assure continued innovation in medicines. In this role, he managed a portfolio of industry activities aimed at modernizing the drug development process by developing innovative new tools in concert with regulatory authorities particularly the US FDA.

Under Mr. Fu's stewardship at PhRMA, a strategic effort was undertaken to identify and apply novel new businesses and mechanisms to address common critical R&D challenges. As result, Mr. Fu became PhRMA's principle architect and chief negotiator in the establishment and operational initiation of two major new public-private-partnerships; "The Biomarker Consortium" and the "Observational Medical Outcomes Partnership" both of which were the first novel mechanisms established joining major industry non-competitively with academia, and regulatory to conduct pre-competitive R&D that addresses critical challenges facing the drug development enterprise. Both these PPP's still stand and have spawned a generation of other consortia using a similar template.

Mr. Fu has over 20 years of industrial drug development experience in the biopharmaceutical industry principally with GSK. During his career at GSK Mr. Fu has held management positions in project management, development alliances, and licensing. At GSK Biologicals, in Rixensart Belgium, he led several successful new biopharmaceutical product development teams, including the development of Lymerix™ a vaccine against Lyme Disease from the pre-clinical phase through licensure in the USA, as well as the early and phase IIb POC development of Cervarix™ a vaccine that prevents cervical cancer. Mr. Fu has also served as consultant to the biotechnology and non-profit sectors on product development, business, and strategic issues.

Mr. Fu holds a B.S. degree in biochemistry from Carnegie Mellon University, and an M.B.A. from George Washington University.

Phyllis Gardner, M.D., BIO

Professor of Medicine; Partner (EWHV)
Stanford University & Essex Woodlands Health Ventures

Phyllis Gardner has over 35 years of experience in academia, medicine and the healthcare industry. She began her professional career in 1984 at Stanford University, where she has held several positions including Senior Associate Dean for Education and Student Affairs and remains today as tenured Professor of Medicine and a member of the Academic Council Committee on Research. Her primary focus at Stanford today is as advisor to Stanford Students for Biodesign and course director of biopharmaceutical and medical innovation courses. From 1994 to 1998, she took a leave of absence as the Vice President of Research and Head of ALZA Technology Institute, a major drug delivery company. Phyllis currently serves on the Board of Fellows at Harvard Medical School and is a member of the Advisory Council on Education and the Campaign Steering Committee. She has conducted extensive research in cell biology and gene therapy, is widely published in the fields of cell biology and pharmacology, and has received numerous national awards and honors recognizing her academic and professional accomplishments.

Phyllis holds a Bachelor of Science degree from the University of Illinois and a Doctor of Medicine degree from Harvard Medical School. She trained in internal medicine at Massachusetts General Hospital, followed by Chief Residency at Stanford University Hospital and post-doctoral fellowships at Columbia University and University College London. In addition to her academic career, she is an adjunct partner at Essex Woodlands, a private equity company focused on the health science industry, where she has been affiliated for 15 years. She has served as the co-founder of three companies, as well as director of multiple private and public companies, the latter of which include Corium International and Revance Therapeutics, Inc.

Stanton L. Gerson, M.D.

Professor of Medicine, Oncology & Environmental Health Sciences, CWRU, Case Western Reserve University

Stanton [Stan] L. Gerson M.D. is the Asa and Patricia Shiverick - Jane Shiverick (Tripp) Professor of Hematological Oncology, Director NCI designated Case Comprehensive Cancer Center, Director of the Seidman Cancer Center, and founding director of the National Center for Regenerative Medicine in Cleveland.

Dr. Gerson discovered that the MGMT DNA repair gene protected multiple organs from alkylating agent induced malignancies. Later, this discovery was also the basis for development of a drug to block MGMT for cancer treatment, and an MGMT hematopoietic stem cell gene therapy approach, currently used in glioma, to protect marrow from chemotherapy. In his stem cell research, he developed mesenchymal stem cells (MSCs) as a therapeutic infusion for blood stem cell transplantation. Others went on to receive International Regulatory approval for use of MSCs in GVHD therapy. Dr. Gerson also discovered the use of methoxyamine (TRC102) as a drug to block base excision repair, and identified its potentiation of anti-cancer efficacy when used in combination with either temozolomide, fludarabine or pemetrexed. Each of these is now in cancer clinical trial and is being evaluated at NCI-CTEP. Finally, Dr. Gerson has developed transgenic mouse models that examine the role of critical DNA repair genes (MGMT, MMR genes, NHEJ genes, and Homologous Recombination genes) in the stability of stem cell populations over the lifetime of the animal, and is studying similar processes in humans. These studies may predict stem cell diseases of aging and cancer. His research has generated 17 patents in the area of gene therapy and cancer drug development that have been licensed to 3 companies. In 2012 he was the recipient of the CWRU Medal for Excellence in Health Science Innovation Award. In 2013, CWRU honored him with the Distinguished University Professor designation.

Dr. Gerson serves on the NCI Board of Scientific Advisors and has chaired the FDA Advisory Board for Cell and Gene Therapy. Since 2003, he has been Director of the National Center of Regenerative Medicine and the NCI designated Case Comprehensive Cancer Center involve coordinating research throughout the medical centers in Cleveland – University Hospitals, Cleveland Clinic and Case Western Reserve University. At University Hospitals, he led effort to bring cancer care under one roof in the Seidman Cancer Center hospital that opened in June 2011.

Mara Ginsberg, Esq.
President, To Life!

Mara Ginsberg, Esq. is a partner in the Albany law firm of Hinman Straub, P.C. where she has both a legal and legislative practice including areas relating to health care and Medicaid compliance, procurement and technology. Prior to joining Hinman Straub, Mara served as Vice President of Government Affairs for AmeriChoice of New York & UnitedHealthcare of New York where she led legislative and regulatory health policy for this Medicaid managed-care company. Mara served for over 25 years in New York State Government as Counsel and Deputy Director at various State agencies involved with technology including broadband and cyber security. Mara also served as a New York State Assistant Attorney General.

Mara is the Founder and President of To Life! She founded To Life! in 1998 and this nonprofit organization in the Capital Region of New York now serves 10+ counties by providing comprehensive education programs and support services relating to breast cancer and women's health and wellness free of charge in non-clinical settings. To Life! has two offices and in addition to providing education forums, one-one mentoring for women, breast self-examination training, health and wellness programs, To Life! has boutiques where women can obtain breast prosthesis, mastectomy bras, hats, scarves and wigs. All programs and services are free of charge and To Life! is a provider for products with many insurance companies and never turns anyone away even if they don't have insurance or other financial resources. Mara has several health policy affiliations:

- NYS Advisory Council for Breast and Cervical Cancer Education and Research
- Advisory Review Panel for Pesticide Information Release
- United States Department of Defense (Consumer Grant Reviewer)

Gwen Harding-Peets, Ph.D.
Regional Coordinator, SHARE: Self-Help for Women with Breast or Ovarian Cancer
Regional Coordinator, Ovarian Cancer National Alliance's signature program, Survivors Teaching Students – Saving Women's Lives®

Gwen Harding-Peets has a PhD in microbiology from the University of Texas at Austin. She joined Texaco, Inc. in 1989 as a Research Microbiologist evaluating means of using microbes to clean up spills and convert waste to more useful products. She moved into the IT department where she became very interested in knowledge management, but left corporate American in 2002 when Texaco merged with Chevron.

Gwen was diagnosed with Stage III C high grade serous ovarian cancer on February 7th, 2005. She has had one recurrence but has been NED since her last chemo in November 2008. Since her diagnosis, she has become very active in the ovarian cancer community. She is SHARE's Regional Coordinator for the Hudson Valley and volunteers on their ovarian cancer national helpline. She is the New York/New Jersey Regional Coordinator for the Ovarian Cancer National Alliance's signature program, Survivors Teaching Students – Saving Women's Lives®. She facilitates Support Connection's monthly toll-free telephone support group for women with ovarian cancer. She

has been a research advocate and a DoD Ovarian Cancer Research Program consumer reviewer for a number of years.

In her spare time, she's a part time docent/educator at Locust Grove – the Samuel Morse historic site, photographs nature, and is a civil war living historian. But most of all enjoys every day that she shares with her family and her cats.

Elaine V. Jones, Ph.D.
Pfizer Venture Investments, Executive Director, Venture Capital

She is responsible for making and managing venture investments for Pfizer and currently manages the PVI investments in Aquinox Pharmaceuticals (Vancouver, British Columbia), Flexion Therapeutics (Boston, MA), Merus B.V. (Utrecht, The Netherlands), and NeuroTherapeutics Pharma (Chicago, IL). Elaine brings 10 years of venture capital experience and a strong background in research and product assessment, built on her significant experience in pharmaceutical drug discovery and business development to the PVI team.

Most recently, Elaine was a General Partner with the venture fund, EuclidSR Partners. There, she was responsible for the fund's investments in Acurian, Fluidigm, InnaPhase and Targacept.

Prior to joining ESR, Dr. Jones began her private equity career in 1999 at S.R. One, GlaxoSmithKline's venture fund, where she managed investments including Adolor, Avantium, Nucleonics, Scynexis and Vicuron. Previously, she served as Director of Scientific Licensing for SmithKline Beecham and was a research scientist in SmithKline Beecham Pharmaceutical R&D.

Dr. Jones is a graduate of Juniata College and received her Ph.D. in Microbiology from the University of Pittsburgh.

James (Jim) F. Jordan, B.B.A, M.B.A.
President, StraTactic, Inc.

James is an accomplished Fortune 20-level executive with strong experience industry and consulting experience. Mr. Jordan also a Distinguished Service Professor with Carnegie Mellon University's Heinz College and the Sr. Program Director of their Health Care and Biotechnology Masters Programs. As a recognized expert in market development and guiding the successful formation of entrepreneurial startup businesses in the Life Sciences Industry, Jim joined the Pittsburgh Life Sciences Greenhouse (PLSG) in 2005 and became Vice President and Chief Investment Officer in 2007. Prior to joining the PLSG, Jim served as Senior Vice President of a $3.0 billion division of McKesson Corporation and Vice President, Marketing at Johnson & Johnson. He has held a range of management positions in sales and marketing, operations, supply chain, information technology, finance, and quality assurance with several Fortune 500 medical device companies including C.R. Bard, Inc. and Boston Scientific, Inc. Jim has leveraged this experience in several startup ventures and is active on several Boards of Directors.

Michael S. Katz, MBA

Co-Chair, Cancer Research Advocate Committee, ECOG-ACRIN
Vice President, International Myeloma Foundation

Mike is a 23 year survivor of multiple myeloma. He is a member of the Executive Board of the International Myeloma Foundation (IMF), Co-Chair of the ECOG-ACRIN Cancer Research Group's Executive Cancer Research Advocate Committee and a member of that group's Executive Committee, past chair of the National Cancer Institute's Director's Consumer Liaison Group (DCLG), a past-member of the National Cancer Institute's Myeloma Steering Committee, a Patient Consultant for the Food and Drug Administration (FDA), past member of the ASCO's Cancer Research Committee as well as past-chair the Association of Cancer Online Resources (ACOR.)

Mike is heavily involved in patient education and support and is broadly involved in publicly- and privately-funded cancer research efforts. He is a frequent speaker at cancer patient/family seminars and medical conferences. Mike produces webcasts from national and international medical meetings that provide detailed information to the scientific and lay communities. He has also developed educational videos for potential participants in clinical trials.

Working through the ECOG-ACRIN Cancer Research Group, Mike was one of the leads in developing a trial that found superior survival with lower steroid doses and ultimately changed the global standard for use of high dose steroids in multiple myeloma. He also played a lead role in the IMF's web-based survey that confirmed the link between bisphosphonates and Osteonecrosis of the Jaw. He played a lead role in the development of the IMF's web site and its "Myeloma Manager™ Personal Care Assistant™," a software tool distributed free of charge to help patients and caregivers manage their personal medical data. Mike serves as a member of the Management Committee for the IMF's Bank on a Cure program. He has also played lead roles in web-based research on drug safety and quality of life issues.

Working with a fellow patient, June Brazil, Mike started the ACOR myeloma and amyloidosis listservs (online discussion groups), which now have over 2500 members. He also leads two in-person myeloma support groups in the New York Metropolitan area.

Mike has degrees in Electrical Engineering/Computer Science and Business from Columbia University. He worked for over 30 years at a major international management consulting firm, at which he served as a senior partner and member of the Board of Directors. He is Chairman and Chief Technology Officer of Expert Logic Systems and is a volunteer with the International Myeloma Foundation.

Gerard (Gerry) Kennealey, M.D.

SVP & CMO, Oncolytics Biotech, Inc.

Gerry Kennealey is currently the SVP and Chief Medical Officer for Oncolytics Biotech, Inc., a publicly traded (ONCY) firm headquartered in Calgary, Alberta. He began his industry career in 1987 at AstraZeneca Pharmaceuticals where he was involved in the development of many products for breast and prostate cancer. He also lead the Expanded Access Program for Iressa® in lung cancer which enrolled >20,000 patients in the US and several thousand more abroad. He has also held executive positions at Eximias Pharmaceuticals, MGI Pharma, and Cephalon, Inc.

Gerry is a board certified medical oncologist and spent several years in private practice in Waterbury, CT prior to joining the pharmaceutical industry.

Moira E. Lawrence, Ph.D.
Vice President, Alliance Management, Onconova Therapeutics

Moira has more than 15 years of experience in business development and technology commercialization. Prior to joining Onconova, she was Director of Oncology Business Development at Forest Laboratories. She also spent several years in business development at Bristol-Myers Squibb and technology commercialization at University of Maryland. Moira received her Ph.D. from University of Virginia in Cell Biology and Anatomy.

Yueming Li, Ph.D.
Professor of Molecular Pharmacology and Chemistry
Memorial Sloan-Kettering Cancer Center

The main interests of my laboratory are to elucidate the mechanism of γ-secretase-dependent Notch signaling and amyloid precursor protein (APP) processing under physiological and pathological conditions and to develop target-based therapies. γ-Secretase represents a novel class of proteases that catalyze proteolysis of substrates within the transmembrane domain, an apparently hydrophobic environment, wherein water is required for peptide hydrolysis. Intramembranous proteases, including γ-secretase, site 2 proteases, rhomboids and signal peptide peptidase, play a essential role in many biological processes ranging from sterol regulation to development. Unraveling the intricacies of these enigmatic proteases is a formidable challenge that requires not only multi-disciplinary approaches, but also development of novel technologies that are suitable to study the structure and catalysis of membrane proteins. I have brought chemical biology into intramembranal proteolysis that significantly advances our understanding of γ-secretase and other proteases. We developed the first in vitro γ-secretase activity assay and made a groundbreaking discovery that γ-secretase activity is catalyzed by the presenilin containing macromolecular complex, providing a molecular basis to search for additional subunits. More significantly, my group has demonstrated that presenilin contains the active site of γ-secretase, revealing the first biochemical identity of γ-secretase using photoaffinity labeling approaches. Publication of this work in Nature was recognized as a "hot paper" by The Scientist, due to the large volume of citations. Furthermore, my lab has reconstituted γ-secretase and presenilinase using recombinant proteins and provided the final proof that presenilin is γ-secretase, which has offered a novel platform for studying the structure and function of γ-secretase at both molecular and atomic levels. This work on the reconstitution of γ-secretase published in PNAS was selected as one of the Alzheimer Research Forum's 13 Top AD Trends in 2010. Recent clinical disappointment of γ-secretase inhibitor studies indicates that development of γ-secretase based therapy is an enormous challenge that requires a comprehensive understanding of the target. We have focused on development of γ-secretase modulators (GSMs) and elucidation of their mechanism of action using an integrated approach of chemical biology and proteomics. We have demonstrated that GSMs target γ-secretase and structurally distinct GSMs occupy different sites of γ-secretase, offering a molecular basis for drug combination studies.

Ramona Lloyd, Ph.D.
President & Principal Consultant, CYMREG CONSULTING

As a regulatory professional for over 20 years, Ramona has led or participated in the submission of numerous global investigational applications and successful marketing applications for small molecules, biologics and devices. Her expertise covers multiple therapeutic areas including oncology.

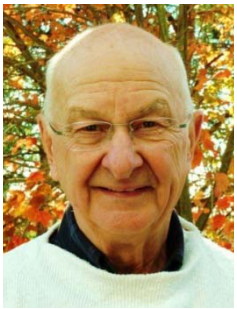
Ramona has served as a consultant in regulatory affairs to the pharmaceutical industry, and

has held executive leadership positions in regulatory affairs and quality in the industry with such companies as Sanofi-Aventis and Johnson and Johnson. Following her time as Vice President, Regulatory Affairs with Bristol-Myers Squibb, she served in the role of Sr Vice President of Regulatory Affairs and Safety for ImClone Systems, a wholly-owned subsidiary of Eli Lilly and Company. Ramona has also served as Vice President of Regulatory Affairs and Quality for public and private biotech companies leading global regulatory strategy, regulatory submissions through product approval and key meetings with global regulatory authorities.

Ramona holds a PhD in Molecular Genetics and Microbiology from Rutgers University – Robert Wood Johnson Medical School, and was a researcher at the Center for Advanced Biotechnology and Medicine. Recognized by the Department of Biomedical Engineering of Rutgers University with the Distinguished Alumni Award, Dr. Lloyd has also served as a member of their Industrial Advisory Board. Ramona earned the professional credential in regulation of healthcare products, Regulatory Affairs Certified (RAC).

H. Kim Lyerly, M.D.
George Barth Geller Professor of Cancer Research and Professor of Surgery, Duke University Medical Center

Kim is the George Barth Geller Professor of Cancer Research and Professor of Surgery at the Duke University Medical Center. He has been named by his peers as one of North Carolina's most outstanding clinical physicians. In addition, he is an internationally recognized expert in cancer therapy and cancer immunotherapy and has published nearly 200 scientific articles and has edited 10 textbooks on surgery, cancer immunotherapy, and novel cancer therapies. He serves on the editorial board of 12 scientific journals. In 2008, Kim was appointed to the National Cancer Advisory Board (NCAB) by President George Bush and was named chair on the Cancer Centers sub-committee of the NCAB. Kim is a highly sought advisor and currently serves on the external advisory boards of the M.D. Anderson Cancer Center, the University of Michigan Cancer Center, the University of Chicago Cancer Center, the University of Alabama Cancer Center, the Boston University Cancer Center, and the Purdue Cancer Center. He also serves as an advisor to the University of Washington, and Case Western Reserve Clinical and Translational Science Institutes. He is currently a member of the Scientific Advisory Board of Susan G. Komen for the Cure. He has previously served as chairperson of the executive committee of the integration panel of the Congressionally Directed Medical Research Programs in Breast Cancer. He also served on American Society of Clinical Oncology's Grants Selection Committee, of which he served as chair in 2006. Kim is a member of the American College of Surgeons, of which he is a fellow. He was invited by former North Carolina Governor Michael Easley to serve on the Advisory Commission of the NC State Museum of Natural Sciences. In 2010, Kim was reappointed as a member of the NC Advisory Committee on Cancer Coordination and Control by Governor Bev Perdue.



Richard (Mac) V. McCloskey, M.S., M.D.
Scientific Adviser, Endo Pharmaceuticals

Mac graduated from The University of Rochester Medical School with an M.D. with honors and an M.S. in Microbiology. Post graduate training was at Duke University Medical Center and the National Institutes of Health. He was a founding faculty member of the University of Texas Medical School at San Antonio. He is certified by the American Boards of Internal Medicine and Infectious Diseases, and is an emeritus member of the Infectious Diseases Society of America. Clinical appointments have been as Chair of Medicine at Albert Einstein Medical Center, Daroff Division, and Chief of Infectious Diseases at Presbyterian-University of Pennsylvania Medical Center, both in Philadelphia. Mac was also Vice President of Clinical Research at Centocor and Vice President of Medical Technology at Johnson and Johnson Development Corporation until 2008. He currently is Scientific Adviser for Endo Pharmaceuticals and was a consultant to the Corporate Office of

Science and Technology of Johnson and Johnson from 2008 to 2012. He also is a member of the Sid Martin Biotech Center Advisory Board of the University of Florida.

Mark Pegram, M.D.
Professor of Medicine, Stanford University

Mark joined Stanford after five years at the University of Miami Miller School of Medicine, where he was a Sylvester Chair professor of medicine in the Braman Family Breast Cancer Institute, and associate director for clinical research in the University's Sylvester Comprehensive Cancer Center.

Mark earned his undergraduate and medical degrees from the University of North Carolina, and then joined the faculty of UCLA in 1993. He played a major role in the development of the drug Herceptin for the treatment of HER-2 positive breast cancer, which contributes to about twenty percent of all breast cancer cases.

Mark conducted laboratory experiments demonstrating that in combination with standard chemotherapy, Herceptin effectively killed breast cancer cells that overproduced HER-2. Mark and others then conducted clinical trials showing Herceptin improved survival rates and even cured some breast cancer patients. This remains one of the premier examples of bench-to-bedside translational research.

Mark's current research efforts include a continued focus on the cancer-associated gene (or oncogene) that encodes HER-2, and developing new ways to target cancer cells expressing this marker. He is also pursuing various strategies for targeting estrogen receptors, implicated in some 70 percent of all breast cancer cases.

Robert T. Sarisky, Ph.D.
Chief Business Officer, FORMA Therapeutics

Rob is an experienced scientific and business professional from the pharmaceutical industry, most recently serving as Vice President of Oncology Business Development and Licensing within Janssen Pharmaceuticals, a Johnson & Johnson company. Prior to that role, he held positions of Vice President of External Research and Early Development within Johnson & Johnson, Sr. Director of Immunology Research at Centocor, and Director of Virology at GlaxoSmithKline Pharmaceuticals. Rob received his B.S. degree in Biology from the University of Scranton, a Ph.D. in Genetics from the Pennsylvania State University College of Medicine, completed his postdoctoral training at the Johns Hopkins School of Medicine, and holds an M.B.A. in Marketing from Lehigh University. He has authored more than 120 publications and patents and served on the Editorial Board for two scientific journals. He has been active in the academic community by serving on the University of Pennsylvania Executive Advisory Committee for the HHMI Graduate Training in Medical Sciences, the University of Miami Innovation Corporate Advisory Council, the University of North Carolina Innovation Transfer and Development Initiative, adjunct Professor for Drexel University School of Medicine, and an Advisory Board member for Indiana University's Biotechnology Program.

Bo Saxberg, M.D., Ph.D.
President, DDO Strategic Services, LLC

Bo Saxberg is originally from Seattle, Washington. He attended the University of Washington, receiving Summa Cum Laude an Honors B.S. degree in Mathematics and an Honors B.S. degree in Chemistry. He then attended Cambridge University in England,

earning an Honours B.A./M.A. Cantab. in Physics. Returning to the United States, he received an M.D. degree from Harvard and his Ph.D. in Physics from the Massachusetts Institute of Technology.

Bo was a National Institutes of Health Fellow at MIT from 1989 to 1991, prior to joining Eli Lilly in Indianapolis as a Senior Research Scientist, continuing his prior research interests in QSAR/genomics/proteomics/physiomics. In 1993, he was named Director of Information Sciences at Eli Lilly. This group subsequently led a number of industry pioneering efforts at Lilly, including the first Internet home page for a pharmaceutical company, as well as developing interactive health economic models evolving to disease management, point of care prescribing, and the development of information resources to support modern product portfolio resource allocation decisions.

He joined Johnson & Johnson in 1995 as Vice President, Corporate Staff, Advanced Communications, leading Johnson & Johnson's efforts in Medical Informatics, focusing on new business opportunities related to information technology in healthcare delivery and product development. As part of these efforts, working with both internal and external venture capital resources as well as member companies, the Advanced Communications Group helped to develop for J&J pioneering creation or investment positions ranging from defined contribution employee benefit models of health insurance, real-time auto-adjudication networks at the point of care supporting cost-quality decisions between doctor and patient, and a variety of technologies in health informatics including telemedicine, clinical studies and outcomes measurement, and electronic medical records. Working with the J&J international pharmaceutical group, innovative programs were created in the development of iterative customer relationships based on clinical information, creating demonstration of product value. Bo and members of the Advanced Communications Group also led the development and implementation of J&J's global policies and procedures for the Internet, including privacy policies, to construct a policy platform to enable future business needs.

In 2002, Bo left J&J to become founder and President of DDO Strategic Services, LLC, ("Design Development Optimization"). He is also founder and Manager of Oro Valley Ventures, LLC, investing in early stage companies. He is continuing his prior work in consulting, venture formation and business development with companies seeking to take leading advantage of change driven by new technologies and information access in health care, with application to product research & development, product and service marketing, financial services innovation, and clinical service innovation. Bo is also a management/advisory board member for a number of entrepreneurial companies, associations and venture firms, including PhDx, IntelliCyt, Boston Millennia Partners, and the Columbia University Center for Advanced Technology.

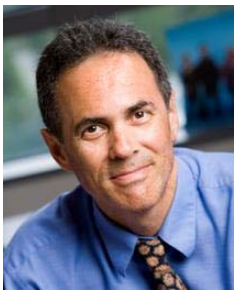
David A. Scheinberg, M.D., Ph.D.
Vincent Astor Chair and Chairman, Molecular Pharmacology and Chemistry Program, Sloan-Kettering Institute
Chair of the Experimental Therapeutics Center and of the Nanotechnology Center, Memorial Sloan-Kettering Cancer Center
Professor of Medicine and Pharmacology, Weill-Cornell University Medical College

David is currently Vincent Astor Chair and Chairman, Molecular Pharmacology and Chemistry Program, Sloan-Kettering Institute. He also founded and Chairs the Experimental Therapeutics Center, and the Nanotechnology Center at Memorial Sloan-Kettering Cancer Center. He is additionally Professor of Medicine and Pharmacology and Co-chair of the Pharmacology graduate program at the Weill-Cornell University Medical College and Professor in the Gerstner-Sloan Kettering Graduate School at MSKCC. From 1992 until 2003, he was Chief of the Leukemia Service at Memorial Hospital. He has been elected into the American Society of Clinical Investigation (ASCI), the Association of American Physicians (AAP), and the Interurban Club. His other awards include the Doris Duke Distinguished Clinical Science Professorship, the Lucille P. Markey Scholarship, Leukemia and Lymphoma Society Translational Investigator Awards, and CapCure Awards. He is an advisor to charitable foundations and cancer centers and sits on the boards of directors of two biotech companies.

David is a physician-scientist, specializing in the care of patients with leukemia and also investigating new therapeutic approaches to cancer, both in the hospital and in the laboratory. The focus of his research is on the discovery and development of novel, specific immuno-therapeutic agents. This includes monoclonal antibodies that target the cell surface of cancers, targeted radiopharmaceuticals that deliver radioactive particles including alpha particles or alpha particle nanogenerators, and targeted nano-devices for selective cell kill, and therapeutic vaccines targeting the oncogene products that cause the cancers. Eight different therapeutic agents developed by David in his laboratory have reached human clinical trials, which include the first humanized antibodies to treat acute leukemia, the first targeted alpha particle therapies and alpha generators, and the first tumor specific fusion oncogene product vaccines. His laboratory is also investigating cellular resistance mechanisms to these agents. David has published more than 250 papers, chapters, or books in these fields.

Ginette Serrero, Ph.D.
CEO, A&G Pharmaceutical Inc.
Adjunct Professor, University of Maryland School of Pharmacy & University of Maryland School of Medicine

Ginette is CEO of A&G Pharmaceutical, a company developing novel targets in Oncology which she co-founded in 2000 based on her discovery of the GP88/PGRN growth factor protein and her pioneering research demonstrating its importance in the tumorigenesis of many cancers. Under her leadership, A&G has advanced several new therapeutic and diagnostic product candidates into preclinical and clinical development, including two breast cancer diagnostics. In particular, a tissue test that measures GP88 in tumor biopsies as predictor of risk of recurrence in early stage breast cancer patients will be commercialized in Q3 2014. With more than 25 years of in protein biochemistry and cell culture, Ginette is a recognized leader in the field of cancer biology research and development, with particular expertise in the characterization of novel targets involved in cell differentiation and tumorigenesis with a focus on cell adipocyte differentiation, and breast cancer. She is an Adjunct Professor at the University of Maryland School of Pharmacy and at the University of Maryland School of Medicine and a member of the Marlene and Stewart Greenebaum Cancer Center in Baltimore. Prior to founding A&G, Ginette was a Professor at the University of Maryland School of Pharmacy and in the Program in Oncology at the University of Maryland Cancer Center. Before moving to Baltimore, she was Senior Scientist at the W. Alton Jones Cell Science Center in Lake Placid. She has published more than 80 papers, invited chapters, and reviews and is the inventor on 40 issued patents and more than 100 pending applications related to obesity and cancer molecular targets. Ginette is Associate Editor of In Vitro Cell and Developmental Biology. She is the 2006 recipient of the Greater Baltimore Life Sciences Entrepreneurial Spirit Award and is a Scientific Advisory board member of the Maryland Industrial Partnerships Program and a Board Member of the Emerging Technology Center located in Baltimore. MD. Ginette received a PhD in Biochemistry from the University of Marseille and a DSc in Cell Biology from the University of Nice.



Neil L. Spector, M.D.
Co-Director: Developmental Therapeutics Program, Duke Cancer Institute

Dr. Neil Spector is currently Sandra P. Coates Associate Professor, Departments of Medicine and Pharmacology/Cancer Biology, Duke University School of Medicine; Associate Director, Clinical Research, Breast Cancer Program, Duke Cancer Institute; Co-Director, Developmental Therapeutics Program, Duke Cancer Institute

Dr. Spector received his B.S. from the University of North Carolina at Chapel Hill in 1978. After graduation, Dr. Spector completed his M.D. from the New Jersey Medical School in 1982, and his internal medicine residency at Parkland Hospital, University of Texas-Southwestern Medical School, Dallas, Texas. Dr. Spector then completed a hematology/medical oncology fellowship at the Massachusetts General Hospital/Dana

Farber Cancer Center, Harvard Medical School. Dr. Spector served as an attending physician in hematology and oncology at the Dana-Farber Cancer Institute at Harvard Medical School and then joined the faculty at the University of Miami, Sylvester Comprehensive Cancer Center where he established the bone marrow transplant program. He then returned to North Carolina after accepting a position at GlaxoSmithKline (GSK) where he spent eight years involved in the development of targeted cancer therapies in his official capacity as Director of Exploratory Medical Sciences. During that time, he was an Adjunct Associate Professor of Medicine in the Division of Hematology/Medical Oncology at the UNC Lineberger Comprehensive Cancer Center at the University of North Carolina-Chapel Hill where he remained clinically active.

While at GSK, Dr. Spector successfully oversaw the development of two drugs that have been effective against cancer. First, Dr. Spector directed the Nelarabine development program, which received FDA approval in December 2005 for the treatment of children with acute lymphoblastic leukemia. Second, he directed the translational research program that supported the development of lapatinib (Tykerb), a targeted therapy approved by the FDA in 2007 for the treatment of HER2+ breast cancers.

Dr. Spector joined the faculty at Duke University in September 2006. In his role as the co-Director of the Developmental Therapeutics Program within the Duke Cancer Institute, Dr. Spector directs Duke's effort to make basic-science applicable in the care of cancer patients. His work is aimed at bridging the gap between laboratory scientists in Duke's basic science departments with physicians in the clinics in order to accelerate the transition of new therapies from the laboratory to the patient.

Colin Turnbull, Ph.D.
President, Colin Turnbull Consulting, LLC

From 1998 until 2003 I was Chairman of the Oncology Development Team at Schering-Plough Research Institute in NJ as well as Head, Clinical Oncology for most of this time. Since 2003 I have consulted for pharmaceutical clients, carrying out clinical and scientific due diligence on cancer drugs in early development in which there is interest in acquiring development and commercialization rights.

Subramanian Vaitheeswaran (Vaithee), Ph.D.
Lecturer, Department of Chemical Engineering at UMass Amherst

Subramanian Vaitheeswaran (Vaithee) was born in Mumbai, India and got his B.S. and M.S. in Physics from the University of Mumbai. In 2004 he earned a Ph.D. in Physics from the University of Maine, using computer simulations to investigate the peculiarities of water in nanoscale confinement. During this time he was a Pre-doctoral Visiting Fellow at the National Institutes of Health in Bethesda, Maryland.

As a Post-doctoral Researcher at the University of Maryland and Rensselaer Polytechnic Institute, he employed computational methods to study proteins and biomaterials. Later, as a Senior Research Fellow at the University of Massachusetts he investigated the fundamental chemistry of biofuel production. He is currently a lecturer in the Department of Chemical Engineering at UMass Amherst.

He is a keen runner and is plotting his second marathon.

Michael (Mike) J. Vasconcelles, M.D.

Senior Vice President, Head of Clinical Development, Millennium: The Takeda Oncology Company

Mike joined Millennium: The Takeda Oncology Company in 2012 as Senior Vice President, Head of Clinical Development. As part of Millennium's Medical Division Management and Administration, Mike has assumed responsibility for the clinical development strategy and execution of the oncology portfolio.

Prior to 2012, Mike served as Global Therapeutic Area Head, Transplant and Oncology, at Genzyme. He was responsible for the clinical development and product support of Genzyme's hematologic transplant and oncology portfolio. As a member of the Transplant and Oncology Management team, and Chair of the Transplant and Oncology R&D Council, Mike also provided strategic support and oversight to oncology research, business development and commercial strategy for the business. In 2011, following the acquisition of Genzyme by Sanofi, he led the realignment of Genzyme Oncology R&D with Sanofi Global Oncology and was named the Head, Personalized Medicine and Companion Diagnostics.

Before he joined Genzyme, Mike was a full time associate physician at Brigham and Women's Hospital and Dana-Farber Cancer Institute. He remains an associate physician at both institutions. He has been on the faculty of the Harvard Medical School since 1996, where he is currently a clinical instructor of medicine.

Mike received both his B.A. and his M.D. from Northwestern University.

Elizabeth (Liz) Yamashita, B.S.

Vice President, Regulatory and Clinical Affairs, Oncobiologics

Liz brings over 30 years of pharmaceutical industry experience with 20+ years in the Regulatory arena. Liz has wide exposure to areas of the pharmaceutical business in small molecule and biotechnology CMC development, clinical and nonclinical development, as well as marketing, and business development.

Liz is currently Vice President, Regulatory and Clinical Affairs at Oncobiologics. Prior to this position, she was Group Vice President, Regulatory Affairs at Savient Pharmaceuticals, Inc. managing all aspects of the regulatory function, and recently lead the Savient team to its first European marketing approval for Krystexxa®(pegloticase) a PEGylated enzyme for the treatment of severe gout. She was a Principal Fellow at ImClone providing regulatory expertise across the ImClone and Lilly biotech pipelines. As Vice President at ImClone Systems, she was responsible for Regulatory CMC strategy and Operations for development and commercial monoclonal antibody projects. Liz began her career at Bristol-Myers Squibb Company holding several positions. Her regulatory focus was working in the CMC arena in the oncology and immunology small and large molecules portfolios. Liz earned her Regulatory Affairs Certification from RAPS in 2002, and holds a B.S. degree in Chemistry from the University of Rochester.

Nancy E. Zeleniak, B.S.
President, Optimus Strategies

Zeleniak has more than 27 years of experience in roles that cross scientific research, healthcare market research, business development, marketing, venture relations, and corporate communications. She is best known for conceptualizing and implementing revenue-generating business models and marketing strategies. Working with global leaders, regional organizations and startups, she has worked on the launch and/or marketing teams for 18 biopharmaceuticals and devices. She also helped launch and market more than 80 healthcare services and information products, some of which she conceptualized.

Prior to founding Optimus Strategies, she served as global head of venture relations at PPD, a then public $1.6B contract research organization. She's held management roles with Burroughs Wellcome, Glaxo, and two startups, and served as associate dean at Duke University. Other roles include the Council of STEM Advisers to the Prime Minister of Belize, and National Space Biomedical Research Institute Industry Council. She has a BS in anthropology with a biology focus from The College of William & Mary.

Valerie Guild

Valerie Guild started AIM at Melanoma after the death of her daughter Charlie from melanoma at the age of 26.

In the area of patient advocacy, among its accomplishments, AIM has lead the fight in the US to ban minors from indoor tanning. The AIM website (www.AIMatMelanoma.org) is considered the most comprehensive information site for patients and caregivers, and has launched in France, Italy, Spain, Germany, U.K. and Australia.

In the area of research she has founded, in conjunction with Dr. John Kirkwood, the International Melanoma Working Group (IMWG) an international think tank that brings together world-renowned translational researchers and industry in an effort to move research forward. The Foundation is currently involved in launching a melanoma brain metastases bank and a first of its kind fully annotated primary melanoma tissue bank at four sites throughout the US and a fifth site in Europe.

She serves as the patient representative on the FDA, NCCN, SWOG, and ECOG, as well as the patient advisor to the Skin Cancer Spore and the CDMRP. Valerie holds a BA, MA, and MBA.

Nora Carbine

Nora worked in publishing for more than thirty years on both electronic and print publications. She worked through the transaction from galleys, pasteup, and burning negatives to plates for printing to electronic files, conversion to pdf and html, and digital printing. As a Senior Production Coordinator, she managed production for scientific research journals for a non-profit scientific association in Washington, D.C. (American Geophysical Union). She coordinated file formatting with overseas vendors, as well as directed text and art file in-house revisions from authors' files for web posting. She also sent out special projects for bid, evaluated, awarded, scheduled and supervised projects with in-house graphics staff and external vendors.

Nora was a Client Services Manager for a commercial publishing small business (Mercury Publishing) in Maryland. She handled projects from clients, scheduling in-house desktop publishing, worked with art directors, page makeup, proofreading, layout, ad managers and sales staff, printers, and mail houses.

Nora attended Project LEAD (National Breast Cancer Coalition science training for breast cancer advocates) in 1995, completed Clinical Trials LEAD training in 2003, and served as an advocate reviewer for the California Breast Cancer Research Program (2000, 01 & 02), an NCI advocate reviewer in 2011, and a Department of Defense Breast Cancer Research Program reviewer in 2014. As an advocate representative for the Georgetown Lombardi Cancer Center breast SPORE from 2002 to 2006, Georgetown TBCRC (Translational Breast Cancer Research Consortium) from 2008 to present, and the Georgetown breast cancer advocates' group (GLBCPAC), she has worked with bench scientists and clinicians evaluating research and clinical trial proposals. She is co-author of a Cochrane Collaboration Systematic Review on the efficacy of prophylactic mastectomy published in 2004 and is currently rewriting its second major revision. She has also edited both the informational web site and a training program for CISN (Cancer Information & Support Network).

She earned a BA in English and Anthropology from the University of Wisconsin, Madison, Wisconsin

Chris A. Rallis
Executive-in-Residence, Pappas Ventures

Chris has over 30 years' experience in the life science industry. His experience has been in the areas of legal, business development, strategic planning and general management.

He has been an Executive-in-Residence at Pappas Ventures, a life science venture capital firm based in Durham, NC, since 2008. From April 2006 until June 2007, he was President and Chief Executive Officer of ImmunoBiosciences, Inc., a vaccine technology company then located in Raleigh, NC. Previously, he was President and Chief Operating Officer of Triangle Pharmaceuticals, Inc. ("Triangle"), which was acquired by Gilead Sciences in January 2003 for approximately $465 million. While at Triangle, he participated in 11 equity financings generating gross proceeds of approximately $500 million. He was also primarily responsible for all business development activities which included a worldwide alliance with Abbott Laboratories and the in-licensing of 10 compounds. Prior to Triangle, he served in various business development, strategic planning and legal management roles with Burroughs Wellcome, Co. for 13 years. He began his career in 1978 as an attorney with Womble, Carlyle, Sandridge & Rice in Winston-Salem, NC.

Chris currently serves on the boards of Oxygen Biotherapeutics, Inc., Aeolus Pharmaceuticals Inc. and Adherex Technologies Inc. He is on the Audit Committees of all three corporations and chairs the Audit Committees of Aeolus and Adherex..

He received his A.B. degree in economics from Harvard College and his J.D. from Duke University.

Robert A. Figlin, M.D., F.A.C.P.
Steven Spielberg Family Chair in Hematology Oncology
Professor of Medicine and Biomedical Sciences
Director, Division of Hematology Oncology
Deputy Director, Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center

Robert A. Figlin, MD, FACP, is the Steven Spielberg Family Chair in Hematology Oncology, Professor of Medicine and Biomedical Sciences, Director of the Division of Hematology/Oncology, and Deputy Director of the Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai Medical Center in Los Angeles, California. Dr. Figlin received his medical degree from the Medical College of Pennsylvania. He completed his residency and chief residency in internal medicine at Cedars-Sinai Medical Center and a fellowship in hematology/oncology at the David Geffen School of Medicine at UCLA. He is an Emeritus Professor of Medicine and Urology at the David Geffen School of Medicine at UCLA.

Prior to joining Cedars-Sinai, Dr. Figlin was the Arthur and Rosalie Kaplan Endowed Chair of the Department of Medical Oncology and Therapeutics Research, and the Associate Director for Clinical Research at the City of Hope Comprehensive Cancer Center. Prior to that, Dr. Figlin served as the Henry Alvin and Carrie L. Meinhardt Endowed Chair in Urologic Oncology and Professor of Medicine and Urology in the Divisions of Hematology/Oncology and Urologic Oncology at the David Geffen School of Medicine at UCLA. Dr Figlin joined the UCLA faculty as Assistant Professor of Medicine in the Division of Hematology/Oncology and was appointed Co-Director of the Jonsson Comprehensive Cancer Center's Oncology Program. He also held the post of Medical Director of the Thoracic and Genitourinary Oncology Program in the Departments of Medicine, Surgery and Urology, and served as Program Director of Solid Tumor Developmental Therapeutics within the Cancer Center. Dr. Figlin serves as Editor for *Kidney Cancer Journal*, and his studies have appeared in *Clinical Cancer Research*, *Journal of Clinical Oncology*, *New England Journal of Medicine*, *Lancet*, *JNCI,* Lancet Oncology, and *Journal of Urology*, among others. He has authored over 300 peer reviewed articles, more than 60 book chapters, and has published as editor multiple books in kidney cancer. He is the Editor of the recently released book by Springer Science entitled, Renal Cell Carcinoma: Translational Biology, Personalized Medicine, and Novel Therapeutic Targets.

A nationally recognized leader in genitourinary and thoracic oncology, Dr. Figlin's research focuses on renal cell carcinoma and thoracic malignancies. He established and directs the Kidney Cancer Program at Cedars-Sinai Medical Center, which aims to understand the biology of kidney cancer and translate that knowledge into novel treatment approaches. His leadership in developing novel anticancer drugs that avoid the toxicity associated with standard treatments furthers Cedars-Sinai's tradition of compassionate patient care.

David Edward Weng, M.D., Ph.D.

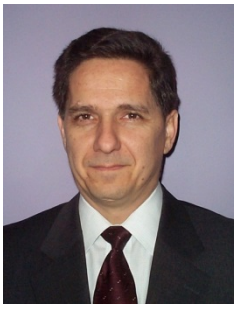
Dr. David E. Weng is a board certified medical oncologist with Anne Arundel Medical Center, joining the medical staff in March, 2014. In addition to clinical responsibilities for the care of patients with hematologic and solid tumor malignancies, he is also involved with clinical trials, health care outcomes and quality management research. Dr. Weng has been involved as an investigator in over 30 oncology studies during his research career. Dr. Weng has over 60 peer-reviewed publications and abstracts in the fields of developmental biology, cancer biology, immunology, and clinical research. He has been an advisor and investigator for multiple biotechnology companies for development of new approaches including target selection, preclinical drug development, chemotherapy cytotoxic agents, hormonal therapies, small molecule agents, monoclonal antibodies, cellular therapies, diagnostics, and imaging.

He was previously the chief medical officer and senior vice president for TetraLogic Pharmaceuticals in Malvern, PA. At TetraLogic, Dr. Weng advanced the clinical development of birinapant, (novel small molecule in the class of Smac mimetic agents) from preclinical studies to phase 2 clinical studies for both solid and hematologic

malignancies. In addition, he was primarily responsible for the development of external preclinical and clinical collaborations, and the building of company capabilities in clinical development, operations, regulatory affairs, and data management. At TetraLogic, he oversaw pharmacovigilance, and management of interactions with contract research organizations, key academic institutions and opinion leaders, in the US, Asia, and Europe. Dr. Weng contributed to strategic planning, corporate development, business development, translational studies, preclinical research, and communication with investors.

Before joining the biotechnology industry, Dr. Weng was a faculty member of the Department of Hematology and Medical Oncology and the Taussig Cancer Center at the Cleveland Clinic Foundation from 1998-2006. While at the Clinic, he was a clinical oncologist, seeing patients of all diagnoses and disease stages, with particular expertise in breast cancer. In addition, he contributed to institutional capabilities as director for the Hematology/Medical Oncology Fellowship Program, overseeing the recruitment and training of fellows to careers for both academic and community practice. Dr. Weng was also vice chairman of the Cleveland Clinic Institutional Review Board, overseeing review of new and ongoing programs of clinical research.

Dr. Weng earned his bachelor's degree in biochemical sciences from Harvard University and medical and doctorate degrees from the Johns Hopkins University School of Medicine. He completed his internal medicine residency training at the Johns Hopkins Hospital, followed by fellowship training in medical oncology at the National Cancer Institute. He continues to maintain active licenses for Federal DEA prescription privileges for controlled substances and state medical licensure in Maryland, Ohio, and California.



Grant Williams, M.D.

Grant Williams, M.D. is a board certified oncologist and regulatory consultant with 25 years of experience focused on oncology drug development including roles in FDA, industry, and consulting . For 16 years (1989 to 2005) he worked for the FDA Division of Oncology Drug Products serving as primary medical reviewer for 8 years, medical team leader for 5 years, and Deputy Division Director to Richard Pazdur, M.D., for 3 years. During his tenure at FDA he drafted guidance documents that are now central to the design and interpretation of pivotal studies for cancer drug approval. This included the Cancer Endpoints Guidance which outlines FDA positions on analysis of PFS, a key endpoint in cancer drug approval. After leaving FDA in 2005 he pursued oncology clinical development at Novartis and GSK . He was a member of the PhRMA statistical subgroup on PFS and coauthored papers on this topic. In September 2008 he formed Williams Cancer Drug Consulting LLC, centered in Wayne, PA, and has consulted extensively for large and small companies on regulatory and development issues related cancer drug approval.

Lee Greenberger, Ph.D.
Chief Scientific Officer, Leukemia and Lymphoma Society

Lee has over 25 years experience in Oncology Research and Development.

Since September 2013, Lee has been Chief Scientific Officer of the Leukemia and Lymphoma Society. His responsibilities focus on planning and executing the strategy for all LLS research programs, including a grant portfolio with 320 active projects, the Therapy Acceleration Program (TAP) with over 15 opportunities, as well as other research initiatives. Dr. Greenberger guides LLS's efforts to translate innovative research into clinical trials that ultimately will pave the way for new therapies to treat blood cancers. The total annual budget for these activities is approximately $75 M.

Immediately prior to LLS, Dr. Greenberger was global head of search and diligence for oncology and immunology at Bristol-Myers Squibb where he examined opportunities for over 200 oncology companies and helped set the

business strategy for oncology and immunology. Prior to that, he served for six years as vice president for research at Enzon Pharmaceuticals where he was responsible for pre-clinical pharmacology, toxicology, process development, and analytical chemistry efforts associated with the discovery and development of oncology assets. Prior to Enzon, Lee held positions of increasing responsibility in the research organizations of Johnson & Johnson and Wyeth Pharmaceuticals, where he began his industry career in 1990 at American Cyanamid/Lederle Laboratories, which was later acquired by Wyeth. He was given the President's Award for his work at Wyeth.
Dr. Greenberger holds a bachelor's degree from the University of Rochester and a Ph.D. from Emory University. He has done post-doctoral work at Columbia University and was on faculty at the Albert Einstein College of Medicine. Dr. Greenberger has produced more than 85 publications, mostly focused on oncology, during his research career.

Meryl Weinreb

Meryl Weinreb is a retired pharmaceutical marketing executive with extensive experience in oncology – both from an industry and personal perspective. As a 3 time breast cancer survivor, she was uniquely equipped to successfully lead consumer marketing strategy and execution for AstraZeneca's US oncology portfolio. She was responsible for a number of awarding-winning patient education and support programs for breast, prostate and lung cancer therapies. She led innovative adherence programs, and worked with company researchers to create patient-friendly PI's and clinical protocols.
As President of Somerset Lake Consulting, Ms. Weinreb has worked with a number of clients to provide strategic help with a variety of business challenges. Clients have included Abbott Labs, Genentech, Onyx, Cardinal Health and GlaxoSmithKline. These projects have covered a variety of tumor types including breast, non-small cell lung, hepacellular carcinoma, and leukemia.
Additionally, for the past 7 years, Ms. Weinreb served on the Executive Board of the Philadelphia affiliate of the Susan G. Komen Foundation, a non-profit organization that educates the community about breast cancer, and funds research, screening and support programs. She continues to serve as the affiliate's Education Chair, and leads public policy initiatives for Komen's Advocacy Alliance in Pennsylvania and Delaware. In 2013, she was invited to join Komen's Advocates in Science Program and has served as a consumer reviewer for the Department of Defense's Breast Cancer Research Program.

Cancer Prevention and Research Institute of Texas
Company and Academic Award Data
As of July 23, 2014

Institution/Organization	Number of Prevention Awards	Prevention Award Amounts($)	Number of Product Development Awards	Product Development Award Amounts ($)	Number of Academic Research Awards	Academic Research Award Amounts ($)	Total Research (Including Product Development) Award Amounts ($)	Research Recruitment Amounts ($)	Research Training Amounts ($)	Basic Research Amounts ($)	Translational Research Amounts ($)	Clinical Research Amounts ($)	Total Number of Awards	Total Award Amount Institution/Organization
Austin														
The University of Texas at Austin	1	$ 266,920	0	$ -	27	$ 37,275,198	$ 37,275,198	$ 14,000,000	$ 4,135,655	$ 6,472,058	$ 12,667,485	$ -	28	$ 37,542,118
The University of Texas System	0	$ -	0	$ -	1	$ 5,000,000	$ 5,000,000	$ 5,000,000	$ -	$ -	$ -	$ -	1	$ 5,000,000
Apollo Endosurgery	0	$ -	1	$ 5,001,063	0	$ -	$ 5,001,063	$ -	$ -	$ -	$ -	$ 5,001,063	1	$ 5,001,063
Mirna Therapeutics, Inc.	0	$ -	2	$ 35,445,068	0	$ -	$ 35,445,068	$ -	$ -	$ -	$ 10,297,454	$ 25,147,614	2	$ 35,445,068
Rules-Based Medicine	0	$ -	1	$ 3,024,432	0	$ -	$ 3,024,432	$ -	$ -	$ -	$ 3,024,432	$ -	1	$ 3,024,432
Asuragen, Inc.	0	$ -	1	$ 6,837,265	0	$ -	$ 6,837,265	$ -	$ -	$ -	$ -	$ 6,837,265	1	$ 6,837,265
ProPep Surgical	0	$ -	1	$ 4,435,857	0	$ -	$ 4,435,857	$ -	$ -	$ -	$ -	$ 4,435,857	1	$ 4,435,857
ProNAi Therapeutics, Inc.	0	$ -	1	$ 14,000,000	0	$ -	$ 14,000,000	$ -	$ -	$ -	$ -	$ 14,000,000	1	$ 14,000,000
Central														
Molecular Templates, Inc.	0	$ -	1	$ 10,600,000	0	$ -	$ 10,600,000	$ -	$ -	$ -	$ -	$ 10,600,000	1	$ 10,600,000
Baylor University	0	$ -	0	$ -	2	$ 4,415,750	$ 4,415,750	$ 4,215,750	$ -	$ -	$ 200,000	$ -	2	$ 4,415,750
Texas Tech University Health Science Center - Abilene	0	$ -	0	$ -	1	$ 756,644	$ 756,644	$ -	$ -	$ -	$ 756,644	$ -	1	$ 756,644
Scott and White Healthcare	0	$ -	0	$ -	1	$ 3,584,521	$ 3,584,521	$ -	$ -	$ -	$ 3,584,521	$ -	1	$ 3,584,521
College Station														
Caliber Biotherapeutics	0	$ -	1	$ 12,808,151	0	$ -	$ 12,808,151	$ -	$ -	$ -	$ -	$ 12,808,151	1	$ 12,808,151
Kalon Biotherapeutics, LLC	0	$ -	1	$ 7,901,420	0	$ -	$ 7,901,420	$ -	$ -	$ -	$ -	$ 7,901,420	1	$ 7,901,420
Texas A&M University	2	$ 839,227	0	$ -	5	$ 1,576,176	$ 1,576,176	$ -	$ -	$ 798,292	$ 777,884	$ -	7	$ 2,415,403
Texas A&M University System Health Science Center	3	$ 4,735,590	0	$ -	3	$ 4,053,945	$ 4,053,945	$ 1,800,000	$ -	$ -	$ 2,253,945	$ -	6	$ 8,789,535
Texas A&M University System Health Science Center Research Foundation	4	$ 1,138,077	0	$ -	1	$ 947,367	$ 947,367	$ -	$ -	$ -	$ 947,367	$ -	5	$ 2,085,444
Texas Agrilife Extension Service	3	$ 3,410,830	0	$ -	0	$ -	$ -	$ -	$ -	$ -	$ -	$ -	3	$ 3,410,830
Texas Agrilife Research	0	$ -	0	$ -	3	$ 599,805	$ 599,805	$ -	$ -	$ 399,911	$ 199,894	$ -	3	$ 599,805
Dallas/Fort Worth														
The University of Texas at Arlington	0	$ -	0	$ -	3	$ 2,285,375	$ 2,285,375	$ -	$ -	$ 789,470	$ 1,495,905	$ -	3	$ 2,285,375
The University of Texas at Dallas	0	$ -	0	$ -	3	$ 5,909,898	$ 5,909,898	$ -	$ -	$ 3,602,853	$ 2,307,045	$ -	3	$ 5,909,898
The University of Texas Southwestern Medical Center	7	$ 9,549,709	0	$ -	111	$ 191,447,124	$ 191,447,124	$ 63,825,000	$ 4,797,616	$ 47,716,065	$ 52,618,318	$ 22,490,125	118	$ 200,996,833
Peloton Therapeutics, Inc.	0	$ -	1	$ 11,044,931	0	$ -	$ 11,044,931	$ -	$ -	$ -	$ 11,044,931	$ -	1	$ 11,044,931
University of North Texas	0	$ -	0	$ -	2	$ 381,419	$ 381,419	$ -	$ -	$ 181,419	$ 200,000	$ -	2	$ 381,419
The University of North Texas Health Science Center at Fort Worth	6	$ 5,792,539	0	$ -	2	$ 179,834	$ 179,834	$ -	$ -	$ 170,334	$ 9,500	$ -	8	$ 5,972,373
Baylor Research Institute	0	$ -	0	$ -	1	$ 3,246,164	$ 3,246,164	$ -	$ -	$ -	$ 1,137,984	$ 2,108,180	1	$ 3,246,164
Gradalis, Inc. (MIRA Sub Award)	0	$ -	0	$ -	0	$ 806,791	$ 806,791	$ -	$ -	$ -	$ 806,791	$ -	0	$ 806,791
Texas Tech University Health Science Center at Dallas	0	$ -	0	$ -	1	$ 2,500,000	$ 2,500,000	$ -	$ -	$ -	$ -	$ 2,500,000	1	$ 2,500,000
Beta Cat Pharmaceuticals, LLC	0	$ -	1	$ 15,908,085	0	$ -	$ 15,908,085	$ -	$ -	$ -	$ -	$ 15,908,085	1	$ 15,908,085
Houston/Galveston														
The University of Texas Medical Branch at Galveston	2	$ 1,239,025	0	$ -	4	$ 7,888,268	$ 7,888,268	$ 1,881,402	$ -	$ -	$ 656,155	$ 5,350,711	6	$ 9,127,293
Baylor College of Medicine	5	$ 8,034,608	0	$ -	57	$ 107,760,193	$ 107,760,193	$ 24,500,000	$ 3,936,573	$ 25,075,472	$ 34,964,633	$ 19,283,515	62	$ 115,794,801
Bellicum Pharmaceuticals, Inc.	0	$ -	1	$ 5,680,310	0	$ -	$ 5,680,310	$ -	$ -	$ -	$ -	$ 5,680,310	1	$ 5,680,310
Statewide Clinical Trials Network of Texas (CTNet)	0	$ -	0	$ -	0	$ 25,213,675	$ 25,213,675	$ -	$ -	$ -	$ -	$ 25,213,675	0	$ 25,213,675
Rice University	0	$ -	0	$ -	10	$ 27,943,428	$ 27,943,428	$ 18,000,000	$ -	$ 200,000	$ 5,837,411	$ 3,906,017	10	$ 27,943,428
The Methodist Hospital Research Institute	0	$ -	0	$ -	8	$ 25,283,225	$ 25,283,225	$ 17,000,000	$ -	$ 4,075,199	$ 3,303,895	$ 904,131	8	$ 25,283,225
The University of Texas Health Science Center at Houston	6	$ 5,282,960	0	$ -	19	$ 22,197,981	$ 22,197,981	$ 6,806,000	$ 4,362,690	$ 4,630,386	$ 3,086,264	$ 3,312,641	25	$ 27,480,941
The University of Texas M.D. Anderson Cancer Center	12	$ 6,433,380	0	$ -	89	$ 154,546,908	$ 154,546,908	$ 47,000,000	$ 4,276,313	$ 45,902,493	$ 35,741,462	$ 21,626,640	101	$ 160,980,288
University of Houston	1	$ 272,753	0	$ -	9	$ 12,684,017	$ 12,684,017	$ 2,000,000	$ 3,979,258	$ 2,585,327	$ 2,839,848	$ 1,279,584	10	$ 12,956,770
Visualase, Inc.	0	$ -	1	$ 2,151,776	0	$ -	$ 2,151,776	$ -	$ -	$ -	$ -	$ 2,151,776	1	$ 2,151,776
Ingeneron, Inc.	0	$ -	1	$ 198,111	0	$ -	$ 198,111	$ -	$ -	$ -	$ 198,111	$ -	1	$ 198,111
Cell Medica	0	$ -	1	$ 15,571,303	0	$ -	$ 15,571,303	$ -	$ -	$ -	$ -	$ 15,571,303	1	$ 15,571,303
Texas A&M University Health Science Center Institute of Biosciences and Technology	0	$ -	0	$ -	0	$ 6,344,572	$ 6,344,572	$ -	$ -	$ -	$ 6,344,572	$ -	0	$ 6,344,572
Pulmotect, Inc.	0	$ -	1	$ 7,126,398	0	$ -	$ 7,126,398	$ -	$ -	$ -	$ -	$ 7,126,398	1	$ 7,126,398
DNAtrix, Inc.	0	$ -	1	$ 10,813,623	0	$ -	$ 10,813,623	$ -	$ -	$ -	$ -	$ 10,813,623	1	$ 10,813,623
ESSA Pharma Inc.	0	$ -	1	$ 12,000,000	0	$ -	$ 12,000,000	$ -	$ -	$ -	$ -	$ 12,000,000	1	$ 12,000,000
North														
Texas Tech University	2	$ 592,546	0	$ -	5	$ 4,326,070	$ 4,326,070	$ 2,500,000	$ -	$ 1,426,166	$ 399,904	$ -	7	$ 4,918,616
Texas Tech University Health Sciences Center	7	$ 7,326,925	0	$ -	9	$ 11,126,060	$ 11,126,060	$ 2,539,259	$ -	$ 742,572	$ 6,623,673	$ 1,220,556	16	$ 18,452,985
Angelo State University	1	$ 1,120,825	0	$ -	0	$ -	$ -	$ -	$ -	$ -	$ -	$ -	1	$ 1,120,825
CerRx, Inc.	0	$ -	1	$ 6,000,000	0	$ -	$ 6,000,000	$ -	$ -	$ -	$ -	$ 6,000,000	1	$ 6,000,000
San Antonio														
The University of Texas at San Antonio	0	$ -	0	$ -	2	$ 898,026	$ 898,026	$ -	$ -	$ 199,906	$ 698,120	$ -	2	$ 898,026
The University of Texas Health Science Center at San Antonio	7	$ 6,741,439	0	$ -	16	$ 19,393,667	$ 19,393,667	$ 3,892,505	$ 3,977,780	$ 499,998	$ 8,251,802	$ 2,771,582	23	$ 26,135,106
West Texas														
The University of Texas at El Paso	0	$ -	0	$ -	0	$ 999,992	$ 999,992	$ -	$ -	$ 999,992	$ -	$ -	0	$ 999,992
Texas Tech University Health Science Center at Amarillo	0	$ -	0	$ -	2	$ 936,652	$ 936,652	$ -	$ -	$ -	$ 936,652	$ -	2	$ 936,652
Texas Tech University Health Science Center at El Paso	0	$ -	0	$ -	1	$ 1,500,000	$ 1,500,000	$ -	$ -	$ -	$ -	$ 1,500,000	1	$ 1,500,000
Prevention or Planning Awards Not Affiliated with an Academic Institution	46	$ 33,953,451	19806145	$ 19,806,145	1	$ 7,745	$ 19,813,890	$ -	$ -	$ -	$ -	$ 19,813,890	48	$ 53,767,341
Totals	**115**	**$ 96,730,804**	**21**	**$ 206,353,938**	**399**	**694,016,490**	**$ 900,370,428**	**$ 214,959,916**	**$ 29,465,885**	**$ 146,467,913**	**$ 214,212,602**	**$ 295,264,112**	**535**	**$ 997,101,232**
								23.87%	**3.27%**	**16.26%**	**23.79%**	**32.79%**		

Dollars reported are contracted amounts if the award has completed the contracting process, otherwise announced award amounts are used.
Of the $25.2 million obligated for the Statewide Clinical Trials Network of Texas (CTNeT) award, $8.7 million was expended by the time it ceased operations.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CPRIT GRANTEE HIGHLIGHTS

While advancements in cancer research, prevention and product development can take years, we are already realizing some incredible returns on the investments CPRIT has made in Texas. CPRIT is playing a critical role in advancing innovation in all three areas and CPRIT's impact will continue to grow far beyond the progress we see today.

PREVENTION
Reaching Underserved Populations, Saving Lives

Grantee: Dr. Samir Gupta, The University of Texas Southwestern Medical Center
Project: *Increasing Colorectal Cancer Screening in a Safety-net Health System with a Focus on the Uninsured: Benefits and Costs*
Dr. Gupta tested outreach strategies to find the best way to screen uninsured populations for colorectal cancer, which included FIT test or colonoscopy. For this uninsured population served by a safety net hospital, results showed that screening was twice as high for at home FIT text vs. colonoscopy and much more cost effective.
Impact: This project resulted in successful new methods to reach uninsured populations with preventative measures.

Grantee: Dr. Abbey Berenson, The University of Texas Medical Branch at Galveston
Project: *Prenatal Education and Postpartum Administration of HPV Vaccine: Strategies to Increase Initiation and Series Completion Among Low Income Women*
Dr. Berenson's project targeted low income pregnant women to take advantage of opportunities for prevention when these women accessed the health care system. This program targeted populations that typically have very low HPV vaccination rates by implementing standing orders for postpartum HPV vaccination(s) during regular doctors' visits associated with pre and post partum care.
Impact: This program has increased the HPV vaccination rates from 9% to 83% in this clinic population in the very first year of operation.

Grantee: Dorothy Gibbons, The Rose (Houston)
Project : *Empower Her to Care*
The Rose's Empower Her to Care project increases mammography screening within the underserved minorities in 24 Texas counties through an expanded Mobile Mammography Outreach program. The program does this by providing free, easy to access breast cancer screening in the neighborhoods where the women work and live, increasing public awareness of the importance of identifying cancer in its earliest chances.
Impact: To date, the project has served 5,044 women; 1,800 of these women had never before been screened.

SCIENTIFIC RESEARCH
Enhancing Research Superiority in Texas; Supporting Groundbreaking Science

Grantee: Dr. James Allison, The University of Texas M.D. Anderson Center
Project: *CPRIT Scholar: Recruitment of Established Investigator*
With the help of a CPRIT recruitment grant, M.D. Anderson brought noted researcher Jim Allison, Ph.D. to Texas. Allison's research has exposed ways to use the immune system to attack cancers, revealing an entirely new way to combat these diseases. This groundbreaking discovery earned him the 2014 Breakthrough Prize in Life Sciences among many other distinguished recognitions.
Impact: Dr. Allison's work has opened a new field of immunotherapy and improved the survival of patients with advanced melanoma, and is now being extended to other types of cancer.

Grantee: Dr. Craig Malloy, The University of Texas Southwestern Medical Center
Project: *TAMU-UT Southwestern Partnership for Cancer Imaging and Spectroscopy at 7 Tesla*
Dr. Malloy's grant created a partnership between Texas A&M University engineers and clinicians and researchers at the University of Texas Southwestern Medical Center to develop new measuring tools to improve locating biomarkers in breast cancer and malignancies of the brain.
Impact: This study resulted in a patent application for the newly created breast coil and an agreement with Samsung Research America in Dallas to develop new technologies in this area.

Grantee: Dr. Zeina Nahleh, Texas Tech University Health Sciences Center in El Paso
Project: *Establishing a Cancer Clinical Research Core facility at Texas Tech University Health Science Center in El Paso*

This project establishes a Cancer Clinical Research facility at Texas Tech University Health Sciences Center in El Paso. This center will allow activation of currently funded cancer-related projects, development of an educational and community outreach office to expand patient awareness and education of cancer programs, and to establish a new cancer database for sharing key data with Texas clinical oncology clinical trials consortia.

Impact: Clinical trials are now available to the Latino community in the El Paso area.

PRODUCT DEVELOPMENT
Moving Science into the Clinic; Supporting New Therapies

Grantee: Mirna Therapeutics, Inc.

Project: *Cancer Treatment Including Drug Discovery/Development and Clinical Trials*

With CPRIT funding, scientists at Mirna Therapeutics, Inc. were among the first to investigate tumor suppressor miRNAs as a new therapeutic approach in the treatment of cancer. Preclinical studies across a range of tumors strongly indicated that miRNA-based therapeutics represent a potent new class of anticancer drugs. The company has now been the first to advance a promising miRNA therapy into a human clinical trial for liver cancer.

Impact: If confirmed through further clinical testing, the Mirna therapeutic will be the first of a new class of anticancer drugs with improved therapeutic performance and tolerability for the patient.

Grantee: Apollo Endosurgery

Project: *Medical Devices for the Treatment of Cancerous Lesions and the Gastrointestinal Tract*

Apollo Endosurgery has developed a surgical device that enables a new procedure to remove early stage lesions from the colon, esophagus and stomach. Prior to the introduction of this device, physicians were limited in their ability to treat a suspicious lesion during a routine colonoscopy. This device allows multiple stages and sizes of lesions to be treated endoscopically, rather than by more invasive surgical procedures.

Impact: Early detection and removal of cancerous and pre-cancerous lesions dramatically improve patient outcomes. By facilitating lesion removal, the Apollo technology is a significant new benefit to patients.

Grantee: Rules-Based Medicine

Project: *Cancer Biology and Genetics Including Oncogenesis Genomics and Proteomics*

Rules-Based Medicine is developing automated, multiplexed immunoassays (tests) for cancer related proteins. When many of these individual assays or tests are taken together from a single analysis, their results can show unique patterns. These patterns can be useful in early cancer diagnosis, prognosis, as well as potentially monitoring how people respond to therapies.

Impact: Novel biomarkers for cancer detection and monitoring provide benefits for both research and patient care. The company was acquired by Myriad Genetics and is continuing to operate its Austin office.

Curing Cancer: Where are we today?

A Q&A with CPRIT Chief Scientific Officer Dr. Margaret Kripke

1. How likely is it that we will be able to cure cancer in the near future?

Actually, cancers are being cured every day. Around 2/3 of people who develop cancer remain cancer-free for five or more years, more than half are cured of their disease, and the number of cancer survivors grows daily. For people who are not cured by today's treatments, we continue to investigate new approaches. It is unlikely that there will be a single breakthrough that will lead to the cure of all cancers. That is because there are many different types of cancer that require different treatments. Not only are cancers of the lung different from breast cancers, but there are many different subtypes of lung and breast cancers, each of which may require a different treatment. Although we are making steady gains in providing new, less toxic treatments for cancer, it will be a long time before we have an effective therapy for every cancer type.

2. Why is cancer so difficult to cure?

In addition to the fact that there are many different subtypes of cancer, each of which may require a different treatment, cancer cells have two characteristics that make them a challenge to treat. One is their ability to spread to other sites of the body (metastasis). This means that removing the original cancer by surgery or radiation will not necessarily cure the disease, which can appear elsewhere in the body months or even years after removal of the primary cancer. Thus, some type of systemic therapy is generally required to eliminate cancer cells that have already spread at the time of diagnosis. The second characteristic is the ability of cancer cells to develop resistance to chemotherapy and radiation. Most cancers have the ability to change their properties, so that they become resistant to treatment. Just like the common cold virus or the influenza virus, cancer cells can change, or mutate, to become resistant to therapy. When one treatment becomes ineffective, another one is needed, but in many cases, no other options are available.

3. What are the most promising avenues of cancer research today?

Research in recent years has revealed that cancer cells have changes in their DNA that distinguish them from normal cells. Some of these changes enable the cells to escape the normal processes that control cell division and cell death. Finding new drugs that target these changes is an intense area of investigation. Such drugs would act against the cancer cells, but would not harm normal cells, thus sparing patients the toxicity that accompanies current chemotherapy. An example of such targeted therapy is gleevec, which destroys

cancer cells having a particular mutation in their DNA. Many more such drugs are under development. Another promising avenue is early detection. Cancers that are found early are more easily cured than advanced cancers that have already spread to distant organs. Many current efforts are directed to development of new screening tests for cancer, particularly pancreatic and ovarian cancers, which are often diagnosed late and are therefore very difficult to cure. Another important focus is using the body's immune system to combat cancer. New findings regarding how the immune system is controlled are being applied to the treatment of melanoma skin cancers with considerable success. Current research is attempting to extend these findings to other types of cancer.

4. What would make the biggest difference in reducing the burden of cancer?

Eliminating tobacco use would have the most dramatic effect on reducing cancer incidence and cancer deaths. In the United States alone, deaths from lung cancer would be reduced by 80%, and deaths from all cancers would be reduced by 30% within 20 years after people stopped using tobacco. Other approaches to preventing cancer, such as exercise, better eating habits, and removing toxic chemicals from the environment would also reduce the incidence of cancer over time. Preventive measures have the added benefit of sparing people from the emotional, physical, and financial toll resulting from a cancer diagnosis. After prevention, the next biggest difference would result from early detection of cancer, for the reasons stated above. For cancer treatment, understanding the mechanisms by which cancer cells become resistant to therapy and finding ways to counteract them is critical to ensuring the effectiveness of all forms of treatment. Finally, improving the access of underserved populations to today's standard of cancer care would also reduce the burden of cancer and would help to address the large disparities in outcomes of cancer treatment that result from differences in socio-economic status.

5. How is CPRIT addressing these challenges?

CPRIT's Prevention Program is bringing cancer risk reduction, screening and survivor programs to rural and underserved populations across the State. These efforts help people reduce the risk of getting cancer, identify cancer earlier and assist them in finding appropriate cancer treatment options, thus reducing the overall burden of cancer in the State. The Research Program is helping research institutions to recruit the most talented cancer researchers to Texas. It also supports cutting-edge research projects that range from understanding how cancer cells are formed, spread, and develop resistance, to development of new anti-cancer drugs and new tools for cancer diagnosis and imaging. The Product Development Program is moving the advances in research out of the laboratory and into the development of devices, drugs, and biological agents for use in cancer detection and treatment.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Key Executive Staff

Margaret Kripke, PhD

Degrees and Institutions:

- Ph.D., University of California, Berkeley (Immunology)
- M.A., University of California, Berkeley (Microbiology and Immunology)
- A.B., University of California, Berkeley (Microbiology and Immunology)

Career Highlights:

- Executive Vice President and Chief Academic Officer, U.T. M.D. Anderson Cancer Center, 2001-2007
- Member, President's Cancer Panel, 2003-2011
- President, American Association for Cancer Research, 1993

Rebecca Garcia, PhD

Degrees and Institutions:

- Ph.D., University of North Texas, Denton, Texas (Department of Higher Education)
- M.A., The University of Texas Health Science Center at Dallas (Department of Biomedical Communications)
- B.S., The University of Texas Health Science Center at Dallas (School of Allied Health Sciences)

Career Highlights:

- Vice President, Continuing Professional Development, Physicians' Education Resource, 2007-2009
- Vice President, Health Sciences, Susan G. Komen for the Cure, 1999 - 2006
- Director, Department of Academic Affairs/Education, American College of Emergency Physicians, 1985 - 1999

Tom Goodman, PhD

Degrees and Institutions:

- Ph.D., University of Wisconsin, Madison (Biochemistry)
- M.B.A., University of California, Berkeley (Haas School - Finance)
- B.S., California State University, Los Angeles (Biochemistry)

Career Highlights:

- Director and later Vice President of Business Development, Arizona Technology Enterprises, 2008-2014
- Vice President of Development, Valeo Medical, 2005-2006

Heidi McConnell

Degrees and Institutions:

- M.P.Aff., Lyndon B. Johnson School of Public Affairs, The University of Texas at Austin
- B.A., Yale University

Career Highlights:

- Senior Budget Advisor and Governor's Advisor on Public Health Policy, Office of the Governor (9/2001-5/2009)
- Budget Analyst, Legislative Budget Board (3/1998-9/2001)

David Reisman

Degrees and Institutions:

- J.D., University of Kentucky College of Law
- M.P.A, University of Kentucky
- B.A., West Virginia Wesleyan College

Career Highlights:

- Executive Director, Texas Ethics Commission (10/2004 – 12/2013)
- Special Assistant to the Army General Counsel, U.S. Army (5/2002-10/2004)
- Fiscal Advisor and Special Projects Director, Office of the Governor for the State of Texas (2/1998-10/2002)

Kristen Doyle

Degrees and Institutions:

- M.S.T.C., McCombs School of Business, The University of Texas at Austin
- J.D., The The University of Texas School of Law
- B.S.P.A., Indiana University (Public Policy)

Career Highlights:

- Partner at an Austin-based law firm representing political subdivisions
- Recognized four times as a Super Lawyers Texas Rising Star by *Texas Monthly*