

CPRIT Administrative Rules: Chapters 701 – 703
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CHAPTER 701 – POLICIES AND PROCEDURES

RULE §701.1 Intent

The Institute shall:

- (1) Create and expedite innovation in the area of cancer research and enhance the potential for medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- (2) Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in Texas; and
- (3) Develop and implement the Texas Cancer Plan.

RULE §701.3 Definitions

The following words and terms, when used in this Chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) **Advisory Committee**--a committee of experts, including practitioners and patient advocates, created by the Oversight Committee to advise the Oversight Committee on issues related to cancer.

(2) **Allowable Cost**--a cost that is reasonable, necessary for the proper and efficient performance and administration of the project, and allocable to the project.

(3) **Annual Public Report**--the report issued by the Institute pursuant to Texas Health and Safety Code Section 102.052 outlining Institute activities, including Grant Awards, research accomplishments, future Program directions, compliance, and Conflicts of Interest actions.

(4) **Authorized Expense**--cost items including honoraria, salaries and benefits, consumable supplies, other operating expenses, contracted research and development, capital equipment, construction or renovation of state or private facilities, travel, and conference fees and expenses.

(5) **Approved Budget**--the financial expenditure plan for the Grant Award, including revisions approved by the Institute and permissible revisions made by the Grant Recipient. The Approved Budget may be shown by Project Year and detailed budget categories.

(6) **Authorized Signing Official (ASO)**--the individual, named by the Grant Applicant, who is authorized to act for the Grant Applicant or Grant Recipient in submitting the Grant Application and executing the Grant Contract and associated documents or requests.

(7) **Bylaws**--the rules established by the Oversight Committee to provide a framework for its operation, management, and governance.

(8) **Cancer Prevention**--a reduction in the risk of developing cancer, including early detection, control and/or mitigation of the incidence, disability, mortality, or post-diagnosis effects of cancer.

(9) **Cancer Prevention and Control Program**--effective strategies and interventions for preventing and controlling cancer designed to reduce the incidence and mortality of cancer and to enhance the quality of life of those affected by cancer.

(10) **Cancer Prevention and Research Fund**--the dedicated account in the general revenue fund consisting of legislative appropriations, gifts, grants, other donations, and earned interest.

(11) **Cancer Research**--research into the prevention, causes, detection, treatments, and cures for all types of cancer in humans, including basic mechanistic studies, pre-clinical studies, animal model studies, translational research, and clinical research to develop preventative measures, therapies, protocols, medical pharmaceuticals, medical devices or procedures for the detection, treatment, cure or substantial mitigation of all types of cancer and its effects in humans.

(12) **Chief Compliance Officer**--the individual employed by the Institute to monitor and report to the Oversight Committee regarding compliance with the Institute's statute and administrative rules. The term may also apply to an individual designated by the Chief Compliance Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(13) **Chief Executive Officer**--the individual hired by the Oversight Committee to perform duties required by the Institute's Statute or designated by the Oversight Committee. The term may apply to an individual designated by the Chief Executive Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(14) **Chief Prevention Officer**--the individual hired by the Chief Executive Officer to oversee the Institute's Cancer Prevention program, including the Grant Review Process, and to assist the Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may also apply to an individual designated by the Chief Prevention Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(15) **Chief Product Development Officer**--the individual hired by Chief Executive Officer to oversee the Institute's Product Development program for drugs, biologicals, diagnostics, or devices arising from Cancer Research, including the Grant Review Process, and to assist the Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may apply to an individual designated by the Chief Product Development Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(16) **Chief Scientific Officer**--the individual hired by the Chief Executive Officer to oversee the Institute's Cancer Research program, including the Grant Review Process, and to assist the Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may apply to an individual designated by the Chief Scientific Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(17) **Code of Conduct and Ethics**--the code adopted by the Oversight Committee pursuant to Texas Health and Safety Code 102.109 to provide guidance related to the ethical conduct expected of Oversight Committee Members, Program Integration Committee Members, and Institute Employees.

(18) **Compliance Program**--a process to assess and ensure compliance by the Oversight Committee Members and Institute Employees with applicable laws, rules, and policies, including matters of ethics and standards of conduct, financial reporting, internal accounting controls, and auditing.

(19) **Conflict(s) of Interest**--a financial, professional, or personal interest held by the individual or the individual's Relative that is contrary to the individual's obligation and duty to act for the benefit of the Institute.

(20) **Encumbered Funds**--funds that are designated by a Grant Recipient for a specific purpose.

(21) **Financial Status Report**--form used to report all Grant Award related financial expenditures incurred in implementation of the Grant Award. This form may also be referred to as "FSR" or "Form 269-A."

(22) **Grant Applicant**--the public or private institution of higher education, as defined by §61.003, Education Code, research institution, government organization, non-governmental organization, non-profit organization, other public entity, private company, individual, or consortia, including any combination of the aforementioned, that submits a Grant Application to the Institute. Unless otherwise indicated, this term includes the Principal Investigator or Program Director.

(23) **Grant Application**--the written proposal submitted by a Grant Applicant to the Institute in the form required by the Institute that, if successful, will result in a Grant Award.

(24) **Grant Award**--funding, including a direct company investment, awarded by the Institute pursuant to a Grant Contract providing money to the Grant Recipient to carry out the Cancer Research or Cancer Prevention project in accordance with rules, regulations, and guidance provided by the Institute.

(25) **Grant Contract**--the legal agreement executed by the Grant Recipient and the Institute setting forth the terms and conditions for the Cancer Research or Cancer Prevention Grant Award approved by the Oversight Committee.

(26) **Grant Management System**--the electronic interactive system used by the Institute to exchange, record, and store Grant Application and Grant Award information.

(27) **Grant Mechanism**--the specific Grant Award type.

(28) **Grant Program**--the functional area in which the Institute makes Grant Awards, including research, prevention and product development.

(29) **Grant Progress Report**--The required report submitted by the Grant Recipient at least annually and at the close of the grant award describing the activities undertaken to achieve

the goals and objectives of the funded project and including information, data and program metrics. Unless the context clearly indicates otherwise, the Grant Progress Report also includes other required reports such as a Historically Underutilized Business and Texas Supplier form, a single audit determination form, an inventory report, a single audit determination form, a revenue sharing form, and any other reports or forms designated by the Institute.

(30) **Grant Recipient**--the entire legal entity responsible for the performance or administration of the Grant Award pursuant to the Grant Contract. Unless otherwise indicated, this term includes the Principal Investigator, Program Director, or Company Representative.

(31) **Grant Review Cycle**--the period that begins on the day that the Request for Applications is released for a particular Grant Mechanism and ends on the day that the Oversight Committee takes action on the Grant Award recommendations.

(32) **Grant Review Process**--the Institute's processes for Peer Review, Program Review and Oversight Committee approval of Grant Applications.

(33) **Indirect Costs**--the expenses of doing business that are not readily identified with a particular Grant Award, Grant Contract, project, function, or activity, but are necessary for the general operation of the Grant Recipient or the performance of the Grant Recipient's activities.

(34) **Institute**--the Cancer Prevention and Research Institute of Texas or CPRIT.

(35) **Institute Employee**--any individual employed by the Institute, including any individual performing duties for the Institute pursuant to a contract of employment. Unless otherwise indicated, the term does not include an individual providing services to the Institute pursuant to a services contract.

(36) **Intellectual Property Rights**--any and all of the following and all rights in, arising out of, or associated therewith, but only to the extent resulting from the Grant Award:

(A) The United States and foreign patents and utility models and applications therefore and all reissues, divisions, re-examinations, renewals, extensions, provisionals, continuations and such claims of continuations-in-part as are entitled to claim priority to the aforesaid patents or patent applications, and equivalent or similar rights anywhere in the world in Inventions and discoveries;

(B) All trade secrets and rights in know-how and proprietary information;

(C) All copyrights, whether registered or unregistered, and applications therefore, and all other rights corresponding thereto throughout the world excluding scholarly and

academic works such as professional articles and presentations, lab notebooks, and original medical records; and

(D) All mask works, mask work registrations and applications therefore, and any equivalent or similar rights in semiconductor masks, layouts, architectures or topography.

(37) **Invention**--any method, device, process or discovery that is conceived and/or reduced to practice, whether patentable or not, by the Grant Recipient in the performance of work funded by the Grant Award.

(38) **License Agreement**--an understanding by which an owner of Technology and associated Intellectual Property Rights grants any right to make, use, develop, sell, offer to sell, import, or otherwise exploit the Technology or Intellectual Property Rights in exchange for consideration.

(39) **Matching Funds**--the Grant Recipient's Encumbered Funds equal to one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. For public and private institutions of higher education, this includes the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by the Section 102.203(c), Texas Health and Safety Code.

(40) **Numerical Ranking Score**--the score given to a Grant Application by the Review Council that is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also signifies the Review Council's view related to how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(41) **Overall Evaluation Score**--the score given to a Grant Application during the Peer Review Panel review that signifies the reviewers' overall impression of the Grant Application. Typically it is the average of the scores assigned by two or more Peer Review Panel members.

(42) **Oversight Committee**--the Institute's governing body, composed of the nine individuals appointed by the Governor, Lieutenant Governor, and the Speaker of the House of Representatives.

(43) **Oversight Committee Member**--any person appointed to and serving on the Oversight Committee.

(44) **Patient Advocate**--a trained individual who meets the qualifications set by the Institute and is appointed to a Scientific Research and Prevention Programs Committee to specifically

represent the interests of cancer patients as part of the Peer Review of Grant Applications assigned to the individual's committee.

(45) **Peer Review**--the review process performed by Scientific Research and Prevention Programs Committee members and used by the Institute to provide guidance and recommendations to the Program Integration Committee and the Oversight Committee in making decisions for Grant Awards. The process involves the consistent application of standards and procedures to produce a fair, equitable, and objective evaluation of scientific and technical merit, as well as other relevant aspects of the Grant Application. When used herein, the term applies individually or collectively, as the context may indicate, to the following review process(es): Preliminary Evaluation, Individual Evaluation by Primary Reviewers, Peer Review Panel discussion and Review Council prioritization.

(46) **Peer Review Panel**--a group of Scientific Research and Prevention Programs Committee members conducting Peer Review of assigned Grant Applications.

(47) **Prevention Review Council**--the group of Scientific Research and Prevention Programs Committee members designated as the chairpersons of the Peer Review Panels that review Cancer Prevention program Grant Applications. This group includes the Review Council chairperson.

(48) **Primary Reviewer**--a Scientific Research and Prevention Programs Committee member responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the general impression of the Grant Application's merit.

(49) **Principal Investigator, Program Director, or Company Representative**--the single individual designated by the Grant Applicant or Grant Recipient to have the appropriate level of authority and responsibility to direct the project to be supported by the Grant Award.

(50) **Product Development Review Council**--the group of Scientific Research and Prevention Programs Committee Members designated as the chairpersons of the Peer Review Panels that review Grant Applications for the development of drugs, biologics, diagnostics, or devices arising from earlier-stage Cancer Research. This group includes the Review Council chairperson.

(51) **Product Development Prospects**--the potential for development of products, services, or infrastructure to support Cancer Research efforts, including but not limited to pre-clinical, clinical, manufacturing, and scale up activities.

(52) **Program Income**--income from fees for services performed, from the use or rental of real or personal property acquired with Grant Award funds, and from the sale of commodities

or items fabricated under the Grant Contract. Except as otherwise provided, Program Income does not include rebates, credits, discounts, refunds, etc. or the interest earned on any of these items. Interest otherwise earned in excess of \$250 on Grant Award funds is considered Program Income.

(53) **Program Integration Committee**--the group composed of the Chief Executive Officer, the Chief Scientific Officer, the Chief Product Development Officer, the Commissioner of State Health Services, and the Chief Prevention Officer that is responsible for submitting to the Oversight Committee the list of Grant Applications the Program Integration Committee recommends for Grant Awards.

(54) **Project Results**--all outcomes of a Grant Award, including publications, knowledge gained, additional funding generated, and any and all Technology and associated Intellectual Property Rights.

(55) **Project Year**--the intervals of time (usually 12 months each) into which a Grant Award is divided for budgetary, funding, and reporting purposes. The effective date of the Grant Contract is the first day of the first Project Year.

(56) **Real Property**--land, including land improvements, structures and appurtenances thereto, excluding movable machinery and equipment.

(57) **Relative**--a person related within the second degree by consanguinity or affinity determined in accordance with Sections 573.021 – 573.025, *Government Code*. For purposes of this definition:

(A) examples of an individual within the second degree by consanguinity are a child, grandchild, parent, grandparent, brother, sister, uncle, aunt, niece, or nephew;

(B) examples of an individual within the second degree by affinity are a spouse, a person related to a spouse within the second degree by consanguinity, or a spouse of such a person;

(C) an individual adopted into a family is considered a Relative on the same basis as a natural born family member; and

(D) an individual is considered a spouse even if the marriage has been dissolved by death or divorce if there are surviving children of that marriage.

(58) **Request for Applications**--the invitation released by the Institute seeking the submission of Grant Applications for a particular Grant Mechanism. It provides information relevant to the Grant Award to be funded, including funding amount, Grant Review Process information, evaluation criteria, and required Grant Application components.

(59) **Review Council**--the term used to generally refer to one or more of the Prevention Review Council, the Product Development Review Council, or Scientific Review Council.

(60) **Scientific Research and Prevention Programs Committee**--a group of experts in the field of Cancer Research, Cancer Prevention or Product Development, including trained Patient Advocates, appointed by the Chief Executive Officer and approved by the Oversight Committee for the purpose of conducting Peer Review of Grants Applications and recommending Grant Awards. A Peer Review Panel is a Scientific Research and Prevention Programs Committee, as is a Review Council.

(61) **Scientific Research and Prevention Programs Committee Member**--an individual appointed by the Chief Executive Officer and approved by the Oversight Committee to serve on a Scientific Research and Prevention Programs Committee. Peer Review Panel Members are Scientific Research and Prevention Programs Committee Members, as are Review Council Members.

(62) **Scientific Review Council**--the group of Scientific Research and Prevention Programs Committee Members designated as the chairpersons of the Peer Review Panels that review Cancer Research Grant Applications. This group includes the Review Council chairperson.

(63) **Scope of Work**--the goals and objectives of the Cancer Research or Cancer Prevention project, including the timeline and milestones to be achieved.

(64) **Senior Member or Key Personnel**—the Principal Investigator, Project Director or Company Representative and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not the individuals receive salary or compensation under the Grant Award.

(65) **Technology**--any and all of the following resulting or arising from work funded by the Grant Award:

(A) Inventions;

(B) Third-Party Information, including but not limited to data, trade secrets and know-how;

(C) databases, compilations and collections of data;

(D) tools, methods and processes; and

(E) works of authorship, excluding all scholarly works, but including, without limitation, computer programs, source code and executable code, whether embodied in software, firmware or otherwise, documentation, files, records, data and mask works; and all instantiations of the foregoing in any form and embodied in any form, including but not

limited to therapeutics, drugs, drug delivery systems, drug formulations, devices, diagnostics, biomarkers, reagents and research tools.

(66) **Texas Cancer Plan**--a coordinated, prioritized, and actionable framework that helps to guide statewide efforts to fight the human and economic burden of cancer in Texas.

(67) **Third-Party Information**--generally, all trade secrets, proprietary information, know-how and non-public business information disclosed to the Institute by Grant Applicant, Grant Recipient, or other individual external to the Institute.

(68) **Tobacco**--all forms of tobacco products, including but not limited to cigarettes, cigars, pipes, water pipes (hookah), bidis, kreteks, electronic cigarettes, smokeless tobacco, snuff and chewing tobacco.

RULE §701.5 Oversight Committee Bylaws

The Oversight Committee shall adopt Bylaws to govern the conduct of its meetings and its management of the Institute, consistent with applicable law.

(1) The Bylaws shall include:

(A) A process to elect a presiding officer, assistant presiding officer, and any other officer positions that may be created by the Oversight Committee and to set terms of service for such positions;

(B) A meeting schedule that permits a public meeting to be held no less than once each calendar quarter, with appropriate notice and opportunity for a formal public comment period;

(C) Duties and responsibilities for the presiding officer and assistant presiding officer, as well as other additional officer positions that may be created by the Oversight Committee;

(D) Responsibilities of the Oversight Committee and the Committee's officers that are distinguished from responsibilities of the Chief Executive Officer and Institute employees;

(E) A process for the Oversight Committee to review the financial practices of the Institute, including a review of the annual financial audit of the Institute's activities and the Comptroller of Public Accounts' report and evaluation of the Institute's annual financial audit;

(F) A prohibition against an interlocking directorate between the Oversight Committee and any foundation established to benefit the Institute;

(G) A process for hiring a Chief Executive Officer and evaluating the Chief Executive Officer's job performance; and

(H) A designation of grounds for removal from the Oversight Committee based on illness, absence, or ineligibility and provide process for removal.

(2) The Bylaws must be posted on the Institute's Internet website.

RULE §701.7 Compliance Program

(a) Oversight Committee Members, Institute Employees, Scientific Research and Prevention Program Committee Members, Program Integration Committee Members, Grant Applicants, Grant Recipients, and contract service providers are expected to comply with applicable laws, rules, regulations, and policies in conduct of their official duties and responsibilities as well as professional standards of business and personal ethics.

(b) The Institute's Compliance Program shall ensure that agency operations conform to federal and state regulations, and that such operations are undertaken consistent with the Institute's administrative rules, policies, and procedures.

(1) The Compliance Program shall specifically address at least the following agency operations: Grant Review Process, Grant Award financial reporting and performance monitoring, Institute financial reporting, internal accounting controls, and auditing.

(2) The Compliance Program shall implement and oversee systems and activities to detect and report instances of conduct that do not conform to applicable law or policy, as well as the timely response to non-conforming conduct and to prevent future similar conduct;

(3) The Compliance Program shall implement and enforce the Code of Conduct and Ethics as well as the consistent enforcement of other compliance standards and procedures adopted by the Oversight Committee.

(c) The Compliance Program shall operate under the direction of the Chief Compliance Officer.

(1) In performing the duties under this program, the Chief Compliance Officer shall have direct access to the Oversight Committee.

(2) The Chief Compliance Officer is responsible and will be held accountable for apprising the Oversight Committee and the Chief Executive Officer of the institutional compliance functions and activities.

(A) The Chief Compliance Officer shall report at least quarterly to the Oversight Committee on the Institute's compliance with the applicable laws, rules and Institute policies. The Chief Compliance Officer may report more frequently to the Audit Subcommittee of the Oversight Committee.

(B) The Chief Compliance Officer shall report at least annually on the Institute's compliance program activities, including any proposed legislation or other recommendations identified through the activities. The compliance report shall be included in the Institute's Annual Public Report.

(C) The Chief Compliance Officer shall report at least annually to the Oversight Committee on the Grant Recipients' compliance with the terms and conditions of the

Grant Contracts. This report shall be made at the first Oversight Committee meeting following the submission of the Institute's Annual Public Report.

(D) The Chief Compliance Officer shall inquire into and monitor the timely submission status of required Grant Recipient reports and notify the Oversight Committee and General Counsel of a Grant Recipient's failure to meaningfully comply with reporting deadlines.

(d) Oversight Committee Members and Institute Employees shall participate in periodic Compliance Program training.

RULE §701.9 Report and Investigation of Compliance Violations

(a) The Chief Compliance Officer oversees the Institute's activities related to the report and investigation of suspected compliance violations.

(b) To encourage good faith reporting of suspected noncompliance, the Institute shall establish a system to receive confidential reports of suspected instances or events that failed to comply with the Institute's applicable laws, rules and policies. The Institute may use a telephonic and/or electronic mailbox system, such as an "ethics hotline" to preserve confidentiality of communications regarding suspected compliance violations and the anonymity of a person making a compliance report or participating in a compliance investigation.

(1) Information describing how to report a suspected compliance violation, including a designated telephone number and electronic mail address for confidentially reporting suspected compliance violations, shall be displayed on the Institute's Internet website and included in all Institute contracts and agreements.

(2) Information describing how to report a suspected compliance violation shall be included in the Institute's employee policies manual, and discussed internally with Institute Employees and included in ethics training sessions.

(3) Only good faith reports made to the designated telephone number or electronic mailbox shall be investigated.

(c) The Institute shall implement procedures to investigate a good faith report of a suspected violation, including:

(1) The prompt initiation of an investigation by the Chief Compliance Officer;

(2) Assignment to an appropriate individual or individuals to conduct the investigation, including the Audit Subcommittee, the Compliance Office, General Counsel, the Internal Auditor, or outside experts or advisors; and

(3) A recommendation for appropriate corrective actions, if any are warranted by the investigation, made to the Oversight Committee.

(d) To the extent allowed by law, the Institute will preserve the confidential nature of the good faith report of a suspected violation, including the identity of the individual submitting the report.

(e) The Chief Compliance Officer shall maintain a log that tracks the receipt, investigation, and resolution of reports made regarding compliance violations.

(f) In performing duties under this rule, the Chief Compliance Officer has direct access to the Oversight Committee. The Chief Compliance Officer shall report to the Oversight Committee at least quarterly on compliance activity.

(g) The following information is confidential and not subject to disclosure under Chapter 552, *Government Code*, unless the information relates to an individual who consents to the disclosure:

(1) information that directly or indirectly reveals the identity of an individual who made a report to the Institute's Compliance Program office, sought guidance from the office, or participated in an investigation conducted under the Compliance Program;

(2) information that directly or indirectly reveals the identity of an individual who is alleged to have or may have planned, initiated, or participated in activities that are the subject of a report made to the Compliance Program if, after completing an investigation, the Compliance Program determines the report to be unsubstantiated or without merit; and

(3) other information that is collected or produced in a Compliance Program investigation if releasing the information would interfere with an ongoing compliance investigation.

(h) The Oversight Committee may meet in a closed session under Chapter 551, *Government Code*, to discuss an on-going compliance investigation into issues related to fraud, waste or abuse of state resources.

RULE §701.11 Texas Cancer Plan

The Institute shall develop, implement, continually monitor, and revise the Texas Cancer Plan as necessary.

(1) The intent of the Texas Cancer Plan is to reduce the cancer burden across the state and improve the lives of Texans by providing a coordinated, prioritized, and actionable framework that will help guide statewide efforts to fight the human and economic burden of cancer in Texas.

(2) Activities undertaken by the Institute to monitor the Texas Cancer Plan will be described in the Annual Public Report required by Texas Health and Safety Code Section 102.052.

(3) The Institute will periodically update the Texas Cancer Plan by issuing a revised version of the Texas Cancer Plan every seven (7) years, unless a different timeline for a revised version of the Texas Cancer Plan is approved by a simple majority of the Oversight Committee.

(4) The Institute may solicit input from public or private institutions, government organizations, non-profit organizations, other public entities, private companies, and individuals affected by cancer to assist the Institute in monitoring, implementing, and revising the Texas Cancer Plan.

(5) The most recent version of the Texas Cancer Plan shall be posted on the Institute's Internet website. A hard copy of the Texas Cancer Plan may be requested by contacting the Institute directly.

RULE §701.13 **Advisory Committees**

The Oversight Committee may rely upon Advisory Committees of experts to advise the Oversight Committee on issues related to cancer and to inform Institute policies and procedures.

(1) The University Advisory Committee shall advise the Oversight Committee and Review Councils regarding the role of higher education in Cancer Research. The committee's membership is composed of the members specified by Section 102.154, *Health and Safety Code*.

(2) The Oversight Committee shall create an ad hoc Advisory Committee to address childhood cancers.

(3) The Oversight Committee may create additional ad hoc Advisory Committees to advise the Oversight Committee on issues related to cancer.

(4) The presiding officer of the Oversight Committee appoints experts, including practitioners and patient advocates, to serve as ad hoc Advisory Committee members, subject to approval by the Oversight Committee, for terms of service determined by the Oversight Committee.

(A) When used in this Section, the term "patient advocates" is not intended to and does not have the meaning ascribed to the same term defined by Section 701.3 of this Chapter. The term, when used herein, applies more generally to the broad category of individuals that advocate, either personally or professionally, on behalf of a group of individuals affected by cancer. A patient advocate serving on an ad hoc Advisory Committee does not undergo the selection process or receive science-based training required by Patient Advocates under Chapter 703, Section 703.5.

(B) An Institute Employee, Oversight Committee Member, or Scientific Research and Prevention Programs Committee Member may not be a member of any Advisory Committee of the Institute.

(C) Grant Applicants and Grant Recipients may be Advisory Committee members.

(5) The Institute may reimburse Advisory Committee members for reasonable and necessary expenses incurred to attend meetings or perform other official duties authorized by the presiding officer of the Oversight Committee.

(6) Each Advisory Committee shall create a committee charter for approval by the Oversight Committee that delineates the role of the Advisory Committee and expected activities.

(7) The Oversight Committee shall establish a process for each Advisory Committee to report no less than annually to the Oversight Committee regarding the activities of the Advisory Committee.

(8) A list of the Institute's Advisory Committees and the reports presented to the Oversight Committee by each Advisory Committee shall be maintained on the Institute's Internet website.

RULE § 701.15 Scientific Research and Prevention Programs Committee Honoraria Policy

The Institute recruits high level, highly respected, well established members of the Cancer Research, Product Development, or Cancer Prevention communities for appointments to Scientific Research and Prevention Programs Committees to conduct Peer Review of Grant Applications. The Institute may pay an honorarium to a Scientific Research and Prevention Programs Committee Member, pursuant to the Institute's honoraria policy.

- (1) The honoraria policy shall be set by the Chief Executive Officer in consultation with the Oversight Committee and updated from time to time as necessary upon written notification to the Oversight Committee. Changes made to the honoraria policy must be supported by written justification.
- (2) Honoraria rates paid by the Institute must be based upon the responsibilities, hours committed, and hourly rate commensurate with the expertise and professional background of the Scientific Research and Prevention Programs Committee Members.
- (3) The honoraria policy may provide a comparison to honoraria and related compensation paid by other similar grant-making organizations to ensure that honoraria payment rates are reasonable and competitive for the value the Institute receives.
- (4) Minimum documentation requirements for honoraria payments shall be set forth in the honoraria policy.
- (5) The Institute's honoraria policy shall be publicly available.

**RULE § 701.17 Scientific Research and Prevention Programs Committee Member
Residency Policy**

(a) To minimize the potential for Conflicts of Interest in the Peer Review of Grant Applications, the Institute recruits individuals who live and work outside of the State to serve as Scientific Research and Prevention Programs Committee Members, including Patient Advocates, unless a special need justifies using one or more individuals living or working in Texas.

(b) If an individual who lives or works in Texas is appointed to serve as a Scientific Research and Prevention Programs Committee Member, an explanation of the special need must be provided at the time the Chief Executive Officer's appointment is approved by the Oversight Committee and recorded in the minutes of the Oversight Committee meeting.

RULE §701.19 Advance Payment of Grant Award Funds

It is the Institute's policy to disburse Grant Award funds on a reimbursement basis; however, the nature and circumstances of the Grant Mechanism or a particular Grant Award may justify advance payment of funds by the Institute pursuant to the Grant Contract.

(1) The Chief Executive Officer shall seek approval from the Oversight Committee to disburse Grant Award funds by advance payment. The Chief Executive Officer's advance payment recommendation for the Grant Award must be approved by a simple majority of Oversight Committee Members present and voting. Unless specifically stated, the Oversight Committee's approval to disburse Grant Award funds by advance payment is effective for the term of the project.

(2) The Grant Contract must specify the amount, schedule, and requirements for advance payment of Grant Award funds.

(3) The Grant Recipient receiving advance payment of Grant Award funds must maintain or demonstrate the willingness and ability to maintain procedures to minimize the time elapsing between the transfer of the Grant Award funds and disbursement by the Grant Recipient.

(4) Grant Recipient must comply with all financial reporting requirements regarding use of Grant Award funds.

(5) Nothing herein creates an entitlement to advance payment of Grant Award funds; the Institute may determine in its sole discretion that circumstances justify limiting the amount of Grant Award funds eligible for advance payment, may restrict the period that advance payment of Grant Award funds will be made, or may revert to payment on a reimbursement-basis.

RULE §701.21 Preference for Texas Suppliers for Purchases Made by Grant Recipients

It is the policy of the Institute to encourage the purchase of goods and services required for the Grant Award from suppliers in the State to the extent reasonably possible. A Grant Recipient shall undertake good faith efforts to purchase from suppliers in the State at least fifty percent (50%) of the goods and services purchased with Grant Award funds.

(1) A Grant Recipient must use good faith efforts to purchase goods and services from suppliers in the State when available at a price and time comparable to products and materials purchased outside of the State.

(2) A Grant Recipient that expends more than forty percent (40%) of the Grant Award funds budgeted for a Project Year on goods and services purchased outside of the State must notify the Institute in writing and provide an explanation of the good faith efforts undertaken to purchase the goods or services from suppliers in the State, including a statement that products and materials were not available in the State at a comparable price and time. Such notification and explanation may be accomplished by completing the Historically Underutilized Business and Texas Supplier form submitted as part of the annual Grant Progress Report.

(3) The Institute may deny reimbursement or require repayment of Grant Award funds already expended if the Grant Recipient fails to provide a statement as required by subsection (2) with a reasonable explanation of the good faith efforts undertaken to purchase the goods or services from suppliers in the State of Texas.

RULE §701.23 Historically Underutilized Businesses Policy for Grant Recipients

It is the policy of the Institute to encourage the use of historically underutilized businesses (HUBs) by Grant Recipients to promote full and equal business opportunities for all businesses.

(1) A Grant Recipient is expected to undertake good faith efforts to utilize HUBs in subcontracts for construction, commodities purchases, and other services, including professional and consulting services, paid for with Grant Award funds.

(2) A Grant Recipient must report to the Institute at least annually regarding efforts undertaken by the Grant Recipient to utilize HUBs in the performance of the Grant Contract by completing the Historically Underutilized Business and Texas Supplier form submitted as part of the annual Grant Progress Report.

RULE §701.25 Electronic Signature Policy

A Grant Recipient's use of the Institute's electronic Grant Management System to create, exchange, execute, submit, and verify legally binding Grant Contract documents and Grant Award reports shall be pursuant to an agreement between the Institute and the Grant Recipient regarding the use of binding electronic signatures. Such agreement shall include at least the following minimum standards:

- (1) The Grant Recipient agrees that by entering the Authorized Signing Official's password in the electronic Grant Management System at certain specified points, the Grant Recipient electronically signs the Grant Contract document or related form. The Grant Recipient further agrees that the electronic signature is the legal equivalent of the Authorized Signing Official's manual signature.
- (2) The Institute may rely upon the electronic signature rendered by entering the Authorized Signing Official's password as evidence that the Grant Recipient consents to be legally bound by the terms and conditions of the Grant Contract or related form as if the document was manually signed.
- (3) The Grant Recipient shall provide prompt written notification to the Institute of any changes regarding the status or authority of the individual(s) designated by the Grant Recipient to be the Grant Recipient's Authorized Signing Official. The notice must be provided to an individual designated by the Institute.

RULE §701.27 Publicly Available Institute Reports and Records

To promote transparency in its activities, the Institute maintains the information described below and makes such information publicly available through the Institute's Internet website or upon request.

- (1) The Texas Cancer Plan;
- (2) The Institute's Annual Public Report;
- (3) The Conflict of Interest information described below for the previous 12 months:
 - (A) A list of disclosed Conflicts of Interest requiring recusal.
 - (B) Any unreported Conflicts of Interest confirmed by an Institute investigation and actions taken by the Institute regarding same.
 - (C) Any Conflict of Interest waivers granted.
- (4) An annual report of political contributions exceeding \$1,000 made to candidates for state or federal office by Oversight Committee Members for the five years preceding the Member's appointment and each year after the Member's appointment until the Member's term expires;
- (5) The annual Grant Program priorities set by the Oversight Committee;
- (6) Oversight Committee Bylaws;
- (7) Code of Conduct and Ethics;
- (8) A list, separated by Grant Program and Peer Review Panel, of the Scientific Research and Prevention Programs Committee Members provisionally appointed or approved by the Oversight Committee;
- (9) The Institute's honoraria policy for Scientific Research and Prevention Programs Committee Members;
- (10) The supporting documentation regarding the Institute's implementation of its Conflict of Interest policy and actions taken to exclude a conflicted Oversight Committee Member, Program Integration Committee Member, Scientific Research and Prevention Programs Committee Member or Institute Employee from participating in the review, discussion, deliberation and vote on the Grant Application.
- (11) The Chief Executive Officer's annual report to the Oversight Committee on the progress and continued merit of each research Program funded by the Institute;

(12) Grant Applicant information:

(A) Name and address;

(B) Amount of funding applied for;

(C) Type of cancer addressed by the Grant Application; and

(D) A high-level summary of work proposed to be funded by the Grant Award.

(13) Information related to Grant Awards, including the name of the Grant Recipient, the amount of the Grant Award approved by the Oversight Committee, the type of cancer addressed, and a high-level summary of the work funded by the Grant Award.

(14) Records of a nonprofit organization established to provide support to the Institute;

(15) Information related to any gift, grant, or other consideration provided to the Institute, Institute Employee, or a member of an Institute committee. Such information shall state:

(A) Donor's name;

(B) Amount of donation; and

(C) Date of donation.

(16) A list of the Institute's Advisory Committees and the reports presented to the Oversight Committee by each Advisory Committee.

(17) The Institute's approved internal audit annual report and the internal audit plan posted no later than thirty (30) after approval by the Oversight Committee, or the Chief Executive Officer if the Oversight Committee is unable to meet.

(18) A detailed summary of the weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit plan or annual report and a summary of the action taken by the Institute to the address concerns, if any, that are raised by the audit plan or annual report.

(19) Information regarding staff compensation in compliance with Section 659.026, *Government Code*.

RULE §701.29 Third-Party Information Held by the Institute

(a) In order to protect the actual or potential value of information submitted to the Institute by a Grant Applicant or a Grant Recipient, the Institute shall undertake reasonable efforts to protect Third-Party Information as described herein from unauthorized public disclosure, consistent with the requirements of Chapter 552, *Government Code*.

(b) With the exception of information set forth in section (f), the Institute shall consider the following material confidential:

(1) Information that relates to a Grant Applicant's or Grant Recipient's product, device, or process that has the potential for being sold, traded, or licensed for a fee, including the application or use of such product, device, or process;

(2) All technological or scientific information developed in whole or in part by the Grant Applicant or Grant Recipient that has the potential for being sold, traded, or licensed for a fee;

(3) All information that relates to the plans, specifications, blueprints, and designs, including related proprietary information, of a scientific research and development facility;

(4) Written comments made by one or more Scientific Research and Prevention Programs Committee Members that reveals, directly or indirectly, information relating to the Grant Applicant's or Grant Recipient's product, device, or process that has the potential for being sold, traded, or licensed for a fee, including the application or use of such product, device, or process; and

(5) Information included in the business operations and management due diligence and intellectual property reviews conducted for the Grant Review Process that reveals, directly or indirectly, information relating to the Grant Applicant's or Grant Recipient's product, device, or process that has the potential for being sold, traded, or licensed for a fee.

(c) The Institute shall consider that a product, device, or process and the technological or scientific information described in the Grant Application submitted to the Institute has the potential for being sold, traded, or licensed for a fee unless the Grant Applicant informs the Institute that no economic potential exists.

(d) The confidential nature of the information submitted by the Grant Applicant or Grant Recipient is not dependent upon whether the information is patentable or capable of being registered under copyright or trademark laws.

(e) Oversight Committee Members, Institute Employees, Program Integration Committee Members, and Scientific Research and Prevention Programs Committee Members may access Third-Party Information solely for Institute purposes. All Third-Party Information in the

individual's possession must be returned to the Institute or destroyed immediately upon the Institute's request or upon the termination of individual's employment with or service to the Institute, whichever comes first. An individual given access to Third-Party Information described herein shall not:

- (1) Publicly disclose Third-Party Information for any reason unless the Institute's General Counsel determines that the disclosure is either permitted or required by law;
- (2) Use non-public Third-Party Information for the individual's own personal gain or for the gain of other parties; or
- (3) Copy Third-Party Information, for any reason, except as required to fulfill their duties for the Institute.

(e) The Institute may establish procedures to protect non-public Third-Party Information from unauthorized disclosure such as the use of non-disclosure agreements.

(f) Notwithstanding the foregoing, the following Third-Party Information is public information and shall be disclosed under Chapter 552, *Government Code*:

- (1) The Grant Applicant's name and address;
- (2) The amount of Grant Award funding applied for;
- (3) The type of cancer to be addressed under the Grant Application;
- (4) The high-level summary of the Grant Application specifically created to be publicly disclosed;
- (5) Any other Third-Party Information submitted to the Institute by a Grant Applicant or Grant Recipient if the third-party consents to the disclosure of the information; and
- (6) The records of a nonprofit organization established to provide support to the Institute.

RULE §701.31 Charges for Copies of Public Records

(a) The charge to any person requesting copies of any public record of the Institute will be:

(1) Standard paper copy--\$.10 per page.

(2) Nonstandard-size copy:

(A) Diskette: \$1.00;

(B) Magnetic tape: actual cost;

(C) Data cartridge: actual cost;

(D) Tape cartridge: actual cost;

(E) Rewritable CD (CD-RW)--\$1.00;

(F) Non-rewritable CD (CD-R)--\$1.00;

(G) Digital video disc (DVD)--\$3.00;

(H) JAZ drive--actual cost;

(I) Other electronic media--actual cost;

(J) VHS video cassette--\$2.50;

(K) Audio cassette--\$1.00;

(L) Oversize paper copy (e.g.: 11 inches by 17 inches, greenbar, bluebar, not including maps and photographs using specialty paper)--\$.50 per page;

(M) Specialty paper (e.g.: Mylar, blueprint, blueline, map, photographic)--actual cost.

(3) Labor charge:

(A) For programming--\$28.50 per hour;

(B) For locating, compiling, and reproducing--\$15 per hour.

(4) Overhead charge-- 20% of labor charge.

(5) Microfiche or microfilm charge:

(A) Paper copy--\$.10 per page;

(B) Fiche or film copy--Actual cost.

(6) Remote document retrieval charge--Actual cost.

(7) Computer resource charge:

(A) Mainframe--\$10 per CPU minute;

(B) Midsize--\$1.50 per CPU minute;

(C) Client/Server system--\$2.20 per clock hour;

(D) PC or LAN--\$1.00 per clock hour.

(8) Miscellaneous supplies--Actual cost.

(9) Postage and shipping charge--Actual cost.

(10) Photographs--Actual cost.

(11) Maps--Actual cost.

(12) Other costs--Actual cost.

(13) Outsourced/Contracted Services--Actual cost for the copy.

(b) The Institute may reduce or waive these charges at the discretion of the Chief Executive Officer if there is a public benefit.

(c) No Sales Tax shall be applied to copies of public information.

RULE § 701.33 Negotiation and Mediation of Certain Breach of Contract Claims

- (a) In accordance with Government Code, Section 2260.052(c), the Institute adopts herein by reference the model rules provided by the Office of the Attorney General relating to procedures for the negotiation and mediation of certain contract claims asserted by contractors against the Institute.
- (b) The procedures, as adopted, are exclusive and required prerequisites to suit against the Institute under the Civil Practice & Remedies Code, Chapter 107, and the Government Code, Chapter 2260.
- (c) Nothing herein waives the Institute's sovereign immunity to suit or liability.
- (d) Unless specifically provided for by the Grant Contract, this rule does not apply to Grant Contracts. The Grant Contract shall specify the process and procedures for terminating a Grant Award, as well as any associated remedy.

**CHAPTER 702 - INSTITUTE STANDARDS ON ETHICS AND
CONFLICTS, INCLUDING ACCEPTANCE OF GIFTS AND DONATIONS
TO THE INSTITUTE**

RULE §702.1 Authority

This chapter is adopted pursuant to and in satisfaction of the provisions of Texas Government Code Annotated, Chapters 572 and 2255, Texas Health and Safety Code, Chapter 102, and other relevant statutes.

RULE §702.3 Definitions

The words and terms used in this chapter shall have the meanings provided in Chapter 701 Section 701.3 (relating to Definitions), unless the context clearly indicates otherwise.

RULE §702.5 Intent

It is the intent of the Institute that the Institute's Grant Review process provide Grant Applicants a fair and unbiased merit-based assessment free from conflicts of interest, impropriety and self-dealing. To implement this policy, this chapter provides standards of conduct and conflict of interest disclosure requirements to be observed by those individuals that are a part of the Grant Review Process and the execution of Grant Contracts. Individuals subject to this chapter include Oversight Committee Members, Program Integration Committee Members, Scientific Research and Prevention Programs Committee Members, and Institute Employees. Independent contractors, such as outside legal counsel, grant management system contractors, and subject matter experts, shall be subject to applicable provisions of this chapter to the extent that the individuals are performing duties associated with Grant Applications under consideration for Grant Awards.

RULE §702.7 Acceptance of Gifts and Donations by the Institute

(a) As authorized by Texas Health and Safety Code Section 102.054, the Institute may solicit and accept gifts from any source to support the operations of the Institute and to further its purposes; except that the Institute may not supplement the salary of any Institute Employee with a gift or grant received by the Institute.

(b) An Oversight Committee Member or an Institute Employee shall not authorize a donor to use the property of the Institute unless the property is used in accordance with a contract between the Institute and the donor, the contract is found by the Institute to serve a public purpose, the contract contains provisions to ensure the public purpose continues, and the Institute is reasonably compensated for the use of the property.

(c) Procedure for acceptance of gifts.

(1) Gifts to the Institute may be designated for one of the following categories:

(A) Unrestricted General Support;

(B) Restricted Programmatic Support;

(C) Endowed and Restricted Funds; or

(D) Other (includes gifts of real or personal property).

(2) Gifts of ten thousand dollars (\$10,000) or less may be accepted on behalf of the Institute by the Chief Executive Officer.

(3) The Executive Committee of the Oversight Committee may accept gifts of cash, stock, bonds, or personal property with a value in excess of ten thousand dollars (\$10,000) but less than one million dollars (\$1,000,000) on behalf of the Institute. If one or more Executive Committee members do not agree with the decision to accept the gift on behalf of the Institute, the decision to accept the gift will be made by a majority vote of the Oversight Committee.

(4) Acceptance of gifts made to the Institute of cash, stock, bonds, or personal property with a value in excess of one million dollars, gifts of real property regardless of value, and all other gifts not herein described shall be approved by a majority vote of the Oversight Committee. To assist in its decision, a report shall be created by the Chief Executive Officer that includes the following information:

(A) Name and biographical data regarding the individual or organization making the gift;

(B) A description of the gift;

(C) A list of conditions or requirements to be imposed on the Institute as a result of accepting the gift;

(D) If one of the conditions is naming, then include a description of the object to be named and whether there is a time limit on continuing the name;

(E) If the gift is real property, an evaluation of the gift by the General Land Office;

(F) If the gift is stock or other investments, a description of how they will be sold and the expected net proceeds; and

(G) A description of how the gift will be used.

(5) All funds received from donations to the Institute will be deposited to the state treasury and used for the purpose specified by the donor or for general Institute programs when no purpose is specified.

(d) The Institute encourages the offer of gifts of additional revenue and real and personal property through naming.

(1) Naming can be given to both real objects and inanimate objects, such as Grant Awards.

(2) The Oversight Committee will consider a request for naming in connection with a gift of real or personal property of substantial value to the Institute and its programs. In determining whether a gift has substantial value, the Oversight Committee will evaluate the following factors:

(A) The size of the real or personal property in relation to other fund sources--including bonds--available at the same time and consideration of whether the donation will make a material contribution to the Institute's goals and programs that otherwise would not be made;

(B) Availability of the real or personal property; and

(C) The degree of flexibility and discretion the Institute will have in the use of the real or personal property.

(3) The Oversight Committee must approve the recommendation to name an object or program by a majority vote of its members.

(e) The Oversight Committee may refuse a gift to the Institute for any reason, including:

(1) The gift requires an initial and/or on-going expenditure that will likely equal or exceed the value of the gift.

(2) The gift is from an institution, entity, or organization, or a director, officer, or an executive of an institution, entity or organization that has applied for funding from the Institute or currently receives funding from the Institute or the gift is from a Senior Member or Key Personnel of the research or prevention program team listed on a Grant Application or Grant Award.

(3) The Institute may return a gift made by an institution, entity, organization, or individual that was otherwise eligible to make the donation at the time that the gift was accepted by the Institute in the event that the donor subsequently submits a Grant Application for funding from the Institute within the fiscal year of the donation.

(4) For purposes of this section, the limitation on gifts does not apply to a donation made as the result of the final bequeathal.

(f) The Institute shall report information pertaining to gifts, grants, or other consideration provided to the Institute, an Institute Employee, or a member of an Institute committee, subject to the requirements below.

(1) The information shall be posted on the Institute's Internet website.

(2) The information to be posted shall include the donor's name, the date of the donor's donation, and the amount of the donor's donation.

(3) The reporting requirement applies to all gifts, grants, or other consideration provided to the Institute except that individual conference registration fees paid to CPRIT by conference attendees shall not be treated as consideration for purposes of the reporting requirement. The total amount received for conference registration fees may be reported.

(4) The reporting requirement applies to all gifts, grants, or other consideration given to a Oversight Committee Member, Institute Employee, or Program Integration Committee Member except that the following items are not considered gifts, grants or consideration subject to the reporting requirement:

(A) Books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of an Oversight Committee Member, Institute Employee, or Program Integration Committee Member and that are accepted by the individual on behalf of Institute for use in performing the individual's job duties;

(B) Items or consideration of any value given to the Oversight Committee Member, Institute Employee, or Program Integration Committee Member by a Relative;

(C) Items or consideration of any value given to the Oversight Committee Member, Institute Employee, or Program Integration Committee Member by a personal friend so long as:

(i) The item or consideration is given based solely on an existing personal relationship;

(ii) The personal friend or a Relative of the personal friend is not an employee of an entity receiving or applying to receive money from the Institute; and

(iii) The individual subject to this provision has no reason to believe that the item or consideration is being offered through an intermediary in an attempt to evade reporting requirements.

(D) Items of nominal intrinsic value less than \$50, such as modest items of food and refreshment on infrequent occasions, shared ground transportation in non-luxury vehicles, and unsolicited advertising or promotional material such as plaques, certificates, trophies, paperweights, calendars, note pads, and pencils, but excluding cash or negotiable instruments.

(5) The reporting requirement applies only to the gifts, grants, or other consideration given to a Scientific Research and Prevention Programs Committee Member by a Grant Applicant or Grant Recipient during the period that the Member is appointed except that that the following items are not considered gifts, grants or consideration subject to the reporting requirement:

(A) Books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of the Scientific Research and Prevention Programs Committee Member and that are accepted by the individual for use in performing the individual's job duties;

(B) Items of nominal intrinsic value less than \$50, such as modest items of food and refreshment on infrequent occasions, shared ground transportation in non-luxury vehicles, and unsolicited advertising or promotional material such as plaques, certificates, trophies, paperweights, calendars, note pads, and pencils, but excluding cash or negotiable instruments.

(6) The reporting requirement applies to a member of an Advisory Committee of the Institute only to the extent that the individual participates in the Grant Review Process.

(A) If the individual participates in the Grant Review Process, then the individual must report gifts, grants, or other consideration given to the Advisory Committee member by a Grant Applicant or Grant Recipient during the period that the Advisory Committee member participates in the Grant Review Process except that that the following items are not considered gifts, grants or consideration subject to the reporting requirement:

(1) Books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of the Advisory Committee member and that are accepted by the individual for use in performing the individual's job duties;

(2) Items of nominal intrinsic value less than \$50, such as modest items of food and refreshment on infrequent occasions, shared ground transportation in non-luxury vehicles, and unsolicited advertising or promotional material such as plaques, certificates, trophies, paperweights, calendars, note pads, and pencils, but excluding cash or negotiable instruments.

(B) For purposes of this subsection, participation in the Grant Review Process by an Advisory Committee member does not include submitting a Grant Application or receiving a Grant Award.

RULE §702.9 Code of Conduct and Ethics for Oversight Committee Members, and Institute Employees, and Program Integration Committee Members

(a) All Oversight Committee Members, Program Integration Committee Members, and Institute Employees shall avoid acts which are improper or give the appearance of impropriety in the disposition of state funds.

(b) The Oversight Committee shall adopt a Code of Conduct and Ethics to provide guidance related to the ethical conduct required of Oversight Committee Members, Program Integration Committee Members, and Institute Employees. The Code of Conduct and Ethics shall be distributed to each new Oversight Committee Member, Program Integration Committee Member, and Institute Employee not later than the third business day after the date that the person begins employment with or service to the Institute.

(c) The Code of Conduct and Ethics shall include at least the following requirements and prohibitions. Nothing herein prevents the Oversight Committee from adopting stricter standards:

(1) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not accept or solicit any gift, favor, or service that could reasonably influence him or her in the discharge of official duties or that he or she knows or should know is being offered with the intent to influence him or her with the intent to influence the member or employee's official conduct.

(2) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not accept employment or engage in any business or professional activity that would reasonably require or induce that person to disclose confidential information acquired by reason of the member or employee's official position.

(3) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not accept other employment or compensation that could reasonably impair his or her independent judgment in the performance of the member or employee's official duties.

(4) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not make personal investments or have a financial interest that could reasonably create a substantial conflict between his or her private interest and the member or employee's official duties-

(5) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not intentionally or knowingly solicit, accept, or agree to accept any benefit for exercising his or

her official powers or performing the member or employee's official duties in favor of another.

(6) An Oversight Committee Member, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not lease, directly or indirectly, any property, capital equipment, employee or service to a Grant Recipient.

(7) A member of the Oversight Committee, Institute Employee, or Program Integration Committee Member, or the spouse of an individual governed by this provision shall not submit a Grant Application to the Institute.

(8) A member of the Oversight Committee, the member's spouse, or an Institute Employee shall not be employed by or participate in the management of a business entity or other organization receiving money from the Institute.

(9) A member of the Oversight Committee or the member's spouse shall not own or control, directly or indirectly, an interest in a business or entity or other organization receiving money from the Institute.

(10) A member of the Oversight Committee or the member's spouse shall not use or receive a substantial amount of tangible goods, services, or money from the Institute other than reimbursement authorized for Oversight Committee Members; attendance; or expenses.

(11) A member of the Oversight Committee, Institute Employee, Program Integration Committee Member, or the spouse of an individual governed by this provision shall not serve on the Grant Recipient's board of directors or similar committee that exercises governing powers over the Grant Recipient. This prohibition also applies to serving on the board of directors or similar committee of a non-profit foundation established to benefit the Grant Recipient.

(12) A member of the Oversight Committee, Institute Employee, Program Integration Committee Member, or the spouse of an individual governed by this provision shall not use non-public Third-Party Information, or knowledge of non-public decisions related to Grant Applicants, received by virtue of the individual's employment or official duties associated with the Institute to make an investment or take some other action to realize a personal financial benefit.

(13) A member of the Oversight Committee, Institute Employee, or a Program Integration Committee Member who is a member of a professional organization shall comply with any standards of conduct adopted by the organizations of which he or she is a member.

(14) A member of the Oversight Committee, Institute Employee, or a Program Integration Committee Member shall be honest in the exercise of all duties and may not take actions that will discredit the Institute.

(15) A member of the Oversight Committee or an Institute Employee shall not have an office in a facility owned by an entity receiving or applying to receive money from the Institute.

(16) An Oversight Committee Member, Institute Employee, or Program Integration Committee Member shall report to the Institute's Chief Executive Officer any gift, grant, or consideration received by the individual as soon as possible, but no later than thirty (30) days after receipt of the gift, grant or consideration. The individual shall provide the name of the donor, the date of receipt, and amount of the gift, grant, or consideration.

(17) An Oversight Committee Member or Institute Employee may not solicit, agree to accept, or accept an honorarium in consideration for services the Oversight Committee Member or Institute Employee would not have been asked to provide but for the person's official position.

(18) An Oversight Committee Member and the Chief Executive Officer shall not make any communication to or appearance before an Institute officer or employee before the second anniversary of the date the Oversight Committee Member or Chief Executive Officer ceased to be a Oversight Committee Member or Chief Executive Officer if the communication or appearance is made:

(A) with the intent to influence; and

(B) on behalf of any person in connection with any matter on which the person seeks official action.

(19) An Oversight Committee Member or Institute Employee who ceases service or employment with the Institute may not represent any person or receive compensation for services rendered on behalf of any person regarding a particular matter in which the former Oversight Committee Member or Institute Employee participated during the period of state service or employment, either through personal involvement or because the issue was a matter within the Oversight Committee Member's or Institute Employee's official responsibility.

(A) This subsection applies to an Institute Employee who is compensated, as of the last date of state employment, at or above the amount prescribed by the General Appropriations Act for step 1, salary group 17, of the position classification salary schedule, including an employee who is exempt from the state's position classification plan.

(B) This subsection does not apply to a rulemaking proceeding that was concluded before the Oversight Committee Member's or Institute Employee's service or employment ceased.

(C) For purposes of this subsection, "participated" means to have taken action as an Oversight Committee member or Institute Employee through decision, approval, disapproval, recommendation, giving advice, investigation or similar matter.

(D) For purposes of this subsection, "particular matter" means a specific investigation, application, request for ruling or determination, rulemaking proceeding, contract, claim, charge, accusation, or judicial or other proceeding.

(d) The Code of Conduct and Ethics shall include information about reporting an actual or potential violation of the standards adopted by the Oversight Committee.

(e) Any reports due under Texas Government Code Chapter 572.021 shall be simultaneously filed with the Institute.

RULE §702.11 Conflicts of Interest Requiring Recusal

(a) For purposes of this chapter, a Conflict of Interest exists when an individual subject to this rule has an interest in the outcome of a Grant Application submitted by an entity receiving or applying to receive money from the Institute such that the individual is in a position to gain financially, professionally, or personally from either a positive or negative evaluation of the Grant Application. Individuals subject to this rule are:

(1) Oversight Committee Members;

(2) Institute Employees;

(3) Scientific Research and Prevention Programs Committee Members;

(4) Program Integration Committee Members; and

(5) Independent Contractors that perform services associated with the Grant Review Process on behalf of the Institute, such as facilitating grant review activities, evaluating the intellectual property held by or licensed to a Grant Applicant, or performing a business management due diligence review.

(b) Except under exceptional circumstances as provided in §702.17 of this chapter (relating to Exceptional Circumstances Requiring Participation), an individual who has a financial, professional, or personal interest, as set forth herein, in an entity receiving or applying to receive money from the Institute shall recuse himself or herself and may not participate in the review, discussion, deliberation, or vote related to the entity.

(c) A financial Conflict of Interest exists if the individual subject to this rule or a Relative of the individual subject to this rule:

(1) Owns or controls, directly or indirectly, an ownership interest in an entity receiving or applying to receive money from the Institute or in a foundation or similar organization affiliated with the entity.

(A) Interests subject to this provision include sharing in profits, proceeds, or capital gains. Examples of ownership or control, include but are not limited to owning shares, stock, or otherwise, and are not dependent on whether voting rights are included.

(B) It is not a financial Conflict of Interest if the ownership interest is limited to shares owned via an investment in a publicly traded mutual fund or similar investment vehicle so long as the individual subject to this rule does not exercise any discretion or control regarding the investment of the assets of the fund or other investment vehicle.

(2) Could reasonably foresee that an action taken by the Scientific Research and Prevention Programs Committee, the Program Integration Committee, the Institute, or its Oversight

Committee related to an entity receiving or applying to receive money from the Institute could result in a financial benefit to the individual.

(3) Has received a financial benefit from the Grant Applicant unrelated to the Grant Application of more than \$5,000 within the past twelve months. This total includes fees, stock and other benefits. It also includes current stock holdings, equity interest, intellectual property or real property interest, but does not include diversified mutual funds or similar investment vehicle in which the person does not exercise any discretion or control regarding the investment of the assets of the fund or other investment vehicle.

(d) For purposes of this rule, a professional Conflict of Interest exists if the individual subject to this rule or a Relative of the individual subject to this rule:

(1) Is a member of the board of directors, other governing board or any committee of an entity or of a foundation or similar organization affiliated with an entity receiving or applying to receive money from the Institute during the same Grant Review Cycle;

(2) Serves as an elected or appointed officer of an entity receiving or applying to receive money from the Institute or of a foundation or similar organization affiliated with the entity;

(3) Is an employee of or is negotiating future employment with an entity receiving or applying to receive money from the Institute or a foundation or similar organization affiliated with the entity;

(4) Represents in business or law an entity receiving or applying to receive money from the Institute or a foundation or similar organization affiliated with the entity;

(5) Is a colleague, scientific mentor, or student of a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application, or is conducting or has conducted research or other significant professional activities with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application within three years of the date of the review;

(6) Is a student, postdoctoral associate, or part of a laboratory research group for a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application or has been within the past six years;

(7) Is engaged or is actively planning to be engaged in collaboration with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application;
or

(8) Has long-standing scientific differences or disagreements with a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application that are known to the professional community and could be perceived as affecting objectivity.

(e) For purposes of this rule, a personal Conflict of Interest exists if a Senior Member or Key Personnel of the research or prevention program team listed on the Grant Application or an applicant is a Relative or close personal friend of an individual subject to this rule.

(f) Nothing herein shall prevent the Oversight Committee from adopting more stringent standards with regard to prohibited conflicts of interest.

(g) The General Counsel and Chief Compliance Officer may provide guidance to individuals subject to this section on what interests would constitute a Conflict of Interest or an appearance of a Conflict of Interest.

RULE §702.13 Disclosure of Conflict of Interest and Recusal from Review

(a) If an Oversight Committee Member or a Program Integration Committee Member has a Conflict of Interest as described in this chapter with respect to an entity or Grant Application that comes before the individual for review or other action, the Member shall:

(1) Provide written notice of the Conflict of Interest to the Chief Executive Officer and the presiding officer of the Oversight Committee or the next ranking member of the Oversight Committee if the presiding officer has the Conflict of Interest;

(2) Disclose the Conflict of Interest in an open meeting of the Oversight Committee; and

(3) Recuse himself or herself from participation in the review, discussion, deliberation and vote on the entity or Grant Application, including access to information regarding the matter to be decided, unless a waiver has been granted pursuant to Section 702.15.

(b) If a Scientific Research and Prevention Programs Committee Member has a Conflict of Interest as described in this chapter with respect to a Grant Application that comes before the individual for review or other action, the member shall:

(1) Provide written notice of the Conflict of Interest to the Chief Executive Officer; and

(2) Recuse himself or herself from any participation in the review, discussion, scoring, deliberation and vote on the Grant Application, including access to information regarding the matter to be decided, unless a waiver has been granted pursuant to Section 702.15.

(c) Some Conflicts of Interest are such that the existence of a conflict with a Grant Applicant applying for a Grant Mechanism raises the presumption that the conflict may affect the individual's impartial review of other Grant Applications pursuant to the same Grant Mechanism in the Grant Review Cycle. The Institute has determined that the existence of one or more of the following Conflicts of Interest for an Oversight Committee Member, Scientific Research and Prevention Programs Committee Member, Program Integration Committee Member, Institute employee, Independent Contractor or a Relative of an individual subject to this rule shall require recusal of the individual from participating in the review, discussion, scoring, deliberation and vote on all Grant Applications competing for the same Grant Mechanism in the entire Grant Review Cycle, unless a waiver has been granted pursuant to Section 702.15:

(1) The individual subject to this provision is an employee of a Grant Applicant;

(2) The individual subject to this provision is actively seeking employment with a Grant Applicant. For the purposes of this subsection, "actively seeking employment" includes activities such as submission of an employment application, resume, curriculum vitae, or similar document and/or interviewing with one or more representatives from the organization with no final action taken by the organization regarding consideration of such employment;

(3) The individual subject to this provision serves on the board of directors or as an elected or appointed officer of a Grant Applicant or a foundation or similar organization affiliated with the Grant Applicant; or

(4) The individual subject to this provision owns or controls, directly or indirectly, an ownership interest in a Grant Applicant or a foundation or similar organization affiliated with the Grant Applicant. Interests subject to this provision include sharing in profits, proceeds, or capital gains. Examples of ownership or control, include but are not limited to owning shares, stock, or otherwise, and are not dependent on whether voting rights are included.

(d) If an Institute Employee or independent contractor involved in the Grant Review Process has a Conflict of Interest as described in this chapter with respect to a Grant Application that comes before the individual for review or other action, the Institute Employee or independent contractor shall:

(1) Provide written notice to the Chief Executive Officer of the Conflict of Interest; and

(2) Recuse himself or herself from participation in the review of the Grant Application and be prevented from accessing information regarding the matter to be decided, unless a waiver has been granted pursuant to Section 702.15.

(e) The Institute shall retain supporting documentation regarding the implementation of its Conflict of Interest policy and actions taken to exclude a conflicted Oversight Committee Member, Program Integration Committee Member, Scientific Research and Prevention Programs Committee Member or Institute Employee from participating in the review, discussion, deliberation and vote on the Grant Application.

(1) The supporting documentation retained by the Institute may be stored by the Institute's electronic Grant Management System.

(2) For purposes of this rule, "supporting documentation" may include Conflict of Interest agreements, Conflict of Interest disclosure forms, action taken to address a previously unreported Conflict of Interest after its existence is determined, approved waivers, sign-out sheets, independent third party observation reports, post-review certifications and Oversight Committee meeting minutes.

(3) All supporting documentation shall be publicly available, except that information included in the supporting documentation that is otherwise protected by Chapter 552, *Government Code* may be redacted.

(f) Individuals subject to this chapter are encouraged to self-report. Any individual who self-reports a potential Conflict of Interest or any impropriety or self-dealing, and who fully complies with any recommendations of the General Counsel and recusal from any discussion, voting, deliberation or access to information regarding the matter, shall be considered by the Institute to

be in compliance with this chapter. The individual is still subject to the operation of other laws, rules, requirements or prohibitions. Substantial compliance with the procedures provided herein constitutes compliance.

(g) Intentional violations of this rule may result in the removal of the individual from further participation in the Institute's Grant Review Process.

RULE §702.15 Investigation of Unreported Conflicts of Interest Affecting the Grant Review Process

(a) An Oversight Committee Member, a Program Integration Committee Member, a Scientific Research and Prevention Programs Committee Member, or an Institute Employee who becomes aware of a potential Conflict of Interest described by Section 702.11 that has not been reported shall immediately notify the Chief Executive Officer of the potential Conflict of Interest. If the potential Conflict of Interest is held by the Chief Executive Officer, then the report shall be made directly to the presiding officer of the Oversight Committee. Upon notification, the Chief Executive Officer must notify the presiding officer of the Oversight Committee and the General Counsel of the unreported conflict.

(b) A Grant Applicant seeking an investigation regarding whether an individual subject to this chapter failed to report a Conflict of Interest described by Section 702.11 shall file a written request with the Institute's Chief Executive Officer. The Grant Applicant shall:

(1) Provide all facts regarding the alleged Conflict of Interest known to the Grant Applicant requesting the investigation; and

(2) Submit the request for investigation not later than the 30th day after the Chief Executive Officer presents final funding recommendations for the affected Grant Review Cycle to the Oversight Committee. Nothing herein prohibits the Chief Executive Officer from initiating an investigation if the Grant Applicant fails to submit the request by the deadline set herein, so long as the Grant Applicant shows good cause for failing to meet the deadline.

(c) On notification of an alleged Conflict of Interest under subsection (a) or (b), the General Counsel shall:

(1) Investigate the matter; and

(2) Provide an opinion to the Chief Executive Officer and presiding officer of the Oversight Committee. If the alleged conflict is held by the presiding officer, then the opinion shall be provided to the next ranking member of the Oversight Committee who has no conflict. The opinion shall include:

(A) A statement of the facts giving rise to the alleged conflict;

(B) A determination of whether a Conflict of Interest, another impropriety, or self-dealing exists; and

(C) If the opinion finds that a Conflict of Interest or another impropriety or self-dealing exists, then recommendations for any appropriate course of action.

(d) After receiving the General Counsel's opinion and consulting with the presiding officer (or, if appropriate, the next highest ranking Oversight Committee Member), the Chief Executive

Officer shall take immediate actions regarding the recusal of the individual from any discussion of or access to information regarding the matter at issue. If the alleged Conflict of Interest is held by the Chief Executive Officer, the presiding officer of Oversight Committee shall take actions regarding recusal.

(e) A determination regarding the existence of a Conflict of Interest involving an individual subject to this chapter shall be made by the Chief Executive Officer, or by the presiding officer of the Oversight Committee if the alleged Conflict of Interest is held by the Chief Executive Officer, and reported to the Oversight Committee. The determination will be considered final unless three or more Oversight Committee Members request that the issue be added to the agenda of the Oversight Committee. The determination must include actions to be taken, if any, to address the Conflict of Interest, impropriety, or self-dealing, including:

(1) Reconsideration of the Grant Application; or

(2) Referral of the Grant Application to a different Scientific Research and Prevention Programs Committee for review.

(f) The Chief Executive Officer or, if applicable, the presiding officer of the Oversight Committee must provide written notice of the final determination to the person requesting the investigation, including a description of further actions to be taken, if any.

(g) Unless specifically stated in the final determination, the validity of an action taken with regard to a Grant Application is not affected by the fact that an individual that failed to report a Conflict of Interest participated in the action.

RULE §702.17 Exceptional Circumstances Requiring Participation

In exceptional cases, as determined by a vote of the simple majority of the Oversight Committee present and voting, the participation of an Oversight Committee Member, Institute Employee, Program Integration Committee Member, independent contractor, or Scientific Research and Prevention Programs Committee Member in the Grant Review Process, the Grant Contract process, or the monitoring of the Grant Award outweighs the potential bias posed by a Conflict of Interest held by the individual and a waiver from recusal required by Section 702.13 may be granted by the Oversight Committee, unless otherwise prohibited by state or federal law.

(1) The Chief Executive Officer or an Oversight Committee Member may propose granting a waiver on behalf of the Oversight Committee Member, the Institute Employee, the Program Integration Committee Member, independent contractor, or the Scientific Research and Prevention Programs Committee Member by submitting a written statement to the presiding officer of the Oversight Committee. The statement must include:

(A) information about the Conflict of Interest, including the name and position of the person with the conflict to be waived;

(B) the exceptional circumstances justifying a waiver of one or more of the Institute's Conflict of Interest provisions;

(C) that the integrity of the Grant Review Process, the Grant Contract process, the monitoring of Grant Awards, or committee action would not be impaired by the individual's participation; and

(D) any proposed limits on certain activities to be taken by the individual.

(2) Oversight Committee and publicly reported at the Oversight Committee meeting. The waiver is granted if a majority of the Oversight Committee Members present and voting approve the waiver. The vote on a proposed waiver may take place prior to the Oversight Committee's decision regarding the Grant Applications recommended for funding.

(3) If the Conflict of Interest is one that is reasonably expected to affect more than one Grant Review Cycle or grant monitoring activities in a fiscal year, the waiver proposal may request that the waiver apply for all activities associated with the Grant Review Process, Grant Contract process, or grant monitoring process during the fiscal year.

(4) The Institute shall report annually to the Governor, the Lieutenant Governor, and the Speaker of the House of Representatives, and the standing committee of each house of the legislature with primary jurisdiction over Institute matters on all waivers granted for the past twelve months. The reporting obligation is fulfilled by including the information in the Institute's Annual Public Report required by Texas Health and Safety Code Section 102.052.

RULE §702.19 Restriction on Communication Regarding Pending Grant Application

(a) Communication regarding the substance of a pending Grant Application between the Grant Applicant and an Oversight Committee Member, a Program Integration Committee Member, or a Scientific Research and Prevention Programs Committee Member is prohibited.

(b) The prohibition on communication begins on the first day that Grant Applications for the Grant Mechanism are accepted by the Institute and extends until the Grant Applicant receives notice regarding a final decision on the Grant Application.

(1) The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted.

(2) In special circumstances, an Oversight Committee Member or a Program Integration Committee Member may respond to a question or request for more information from a Grant Applicant so long as the response is made available to all Grant Applicants.

(c) Intentional, serious, or frequent violations of this rule may result in the disqualification of the Grant Applicant from further consideration for a Grant Award.

(d) This rule is not intended to prohibit open dialogue between the public and the Chief Executive Officer, a Program Integration Committee Member, or a member of the Oversight Committee regarding the general status or nature of pending Grant Applications.

(e) The Chief Executive Officer may grant a waiver from the general prohibition on communication upon finding that the waiver is in the interest of promoting the objectives of the Institute and is not intended to give one or more Grant Applicants an unfair advantage. The waiver shall be in writing and state the reasons for the granting the waiver. The waiver shall be publicly available.

(f) A Program Integration Committee Member shall not communicate individually with one or more Oversight Committee Members about a Grant Award recommendation for a Grant Application in a pending Grant Review Cycle until such time that the Program Integration Committee has submitted the list of Grant Award Recommendations to the Oversight Committee and the Chief Executive Officer has submitted the written affidavit required by Section 703.7. Nothing herein shall prohibit the Chief Executive Officer or a Program Integration Committee Member from responding to an individual Oversight Committee Member's question or request for more information so long as the response is made available to all Oversight Committee Members.

RULE §702.21 Availability of Information

The members of the Oversight Committee shall receive training on the Texas Public Information Act and the Texas Open Meetings Act after the conclusion of each regular session of the Texas Legislature. This requirement is in addition to any statutorily required training and may be met by attending a training session during a meeting of the Oversight Committee, or via other form of in-person, video, or on-line training approved by the Attorney General.

CHAPTER 703 – GRANTS FOR CANCER RESEARCH AND PREVENTION

RULE §703.1 Purpose and Application

(a) Grant Awards from the Institute shall fund:

- (1) Research into the causes of and cures for all types of cancer in humans;
- (2) Facilities for use in research into the causes and cures for cancer;
- (3) Research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans;
- (4) Cancer Prevention and Control Programs in this state to mitigate the incidence of all types of cancer in humans;
- (5) Support for institutions of learning and advanced medical research facilities and collaborations in this state in all stages in the process of finding the causes of all types of cancer in humans and developing cures, from laboratory research to clinical trials and including programs to address the problem of access to advanced cancer treatment; and
- (6) Implementation of the Texas Cancer Plan.

(b) The Oversight Committee shall annually set priorities for each of the Institute's Grant Programs to be considered during the Institute's Grant Review Process,

- (1) The presiding officer of the Oversight Committee is responsible for establishing a process to develop annual Grant Program priorities.
- (2) The annual Grant Program priorities shall be approved by a simple majority of the Oversight Committee and posted on the Institute's Internet website.

RULE §703.2 Definitions

The words and terms, when used in this chapter, shall have the meanings provided in Chapter 701 Section 701.3 (relating to Definitions), unless the context clearly indicates otherwise.

RULE §703.3 Grant Applications

(a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.

(b) Each Request for Applications shall be publicly announced in the *Texas Register* and available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the Requests for Applications from time to time. Notice of modifications will be announced and available through the Institute's Internet website. The Request for Applications shall:

(1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute;

(2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.

(A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.

(B) When the Institute will use a preliminary evaluation process as described in Section 703.6 of this Chapter for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.

(c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:

(1) Basic research;

(2) Translational research, including proof of concept, preclinical, and Product Development activities;

(3) Clinical research;

(4) Population based research;

(5) Training;

(6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;

(7) Infrastructure, including centers, core facilities, and shared instrumentation;

(8) Implementation of the Texas Cancer Plan; and

(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

(d) An applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.

(e) The request for Grant Applications for Cancer Research projects shall seek information from Grant Applicants regarding whether the proposed project has Product Development prospects, including, but not limited to anticipated regulatory filings, commercial abstracts or business plans.

(f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.

(g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.

(1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause.

(2) The Institute shall document any deadline extension granted, including the reason for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.

(h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.

(1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.

(2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child of the following individuals:

(A) the Principal Investigator, Program Director, or Company Representative;

(B) a Senior Member or Key Personnel listed on the Grant Application;

(C) an officer or director of the Grant Applicant.

(3) Notwithstanding the foregoing, one or more donations exceeding \$500 by an employee of a Grant Applicant not described by subsection (2) shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.

(3) The certification shall be made at the time the Grant Application is submitted.

(4) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.

(5) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.

(6) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:

(A) Withdrawal of the Grant Application from further consideration;

(B) Return of the donation, if the return of the donation is possible without impairing Institute operations.

(7) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.

(i) Grant Applicants shall identify by name all sources of funding, including a capitalization table that reflects private investors, if any, contributing to the project proposed for a Grant Award. This information shall include those individuals or entities that have an investment, stock or rights in the project. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.

(j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal grant funds or if the Grant Applicant has had a grant terminated for cause within five years prior to the submission date of the Grant Application. For purposes of the provision, the term Grant Applicant includes the Senior Member and Key Personnel.

(k) The Institute may require each Grant Applicant for a Cancer Research Grant Award for Product Development to submit an application fee.

- (1) The Chief Executive Officer shall adopt a policy regarding the application fee amount.
- (2) The Institute shall use the application fee amounts to defray the Institute's costs associated with the Product Development review processes, including due diligence and intellectual property reviews, as specified in the Request for Application.

RULE §703.4 Grants Management System

The Institute may engage third-party grants management services. Such services may include the deployment and maintenance of an electronic Grants Management System to facilitate the Institute's receipt and review of Grant Applications, execution of Grant Contracts, and the ongoing monitoring and management of Grant Awards, including required Grant Recipient reports and submissions.

(1) The Institute may use the electronic Grants Management System to:

(A) Facilitate the Institute's receipt and review of Grant Applications;

(B) Maintain complete Grant Review Process records for Grant Applications undergoing Peer Review, including the final Overall Evaluation Score and Numerical Ranking Score assigned to Grant Applications during the Peer Review Process;

(C) Maintain supporting documentation regarding the implementation of the Institute's Conflict of Interest process for each Grant Review Cycle, including a list of any Conflicts of Interest requiring recusal, any unreported Conflicts of Interest confirmed by an investigation and the actions taken, any waivers, the identity of the Primary Investigator, Program Director or Company Representative and the funding sources for the Grant Award project;

(D) Expedite execution of Grant Contracts and the electronic submission of Grant Contract change requests and required Grant Award reports;

(E) Maintain complete Grant Award records, including the Grant Contract and Matching Funds certification, required Grant Award financial reports and Grant Progress Reports, and the Institute's review of those reports;

(F) Support the Institute's Grant Award compliance monitoring by tracking the due dates and submission status for required Grant Award reports; and

(G) Monitor the status of past-due required Grant Award financial reports and Grant Progress Reports.

(2) The Institute may require, as a condition of receiving a Grant Award, that the Grant Recipient use the Institute's electronic Grant Management System to exchange, execute, and verify legally binding Grant Contract documents and Grant Award reports. Such use shall be in accordance with the Institute's electronic signature policy as set forth in Chapter 701, Section 701.25 (relating to Electronic Signature Policy).

(3) The Institute shall require periodic audits of any electronic Grant Management System. Weaknesses identified by system audits must be timely addressed pursuant to a specified timeline.

RULE §703.5 Scientific Research and Prevention Programs Committees Members

(a) The Oversight Committee shall establish Scientific Research and Prevention Programs Committees for the purpose of conducting Peer Review of Grant Applications submitted to the Institute. The Chief Executive Officer, with approval by simple majority of the Oversight Committee, is responsible for appointing experts in the fields of Cancer Research, Prevention, life science Product Development, and patient advocacy to serve as Scientific Research and Prevention Programs Committee members for terms designated by the Chief Executive Officer.

(b) The Chief Executive Officer may provisionally appoint an individual as a Scientific Research and Prevention Programs Committee Member until such time that the individual can be considered for approval by the Oversight Committee. The provisional appointee may participate in the Peer Review Process prior to a vote of the Oversight Committee on the appointment so long as the appointment is considered at the next regular Oversight Committee meeting.

(c) A Scientific Research and Prevention Programs Committee Members is responsible for conducting Peer Review of the Grant Applications assigned to the individual member's Peer Review Panel.

(d) A Scientific Research and Prevention Programs Committee Member may receive an honorarium in accordance with the policy described in Chapter 701, Section 701.15 of this title (relating to the Scientific Research and Prevention Programs Committee Honoraria Policy).

(e) A member of a Scientific Research and Prevention Programs Committee is prohibited from attempting to use the committee member's official position to influence a decision to approve or award a grant or contract to the committee member's employer.

(f) A member of a Scientific Research and Prevention Programs Committee must comply with the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Health and Safety Code.

(g) The Scientific Research and Prevention Programs Committee Member shall not provide professional services for compensation exceeding \$5,000 to any Grant Recipient that was reviewed by the Scientific Research and Prevention Programs Committee Member's Peer Review Panel.

(1) The term of this restriction is for a period of one year from the effective date of the Grant Award, unless waived by a vote of the Oversight Committee.

(2) For purposes of this restriction, "professional services" do not include those services for which an honorarium is paid; however, honoraria exceeding \$5,000 paid to a Scientific Research and Prevention Programs Committee Member by a Grant Recipient while the

individual is serving as a Committee Member shall be reported within 30 days to the Institute's Chief Executive Officer.

(3) Even if a payment to a Scientific Research and Prevention Programs Committee Member is not otherwise prohibited, a Grant Recipient shall not pay a Scientific Research and Prevention Programs Committee Member with Grant Award funds.

(h) An individual that serves as a Scientific Research and Prevention Programs Committee Member may not concurrently serve on the Board of Directors or other governing board of a Grant Recipient or of a foundation or similar organization affiliated with the entity. This prohibition lasts so long as the Grant Recipient receives Grant Award funds or the Scientific Research and Prevention Programs Committee Member receives an honorarium from the Institute, whichever ends first.

(i) The Scientific Research and Prevention Programs Committee Member shall not use non-public Third-Party Information or knowledge of non-public decisions related to Grant Applicants, gained by virtue of the individual's participation in the Institute's Peer Review Process, to make an investment or take some other action resulting in a financial benefit to the individual or the individual's employer.

(j) A violation of any requirement of this section may result in the removal of the Scientific Research and Prevention Programs Committee Member from further participation in the Institute's Peer Review Process.

(k) The Institute shall provide on the Institute's Internet website a register of the individuals appointed as Scientific Research and Prevention Programs Committee Members, including provisional members. The register may list the Scientific Research and Prevention Programs Committee members by Peer Review Panel. For the purpose of identifying undisclosed Conflicts of Interest, a Grant Applicant may be notified of the Peer Review Panel to which the Grant Application has been assigned.

(l) The Chief Executive Officer shall ensure that at least one Patient Advocate is appointed to each Peer Review Panel. To be considered for a Patient Advocate appointment by the Chief Executive Officer as a Scientific Research and Prevention Programs Committee Member, an applicant must:

- (1) Represent an organization or other community of people;
- (2) Demonstrate prior community involvement or other work on behalf of cancer patients;
- (3) Possess good communication and writing skills, including the ability to analyze information and make judgments with consideration of patient impact;

(4) Express interest in and fundamental knowledge of the medical research process, including basic and translational scientific research and prevention concepts;

(5) Reside outside of the state of Texas;

(6) Have science-based training. This training requirement shall be considered fulfilled if the Patient Advocate has:

(A) attended a science-based training program from the American Association for Cancer Research Survivor-Scientist Program, American Society of Clinical Oncology Research Review Sessions for Patient Advocates, Research Advocacy Network Advocate Institute or National Breast Cancer Coalition Project LEAD no more than three years prior to appointment to the Institute's Scientific Research and Prevention Programs Committee;
or

(B) participated in at least one full cycle of grant review conducted by the Institute, National Institutes of Health, Department of Defense Congressionally Directed Medical Research Programs, Federal Drug Administration or Patient-Centered Outcomes Research Institute no more than three years prior to appointment to the Institute's Scientific Research and Prevention Programs Committee.

(m) An individual interested in a Patient Advocate appointment shall submit an application, in a format specified by the Institute that includes at least the following information:

(1) Dates of service on a peer review panel within the past three years, or dates of attendance at advocate training programs within the past 3 years as documentation of the fulfillment of the science-based training program requirement;

(2) Current resume or curriculum vitae;

(3) A letter of recommendation from a community-based organization and a personal statement on advocacy and education if the applicant has attended a training program but not yet served on a peer review panel.

RULE §703.6 Grants Review Process

(a) For all Grant Applications that are not administratively withdrawn by the Institute for noncompliance or otherwise withdrawn by the Grant Applicant, the Institute shall use a two-stage Peer Review process.

(1) The Peer Review process, as described herein, is used to identify and recommend meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control projects for Grant Award consideration by the Program Integration Committee and the Oversight Committee.

(2) Peer Review will be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, *Health and Safety Code*.

(b) The two stages of the Peer Review Process used by the Institute are:

(1) Evaluation of Grant Applications by Peer Review Panels; and

(2) Prioritization of Grant Applications by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council, as may be appropriate for the Grant Program.

(c) Except as described in subsection (e), the Peer Review Panel evaluation process encompasses the following actions, which will be consistently applied:

(1) The Institute distributes all Grant Applications submitted for a particular Grant Mechanism to one or more Peer Review Panels.

(2) The Peer Review Panel chairperson assigns each Grant Application to no less than two panel members that serve as the Primary Reviewers for the Grant Application. Assignments are made based upon the expertise and background of the Primary Reviewer in relation to the Grant Application.

(3) The Primary Reviewer is responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the Primary Reviewer's general impression of the Grant Application's merit. The Primary Reviewers' individual Overall Evaluation Scores are averaged together to produce a single initial Overall Evaluation Score for the Grant Application.

(4) The Peer Review Panel meets to discuss the Grant Applications assigned to the Peer Review Panel. If there is insufficient time to discuss all Grant Applications, the Peer Review Panel chairperson determines the Grant Applications to be discussed by the panel. The

chairperson's decision is based largely on the Grant Application's initial Overall Evaluation Score; however a Peer Review Panel member may request that a Grant Application be discussed by the Peer Review Panel.

(A) If a Grant Application is not discussed by the Peer Review Panel, then the initial Overall Evaluation Score serves as the final Overall Evaluation Score for the Grant Application. The Grant Application is not considered further during the Grant Review Cycle.

(B) If a Grant Application is discussed by the Peer Review Panel, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(i) The panel chairperson participates in the discussion but does not score Grant Applications.

(ii) A Primary Reviewer has the option to revise his or her score for the Grant Application after panel discussion or to keep the same score submitted during the initial review.

(C) If the Peer Review Panel recommends changes to the Grant Award funds amount requested by the Grant Applicant or to the goals and objectives or timeline for the proposed project, then the recommended changes and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(5) At the conclusion of the Peer Review Panel evaluation, the Peer Review Panel chairperson submits to the appropriate Review Council a list of Grant Applications discussed by the panel ranked in order by the final Overall Evaluation Score. Any changes to the Grant Award funding amount or to the project goals and objectives or timeline recommended by the Peer Review Panel shall be provided to the Review Council at that time.

(d) The Review Council's prioritization process for Grant Award recommendations encompasses the following actions, which will be consistently applied:

(1) The Review Council prioritizes the Grant Application recommendations across all the Peer Review Panels by assigning a Numerical Ranking Score to each Grant Application that was discussed by a Peer Review Panel. The Numerical Ranking Score is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(2) The Review Council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. The recommendations, listed in order by Numerical Ranking Score shall include:

(A) An explanation describing how the Grant Application meets the Review Council's standards for Grant Award funding;

(B) The final Overall Evaluation Score assigned to the Grant Application by the Peer Review Panel, including an explanation for ranking one or more Grant Applications ahead of another Grant Application with a more favorable final Overall Evaluation Score; and

(C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline.

(e) Circumstances relevant to a particular Grant Mechanism or to a Grant Review Cycle may justify changes to the dual-stage Peer Review process described in subsections (c) and (d). Peer Review process changes the Institute may implement are described below. The list is not intended to be exhaustive. Any material changes to the Peer Review process, including those listed below, shall be described in the Request for Applications or communicated to all Grant Applicants.

(1) The Institute may use a preliminary evaluation process if the volume of Grant Applications submitted pursuant to a specific Request for Applications is such that timely review may be impeded. The preliminary evaluation will be conducted after Grant Applications are assigned to Peer Review Panels but prior to the initial review described in subsection (c). The preliminary evaluation encompasses the following actions:

(A) The criteria and the specific Grant Application components used for the preliminary evaluation shall be stated in the Request for Applications;

(B) No less than two Peer Review Panel members are assigned to conduct the preliminary evaluation for a Grant Application and provide a preliminary score that conveys the general impression of the Grant Application's merit pursuant to the specified criteria; and

(C) The Peer Panel Review chairperson is responsible for determining the Grant Applications that move forward to initial review as described in subsection (c). The decision will be based upon preliminary evaluation scores. A Grant Application that does not move forward to initial review will not be considered further and the average of the preliminary evaluation scores received becomes the final Overall Evaluation Score for the Grant Application.

(2) The Institute shall assign all Grant Applications submitted for recruitment of researchers and clinicians to the Scientific Review Council.

(A) The Scientific Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the proposed recruitment.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one recruitment Grant Application is reviewed by the Scientific Review Council during the Grant Review Cycle, then the Scientific Review Council shall assign a Numerical Ranking Score to each Grant Application to convey its prioritization ranking.

(D) If the Scientific Review Council recommends a change to the Grant Award funds requested by the Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Scientific Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this Section.

(3) The Institute may assign continuation Grant Applications to the appropriate Review Council.

(A) The Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the progress and continued funding.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one continuation Grant Application is reviewed by the Review Council during the Grant Review Cycle, then the Review Council shall assign a Numerical Ranking Score to each continuation Grant Application to convey its prioritization ranking.

(D) If the Review Council recommends a change to the Grant Award funds or to the scope of work or timeline requested by the continuation Grant Application, then the

recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this Section.

(4) The Institute's Peer Review process described in subsections (c) and (d) of this Section may include the following additional process steps for Product Development of Cancer Research Grant Applications:

(A) A Grant Applicant may be invited to deliver an in-person presentation to the Peer Review Panel. The Product Development Review Council chairperson is responsible for deciding which Grant Applicants will make in-person presentations. The decision is based upon the initial Overall Evaluation Scores of the primary reviewers following a discussion with Peer Review Panel members, as well as explicit criteria published in the Request for Applications.

(i) Peer Review Panel members may submit questions to be addressed by the Grant Applicant at the in-person presentation.

(ii) A Grant Application that is not presented in-person will not be considered further. The average of the primary reviewers' initial Overall Evaluation Scores will be the final Overall Evaluation Score for the Grant Application.

(iii) Following the in-person presentation, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review conducted by third parties. The Peer Review Panel decides which Grant Applications will undergo business operations and management due diligence and intellectual property review. The decision is based upon the Grant Application's final Overall Evaluation Score, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications. A Grant Application that is not recommended for due diligence and intellectual property review will not be considered further.

(C) After receipt of the business operations and management due diligence and intellectual property reviews for a Grant Application, the Product Development Review

Council and the Primary Reviewers meet to determine whether to recommend the Grant Application for a Grant Award based upon the information set forth in the due diligence and intellectual property reviews. The Product Development Review Council may recommend changes to the Grant Award budget and goals and objectives or timeline.

(D) The Product Development Review Council assigns a Numerical Ranking Score to each Grant Application recommended for a Grant Award.

(f) Institute Employees may attend Peer Review Panel and Review Council meetings. If an Institute Employee attends a Peer Review Panel meeting or a Review Council meeting, the Institute Employee's attendance shall be recorded and the Institute Employee shall certify in writing that the Institute Employee complied with the Institute's Conflict of Interest rules. The Institute Employee's attendance at the Peer Review Panel meeting or Review Council meeting is subject to the following restrictions:

(1) Unless waived pursuant to the process described in Section 702.17, the Institute Employee shall not be present for any discussion, vote, or other action taken related to a Grant Applicant if the Institute Employee has a Conflict of Interest with that Grant Applicant; and

(2) The Institute Employee shall not participate in a discussion of the merits, vote, or other action taken related to a Grant Application, except to answer technical or administrative questions unrelated to the merits of the Grant Application and to provide input on the Institute's Grant Review Process.

(g) The Institute shall engage an independent third party to observe meetings of the Peer Review Panel and Review Council where Grant Applications are discussed.

(1) The independent third party shall serve as a neutral observer to document that the Institute's Grant Review Process is consistently followed, including observance of the Institute's established Conflict of Interest rules and that participation by Institute employees, if any, is limited to providing input on the Institute's Grant Review Process and responding to committee questions unrelated to the merits of the Grant Application. Institute Program staff shall not participate in a discussion of the merits, vote, or any other action taken related to a Grant Application.

(2) The independent third party reviewer shall issue a report to the Chief Compliance Officer specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(h) Excepting a finding of an undisclosed Conflict of Interest as set forth in Section 703.9 of this Chapter, the Review Council's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Program Integration Committee and the Oversight

Committee is final. A Grant Application not included on the prioritized list created by the Review Council shall not be considered further during the Grant Review Cycle.

(i) At the time that the Peer Review Panel or the Review Council concludes its tasks for the Grant Review Cycle, each member shall certify in writing that the member complied with the Institute's Conflict of Interest rules.

(j) The Institute shall retain a review record for a Grant Application submitted to the Institute, even if the Grant Application did not receive a Grant Award. Such records will be retained by the Institute's electronic Grant Management System. The records retained by the Institute must include the following information:

(1) The final Overall Evaluation Score and Numerical Ranking Score, if applicable, assigned to the Grant Application;

(2) The specified amount of the Grant Award funding for the Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline;

(3) The Scientific Research and Prevention Programs Committee that reviewed the Grant Application;

(4) Conflicts of Interest, if any, with the Grant Application identified by a member of the Scientific Research and Prevention Programs Committee, the Review Council, the Program Integration Committee, or the Oversight Committee; and

(5) Documentation of steps taken to recuse any member or members from the Grant Review Process because of disclosed Conflicts of Interest.

RULE §703.7 Program Integration Committee Funding Recommendation

(a) The Institute uses a Program Review process undertaken by the Institute's Program Integration Committee to identify and recommend for funding a final list of meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control Program projects that are in the best overall interest of the State.

(b) Program Review shall be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Health and Safety Code.

(c) The Program Integration Committee shall meet pursuant to a schedule established by the Chief Executive Officer, who serves as the Committee's presiding officer, to consider the prioritized list of Grant Applications submitted by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council.

(d) The Program Integration Committee shall approve by a majority vote a final list of Grant Applications recommended for Grant Awards to be provided to the Oversight Committee. In composing the final list of Grant Applications recommended for Grant Award funding, the Program Integration Committee shall:

(1) Substantially base the list upon the Grant Award recommendations submitted by the Review Council.

(2) To the extent possible, give priority for funding to Grant Applications that:

(A) Could lead to immediate or long-term medical and scientific breakthroughs in the area of Cancer Prevention or cures for cancer;

(B) Strengthen and enhance fundamental science in Cancer Research;

(C) Ensure a comprehensive coordinated approach to Cancer Research and Cancer Prevention;

(D) Are interdisciplinary or interinstitutional;

(E) Address federal or other major research sponsors' priorities in emerging scientific or Technology fields in the area of Cancer Prevention, or cures for cancer;

(F) Are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;

(G) Are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;

(H) Have a demonstrable economic development benefit to this state;

(I) Enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources;

(J) Expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and

(K) Address the goals of the Texas Cancer Plan.

(3) Document the factors considered in making the Grant Award recommendations, including any factors not listed in subsection (d)(2) of this section;

(4) Explain in writing the reasons for not recommending a Grant Application that was recommended for a Grant Award by the Review Council;

(5) Specify the amount of Grant Award funding for each Grant Application.

(A) Unless otherwise specifically stated, the Program Integration Committee adopts the changes to the Grant Award amount recommended by the Review Council.

(B) If the Program Integration Committee approves a change in the Grant Award amount that was not recommended by the Review Council, then the Grant Award amount and a written explanation for the change shall be provided.

(6) Specify changes, if any, to the Grant Application's goals and objectives or timeline recommended for a Grant Award and provide an explanation for the changes made; and

(7) Address how the funding recommendations meet the annual priorities for Cancer Prevention, Cancer Research and Product Development programs and affect the Institute's overall Grant Award portfolio established by the Oversight Committee.

(e) In the event that the Program Integration Committee's vote on the final list of Grant Award recommendations is not unanimous, then the Program Integration Committee Member or Members not voting with the majority may submit a written explanation to the Oversight Committee for the vote against the final list of Grant Award recommendations. The explanation

may include the Program Integration Committee Member or Members' recommended prioritized list of Grant Award recommendations.

(f) The Program Integration Committee's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Oversight Committee is final. A Grant Application not included on the prioritized list created by the Program Integration Committee shall not be considered further during the Grant Review Cycle, except for the following:

(1) In the event that the Program Integration Committee's vote on the final list of Grant Award recommendations is not unanimous, then, upon a motion of an Oversight Committee Member, the Oversight Committee may also consider the Grant Award recommendations submitted by the non-majority Program Integration Committee Member or Members; or

(2) A finding of an undisclosed Conflict of Interest as set forth in Section 703.9 of this Chapter.

(g) The Chief Compliance Officer shall attend and observe Program Integration Committee meetings to document compliance with Chapter 102, *Health and Safety Code* and the Institute's administrative rules.

(h) At the time that the Program Integration Committee's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the Program Integration Committee containing relevant information related to the Grant Application recommendation.

(1) Information to be provided in the Chief Executive Officer's affidavit may include:

(A) The Peer Review process for the recommended Grant Application, including:

(i) The Request for Applications applicable to the Grant Application;

(ii) The number of Grant Applications submitted in response to the Request for Applications;

(iii) The name of the Peer Review Panel reviewing the Grant Application;

(iv) Whether a preliminary review process was used by the Peer Review Panel for the Grant Mechanism in the Grant Review Cycle;

(v) An overview of the Conflict of Interest process applicable to the Grant Review Cycle noting any waivers granted; and

(vi) A list of all final Overall Evaluation Scores for all Grant Applications submitted pursuant to the same Grant Mechanism, de-identified by Grant Applicant.

(B) The final Overall Evaluation Score and Numerical Ranking Score assigned for the Grant Applications recommended during the Peer Review process; and

(C) A high-level summary of the business operations and management due diligence and intellectual property reviews, if applicable, conducted for a Cancer Research Product Development Grant Application.

(2) In the event that the Program Integration Committee's final Grant Award recommendations are not unanimous and the Program Integration Committee Member or Members in the non-majority recommend Grant Applications not included on the final list of Grant Award recommendations, then the Chief Executive Officer shall also prepare a written affidavit for each Grant Application recommended by the non-majority Program Integration Committee Member or Members.

(i) To the extent that the information or documentation for one Grant Application is the same for all Grant Applications recommended for Grant Award funding pursuant to the same Grant Mechanism, it shall be sufficient for the Chief Executive Officer to provide the information or documentation once and incorporate by reference in each subsequent affidavit.

(j) At least three business days prior to the Oversight Committee meeting held to consider the Grant Applications for Grant Award funding, the Chief Executive Officer shall provide a list of Grant Applications, if any, recommended for an advance of Grant Award funds upon execution of the Grant Contract. The list shall include the reasons supporting the recommendation to advance funds.

RULE §703.8 Oversight Committee Consideration of the Program Integration Committee's Funding Recommendation

The Oversight Committee must vote to approve each Grant Award recommendation submitted by the Program Integration Committee.

(1) Prior to the Oversight Committee's consideration and approval of the Program Integration Committee's Grant Award recommendations, the Chief Compliance Officer must review the process documentation for each Grant Application recommended for a Grant Award by the Program Integration Committee and report the findings to the Chief Executive Officer and to the Oversight Committee. The Chief Compliance Officer's report shall:

(A) Publicly certify that the Grant Review Process complied with the Institute's administrative rules and procedures, including those procedures stated in the Request for Applications.

(B) Indicate variances, if any, in the Grant Review Process. The Chief Compliance Officer may recommend corrective actions to address variances, if any, and the Oversight Committee may consider and approve corrective actions at that time that the Grant Award recommendations are approved.

(C) Compare the list of Grant Applicants recommended for a Grant Award to a list of donors from any nonprofit organization established to provide support to the Institute.

(2) Two-thirds of the Oversight Committee Members present and voting must approve each Grant Award recommendation. At the time that the Oversight Committee approves the Grant Award recommendation:

(A) The total amount of money approved to fund a multiyear project must be specified.

(B) The Chief Executive Officer's recommendation, if any, regarding an advance of Grant Award funds must be approved by a majority vote of the Oversight Committee.

(3) If the Oversight Committee does not approve a Grant Award recommendation made by the Program Integration Committee, the minutes of the meeting shall record the explanation for the failure to follow the Grant Award recommendation.

(4) The Oversight Committee may not award more than \$300 million in Grant Awards in a fiscal year.

RULE §703.9 Limitation on Review of Grant Process

(a) The decision to recommend a Grant Application for funding is based upon the sufficiency, merit, and, if applicable, Product Development prospects of the Grant Application, as determined by the Institute's Peer Review and Program Review processes as described in the Chapter.

(b) By submitting a Grant Application, the Grant Applicant understands and accepts that grounds for reconsideration of the Institute's final decision regarding a Grant Application are limited to an undisclosed Conflict of Interest as set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute).

(c) The Grant Applicant shall file a request with the Chief Executive Officer for a review of the Grant Review Process based on the undisclosed Conflict of Interest pursuant to the process and timeline set forth in Chapter 702 of this title.

RULE §703.10 Awarding Grants by Contract

(a) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.

(b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.

(c) The Grant Contract shall include the following provisions:

(1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Contract, including an acknowledgement of Institute funding and copyright ownership, if applicable;

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the standards established by the Oversight Committee in Chapter 701 to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and

from historically underutilized businesses as defined by Chapter 2161, Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that include information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office, if applicable, unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, *Health and Safety Code*, or the Institute's administrative rules. Such interpretation of the Institute rules and UGMS shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

(13) An agreement that the design, conduct, and reporting of the Cancer Research or Prevention project will not be biased by conflicting financial interest of the Grant Recipient or any individuals associated with the Grant Award. This duty is fulfilled by certifying that an appropriate written, enforced Conflict of Interest policy governs the Grant Recipient.

(14) An agreement regarding the amount, schedule, and requirements for payment of Grant Award funds, if such advance payments are approved by the Oversight Committee in accordance with this Chapter. Notwithstanding the foregoing, the Institute may require that up to ten percent of the final tranche of funds approved for the Grant Award must be expended on a reimbursement basis. Such reimbursement payment shall not be made until close out documents described in this section and required by the Grant Contract have been submitted and approved by the Institute;

(15) An agreement to provide quarterly Financial Status Reports and supporting documentation for expenses submitted for reimbursement or, if appropriate, to demonstrate how advanced funds were expended;

(16) A statement certifying that, as of June 14, 2013, the Grant Recipient has not made and will not make a contribution, during the term of the Grant Contract, to the Institute or to any foundation established specifically to support the Institute;

(17) A statement specifying the agreed effective date of the Grant Contract and the period in which the Grant Award funds must be spent. If the effective date specified in the Grant Contract is different from the date the Grant Contract is signed by both parties, then the effective date shall control;

(18) A statement providing for reimbursement with Grant Award funds of expenses made prior to the effective date of the Grant Contract at the discretion of the Institute. Pre-contract reimbursement shall be made only in the event that:

(A) The expenses are allowable pursuant to the terms of the Grant Contract;

(B) The request is made in writing by the Grant Recipient and approved by the Chief Executive Officer; and

(C) The expenses to be reimbursed were incurred on or after the date the Grant Award recommendation was approved by the Oversight Committee.

(19) Requirements for closing out the Grant Contract at the termination date, including the submission of a Financial Status Report, a final Grant Progress Report, a equipment inventory, a HUB and Texas Business report, a revenue sharing form, a single audit determination report form and a list of contractual terms that extend beyond the termination date;

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds are to be dedicated, as specified in Section 703.11 of this Chapter;

(21) The project deliverables as described by the Grant Application and stated in the Scope of Work for the Grant Contract reflecting modifications, if any, approved during the Peer Review process or during Grant Contract negotiation; and

(22) An agreement that the Grant Recipient shall notify the Institute and seek approval for a change in effort for any of the Senior Members or Key Personnel of the research or prevention team listed on the Grant Application.

(d) The Grant Recipient's failure to comply with the terms and conditions of the Grant Contract may result in termination of the Grant Contract pursuant to the process prescribed in the Grant Contract and trigger repayment of the Grant Award funds.

Requirement to Demonstrate Available Funds for Cancer Research Grants

(a) Prior to the disbursement of Grant Award funds, the Grant Recipient of a Cancer Research Grant Award shall demonstrate that the Grant Recipient has an amount of Encumbered Funds equal to one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract. A Grant Recipient of a multiyear Grant Award may certify Matching Funds on a year-by-year basis for the amount of Award Funds to be distributed for the Project Year based upon the Approved Budget. A Grant Recipients receiving multiple Grant Awards may provide certification at the institutional level.

(b) For purposes of the certification required by subsection (a) of this section, a Grant Recipient that is a public or private institution of higher education, as defined by Section 61.003, Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by the Section 102.203(c), Texas Health and Safety Code, subject to the following requirements:

(1) The Grant Recipient shall file certification with the Institute documenting the federal indirect cost rate authorized for research grants awarded to the Grant Recipient; and

(2) To the extent that the Grant Recipient's Matching Funds credit does not equal or exceed one-half of the Grant Award funds to be distributed for the Project Year, then the Grant Recipient's Matching Funds certification shall demonstrate that a combination of the dollar amount equivalent credit and the funds to be dedicated to the Grant Award project as described in subsection (c) is available and sufficient to meet or exceed the Matching Fund requirement.

(c) For purposes of the certification required by subsection (a) of this section, Encumbered Funds may include:

(1) Federal funds, including, but not limited to American Recovery and Reinvestment Act of 2009 funds, and the fair market value of drug development support provided to the recipient by the National Cancer Institute or other similar programs;

(2) State of Texas funds;

(3) funds of other states;

(4) Non-governmental funds, (including private funds, foundation grants, gifts and donations; and

(5) Unrecovered Indirect Costs not to exceed ten percent (10%) of the Grant Award amount, subject to the following conditions:

(A) These costs are not otherwise charged against the Grant Award as the five percent (5%) indirect funds amount allowed under §703.12(c) of this Chapter (relating to Limitation on Use of Funds);

(B) The Grant Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm;

(C) The allowance for unrecovered Indirect Costs must be specifically approved by the Chief Executive Officer; and

(D) The Grant Recipient is not a public or private institution of higher education as defined by Section 61.003 of the Texas Education Code.

(d) For purposes of the certification required by subsection (a) of this section, the following items do not qualify as Encumbered Funds:

(1) In-kind costs;

(2) Volunteer services furnished to the Grant Recipient;

(3) Noncash contributions;

(4) Income earned by the Grant Recipient that is not available at the time of Grant Award;

(5) Pre-existing real estate of the Grant Recipient including building, facilities and land;

(6) Deferred giving such as a charitable remainder annuity trust, a charitable remainder unitrust, or a pooled income fund; or

(7) Other items as may be determined by the Oversight Committee.

(e) To the extent that a Grant Recipient of a multiyear Grant Award elects to certify Matching Funds on a yearly basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year shall serve as grounds for terminating the Grant Contract.

(f) In no event shall Grant Award funds for a Project Year be advanced or reimbursed, as may be appropriate for the Grant Award and specified in the Grant Contract, until the certification required by subsection (a) of this section is filed and approved by the Institute.

(g) No later than 60 days from the anniversary of the Effective Date of the Grant Contract, the Grant Recipient shall file a form with the Institute reporting the amount of Matching Funds spent for the preceding Project Year.

(h) If the Grant Recipient failed to expend Matching Funds equal to one-half of the actual amount of Grant Award funds distributed to the Grant Recipient for the same period, the Institute shall:

(1) Carry forward and add to the Matching Fund requirement for the next Project Year the dollar amount equal to the deficiency between the actual amount of Grant Award funds distributed and the actual Matching Funds expended, so long as the deficiency is equal to or less than twenty percent (20%) of the total Matching Funds required for the same period and the Grant Recipient has not previously had a Matching Funds deficiency for the project;

(2) Suspend distributing Grant Award funds for the project to the Grant Recipient if the deficiency between the actual amount of Grant Funds distributed and the Matching Funds expended is greater than twenty percent (20 %) but less than fifty percent (50%) of the total Matching Funds required for the period.

(A) The Grant Recipient will have no less than eight months from the anniversary of the Grant Contract's effective date to demonstrate that it has expended Encumbered Funds sufficient to fulfill the Matching Funds deficiency for the project.

(B) If the Grant Recipient fails to fulfill the Matching Funds deficiency within the specified period, then the Grant Contract shall be considered in default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract;

(3) Declare the Grant Contract in default if the deficiency between the actual amount of Grant Award funds distributed and the Matching Funds expended is greater than fifty percent (50%) of the total Matching Funds required for the period. The Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract; or

(4) Take appropriate action, including withholding reimbursement, requiring repayment of the deficiency, or terminating the Grant Contract if a deficiency exists between the actual amount of Grant Award funds distributed and the Matching Funds expended and it is the last year of the Grant Contract;

(i) Nothing herein shall preclude the Institute from taking action other than described in subsection (h) based upon the specific reasons for the deficiency. To the extent that other action not described herein is taken by the Institute, such action shall be documented in writing and included in Grant Contract records. The options described in subsections (h)(1) and (2) may be used by the Grant Recipient only one time for the particular project. A second deficiency of any amount shall be considered an event of default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.

(j) The Grant Recipient shall maintain adequate documentation supporting the source and use of the Matching Funds reported in the certification required by subsection (a) of this section. The Institute shall conduct an annual review of the documentation supporting the source and use of Matching Funds reported in the required certification for a risk-identified sample of Grant Recipients. Based upon the results of the sample, the Institute may elect to expand the review of supporting documentation to other Grant Recipients. Nothing herein restricts the authority of the Institute to review supporting documentation for one or more Grant Recipients or to conduct a review of Matching Funds documentation more frequently.

(a) A Grant Recipient may use Grant Award funds only for Cancer Research and Cancer Prevention projects consistent with the purpose of the Act, and in accordance with the Grant Contract. Grant Award funds may not be used for purposes other than those purposes for which the grant was awarded. The Institute may require a Grant Recipient to repay Grant Award funds if the Grant Recipient fails to expend the Grant Award funds in accordance with the terms and conditions of the Grant Contract and the provisions of this chapter.

(b) Grant Award funds must be used for Authorized Expenses.

(1) Expenses that are not authorized and shall not be paid from Grant Award funds, include, but are not limited to:

(A) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(B) Contributions to a contingency reserve or any similar provision for unforeseen events.

(C) Contributions and donations made to any individual or organization.

(D) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(E) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(F) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(G) An honorary gift or a gratuitous payment.

(H) Interest and other financial costs related to borrowing and the cost of financing.

(I) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(J) Liability insurance coverage.

(K) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(L) Professional association fees or dues for the Grant Recipient or an individual.

(M) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(N) Patient support services costs relating to services such as personal care items and financial assistance for low-income clients.

(2) Additional guidance regarding Authorized Expenses for a specific program may be provided by the terms of the Grant Contract and by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office. If guidance from UGMS on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, *Health and Safety Code*, or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(3) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Authorized Expense.

(c) A Grant Recipient of Grant Award funds for a Cancer Research project may not spend more than five percent (5%) of the Grant Award funds for Indirect Costs.

(d) The Institute may not award more than five percent (5%) of the total Grant Award funds for each fiscal year to be used for facility purchase, construction, remodel, or renovation purposes during any year. Any Grant Award funds that are to be expended by a Grant Recipient for facility purchase, construction, remodel, or renovations are subject to the following conditions:

(1) The use of Grant Award funds must be specifically approved by the Chief Executive Officer with notification to the Oversight Committee;

(2) Grant Award funds spent on facility purchase, construction, remodel, or renovation projects must benefit Cancer Prevention and Research;

(3) If Grant Award funds are used to build a capital improvement, then the state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award funds used to pay for the capital improvement. If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award funds used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale.

(e) The Institute may not award more than ten percent (10%) of the money awarded from the Cancer Prevention and Research Fund or from the proceeds of bonds issued on behalf of the Institute to be used for Cancer Prevention and Control programs during any year. Grant Awards for Cancer Prevention research projects shall not be counted toward the Grant Award amount limit for Cancer Prevention and Control Programs. For purposes of this subsection, the Institute is presumed to award the full amount of funds available.

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the end of the Grant Recipient's fiscal year during which the Grant Contract was terminated.

(b) Notwithstanding the foregoing, a Grant Recipient expending \$500,000 or more in state awards during its fiscal year shall obtain either an annual single independent audit or a program specific independent audit.

(1) A single audit is required if funds from more than one state program are spent by the Grant Recipient.

(2) The audited time period is the Grant Recipient's fiscal year.

(3) The audit must be submitted to the Institute no later than nine (9) months following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to apply for a Grant Award until the required audit and corrective action plan is submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to apply for a Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(a) The termination date of a Grant Contract shall be the date stated in the Grant Contract, except:

(1) The Chief Executive Officer may elect to terminate the Grant Contract earlier because the Grant Recipient has failed to fulfill contractual obligations, including timely submission of required reports or certifications;

(2) The Institute terminates the Grant Contract because funds allocated to the Grant Award are reduced, depleted, or unavailable during the award period, and the Institute is unable to obtain additional funds for such purposes; or

(3) The Institute and the Grant Recipient mutually agree to terminate the Grant Contract earlier.

(b) If the Institute elects to terminate the Grant Contract pursuant to subsections (a)(1) or (a)(2) of this Section, then the Chief Executive Officer shall notify the Grant Recipient in writing of the intent to terminate funding at least 30 days before the intended termination date. The notice shall state the reasons for termination, and the procedure and time period for seeking reconsideration of the decision to terminate. Nothing herein restricts the Institute's ability to terminate the Grant Contract immediately or to seek additional remedies if justified by the circumstances of the event leading to early termination.

(c) The Institute may approve the Grant Recipient's written request to extend the termination date of the Grant Contract to permit the Grant Recipient additional time to complete the work of the project.

(1) A no cost extension may be granted only if the Grant Recipient is in good fiscal and programmatic standing.

(2) The Grant Recipient may request a no cost extension no earlier than 180 days and no later than 30 days prior to the termination date of the Grant Contract.

(3) The Institute may approve one no cost extension, the duration of which may be no longer than six months from the termination date of the Grant Contract, unless the Institute finds that special circumstances justify authorizing additional time to complete the work of the project.

(4) If the Institute approves the request to extend the termination date of the Grant Contract, then the termination date shall be amended to reflect the change.

(d) Within ninety (90) days after the termination of the Grant Contract, the Grant Recipient must submit a final Financial Status Report and final Grant Progress Report as well as any other required reports as specified in the Grant Contract. The final reimbursement payment shall not

be made until such close out documents have been submitted and approved by the Institute. Failure to submit close out documents within 180 days of the Grant Contract termination date may result in the Grant Recipient being ineligible for other Institute Grant Awards until such time that the close out documents are submitted.

(e) The Institute may make upward or downward adjustments to the Allowable Costs requested by the Grant Recipient within ninety (90) days following the receipt of the close out reports.

(f) Nothing herein shall affect the Institute's right to disallow costs and recover Grant Award funds on the basis of a later audit or other review or the Grant Recipient's obligation to return Grant Award funds owed as a result of a later refund, correction, or other transaction.

(g) Any Grant Award funds paid to the Grant Recipient in excess of the amount to which the Grant Recipient is finally determined to be entitled under the terms of the Grant Contract constitute a debt to the state. If not paid within a reasonable period after demand, the Institute may reduce the debt owed by:

- (1) Making an administrative offset against other requests for reimbursements,
- (2) Withholding advance payments otherwise due to the Grant Recipient, or
- (3) Other action permitted by law.

RULE §703.15 **Multiyear Projects**

- (a) The Oversight Committee may approve Grant Award funds for a multiyear project. The total amount of Grant Award funds for the project shall be specified at the time that the Grant Award recommendation is approved by the Oversight Committee.
- (b) The Grant Contract shall include an Approved Budget that reflects the amount of the Grant Award funds to be spent for each Project Year.
- (c) The Institute shall distribute Grant Award funds to reimburse Allowable costs as reflected in the Approved Budget and pursuant to the Grant Recipient's submission of the quarterly Financial Status Report or the request to advance Grant Award funds. Remaining Grant Award funds shall be distributed as needed in each subsequent Project Year of the Grant Contract.
- (d) A Grant Recipient awarded a Grant Award for a multiyear project that fails to expend the total Project Year budget may carry forward the unexpended budget balance to the next Project Year. If the amount of the unexpended budget balance to carry forward exceeds ten percent (10%) of the total Grant Award amount, the Grant Recipient must provide specific justification for why the total Grant Award amount should not be reduced by the unexpended balance.

(a) To the extent that there is a conflict between this chapter and the Grant Contract between the Institute and the Grant Recipient, the Grant Contract terms will control.

(b) The Grant Recipient may retain, assign or transfer all or a portion of any of the Intellectual Property Rights relating to the project results. Any such assignment or transfer to a third party is subject to the following requirements:

(1) The Grant Recipient shall notify the Institute of the proposed transfer or assignment;

(2) The Grant Recipient shall ensure that the assignment or transfer is subject to the licenses, interests and other rights provided to the Institute pursuant to the Grant Contract and any applicable law or regulation; and

(3) Unless the transfer is taking place pursuant to an exercise of the United States government's rights under 35 U.S.C. §203, the Institute may provide comments to the Grant Recipient related to the proposed transfer or assignment of rights, which the Grant Recipient shall consider in good faith and use reasonable efforts to account for and incorporate such comments into the actual transfer or assignment of such rights.

(c) Unless specifically authorized by the Institute, Grant Award proceeds shall not be used to pay the costs or expenses associated with the efforts to protect the Intellectual Property Rights or to pay the costs or expenses associated with commercialization activities.

(d) As a condition of accepting Grant Award funding from the Institute, the Grant Recipient agrees to the following required commitments as defined in the Grant Contract with regard to any project results:

(1) To use commercially reasonable efforts to protect, develop, commercialize, or otherwise bring Project Results to practical application to the fullest extent feasible as determined by the Grant Recipient. The Grant Recipient is relieved of its obligations pursuant to this section so long as the Grant Recipient complies with paragraph (3) of this subsection and §703.19 of this chapter.

(2) To share with the Institute a portion of the benefit derived from the commercial development of the Project Results, as set forth in the Grant Contract.

(3) To notify the Institute in writing prior to declining to pursue, abandoning, waiving or disclaiming some or all Intellectual Property Rights related to the Project Results. Such notification shall be made with sufficient time to provide the Institute an opportunity to license or pursue the appropriate applications and other protections for such Intellectual Property Rights to the fullest extent permitted by law.

(4) To keep the Institute promptly and reasonably informed regarding the activities undertaken by the Grant Recipient to protect and/or commercialize the Project Results and to consider in good faith Institute input, if any, regarding same. Such activities may include, but are not limited to, the following:

(A) Filing of an invention disclosure forms (including updates and revisions);

(B) Creation of commercial development plans;

(C) Application, issuance, prosecution and maintenance of patents; and

(D) Negotiation of final term sheets and License Agreements.

(5) To allow access to the books and records of the Grant Recipient for the purpose of conducting an audit during normal business hours with reasonable notice to verify amounts paid to the Institute pursuant to this chapter. Notwithstanding the time limitation provided in §703.13 of this chapter, the right to audit the books and records of the Grant Recipient to verify amounts required to be paid to the Institute shall continue for so long as the payments shall be made.

(6) To report to the Institute at least annually describing commercialization activities for the Project Results in a manner and form to be prescribed by the Institute.

RULE §703.17 **Revenue Sharing Standards**

(a) The Institute shall share in the financial benefit received by the Grant Recipient resulting from the patents, royalties, assignments, sales, conveyances, licenses and/or other benefits associated with the Project Results, including interest or proceeds resulting from securities and equity ownership. Such payment may include royalties, income, milestone payments, or other financial interest in an existing company or other entity.

(b) The Institute's election as to form of payment and the calculation of such payment shall be specified in the Grant Contract.

(c) Unless otherwise provided by the Grant Contract between the Institute and the Grant Recipient, payments to the Institute required by this section shall be made no less than annually pursuant to a schedule set forth in the Grant Contract and shall be accompanied by an appropriate financial statement supporting the calculation of the payment.

(d) Nothing herein shall affect or otherwise impair the application of federal laws for projects receiving some portion of funding from the U.S. Government.

- (a) The Grant Recipient bears the responsibility for licensing activities including identification of potential licensees, negotiation of License Agreements, documentation of the progress and development under a License Agreement, monitoring the performance of the licensee, and taking commercially reasonable actions to enforce the terms of the License Agreements.
- (b) Each License Agreement for Project Results entered into by the Grant Recipient shall include an acknowledgement by the licensee that such License Agreement is subject to the Institute's licenses, interests and other rights, if any.
- (c) Nothing herein prohibits the Grant Recipient from negotiating an exclusive License Agreement for Project Results if exclusivity is reasonably believed by the Grant Recipient to provide an economic incentive necessary for achieving commercial development and availability of the Project Results. The Grant Recipient shall take reasonable action to enforce the terms of the exclusive license and report any default notice to the Institute.
- (d) A not-for-profit Grant Recipient negotiating exclusive or non-exclusive License Agreements shall seek to retain the right to exploit the use of its Project Results and utilize the same for its non-commercial purposes.

(a) The Institute shall have the option, but not the obligation, to pursue protection of the applicable Intellectual Property Rights and/or to commercialize or otherwise bring to practical application the applicable Project Results either directly or through one or more licensees, in the event of the following:

(1) Upon receipt of Grant Recipient's notice of its election to abandon, waive or disclaim any Intellectual Property Rights or to cease its efforts to commercialize or otherwise bring to practical application any particular Project Results; or

(2) Grant Recipient's failure to materially comply with its obligations to protect the Intellectual Property Rights or to use diligent and commercially reasonable efforts to commercialize or otherwise bring to practical application the Project Results in accordance with the Grant Recipient's commercial development plan(s), and Grant Recipient fails to cure such non-compliance within a reasonable period of time following written notice from the Institute specifically describing the events of non-compliance.

(b) If the Institute elects to exercise its options pursuant to this section, it shall notify the Grant Recipient in writing of such election. Upon receipt of notification, the Grant Recipient shall:

(1) Fully cooperate with the Institute's efforts to protect, commercialize or otherwise bring to practical application the applicable Project Results at the Institute's cost, including but not limited to the transfer to the Institute or the Institute's designee of the Grant Recipient's rights, title and interest in and to the applicable Project Results, to the maximum extent allowed by law;

(2) Not take any action that would materially impede the Institute's ability to protect, commercialize or otherwise bring to practical application the applicable Project Results.

(c) If the Institute exercises its option under this section, the Grant Recipient shall have no further claim to or interest in ~~or~~ to the applicable Project Results and shall not be entitled to any share of the revenue or other compensation with respect to such Project Results, except to the minimum extent required by law, if any.

(d) The Institute's exercise of rights pursuant to this section is subject to any applicable rights of the United States government.

RULE §703.20 Certification of Tobacco-Free Policy for Grant Recipients

To be eligible to receive a Grant Award, a Grant Recipient shall certify that the entity has adopted and enforces a Tobacco-free workplace policy.

(1) A Tobacco-free workplace policy will comply with the certification required by this section if the policy is adopted by the Grant Recipient's board of directors, governing body, or similar and, at a minimum, includes provisions:

(A) Prohibiting the use of all Tobacco products by all employees and visitors to the property owned, operated, leased, occupied, or controlled by the Grant Recipient. For purposes of the Tobacco-free workplace policy, the Grant Recipient may designate the property to which the policy applies, so long as the workplace policy encompasses all buildings and structures where the Grant Award project is taking place as well as the sidewalks, parking lots, walkways, and attached parking structures immediately adjacent, but only to the extent the Grant Recipient owns, leases or controls the building, sidewalks, parking lots and parking structures.

(B) Providing for and/or referring to Tobacco use cessation services for employees.

(2) Upon request by a Grant Recipient, the Chief Executive Officer may authorize a waiver of compliance with this section. If approved, the waiver is effective only for the State fiscal year during which it was approved.

(3) The certification and waiver requests addressed herein shall be submitted by the Grant Recipient via the Institute's electronic Grant Management System.

RULE §703.21 Monitoring Grant Award Performance and Expenditures

(a) The Institute, under the direction of the Chief Executive Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.

(b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:

(1) Financial Status Reports Review - Quarterly financial status reports shall be submitted to the Institute within 90 days of the end of the state fiscal quarter (based upon a September 1 – August 31 fiscal year.) The Institute shall review expenditures and supporting documents to determine whether expenses charged to the Grant Award are:

(A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(2) Timely submission of Financial Status Reports - The Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the financial status report for that quarter is not submitted to the Institute within 30 days of the due date. The Chief Executive Officer may approve an extension of the submission deadline if, prior to the FSR due date, the grant recipient submits a written explanation for the grant recipient's inability to complete a timely submission of the FSR.

(3) Grant Progress Reports – The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.

(A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

(B) The annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:

(i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;

- (ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;
- (iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;
- (iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;
- (v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;
- (vi) A Historically Underutilized Businesses report;
- (vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;
- (viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;
- (ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;
- (x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report;
- (xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and
- (xii) A single audit determination form.

(C) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

(D) The Grant Progress Report will be evaluated by a grant manager pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific

Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff.

(E) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in Section 703.14 of this Chapter.

(F) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(4) Desk Reviews - The Institute may conduct a desk review for a Grant Award to review 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.

(5) Site Visits and Inspection Reviews – The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports - The Institute shall review audit reports submitted pursuant to Section 703.13 of this Chapter.

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

(1) To the extent that the methods described in subsection (b) are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in Section 703.4.

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff.