

Clinical and Translational Research

Self-study Project

STANDARDS

Preface: The Clinical and Translational Research (CTR) Self-study Project is a voluntary, peer-reviewed evaluation of the quality and scope of the clinical and translational research structure and function at the Penn State College of Medicine and its affiliated community entities. The essential functions of the self-study are to assess the institution's position to meet the standards set forth in this document, and evaluate the institution's position for being awarded a clinical and translational science award. The goal is to ensure that the research meets the expected levels of excellence and superior quality to be meritorious in its accomplishments.

Institutional Context (IC)

Clinical and Translational Science Award (CTSA) key functions: Development of Novel Clinical and Translational Methodology; Regulatory Knowledge and Support; Participant and Clinical Interactions Resources

- IC-1 The institution must have an established planning process in place that sets the direction of CTR, guides the implementation, and measures the outcomes.
- The plan should clearly explain the overall governance and organizational structure of the CTR.
 - The plan must clearly describe the experience and role of the principle investigator. This description should include:
 - The role and function of the position;
 - The expectation that the person is an established clinician scientist;
 - The expectation that the person reports directly to an official with broad trans-institutional authority;
 - The expected level of effort (not less than 20%); and
 - Any assistants (e.g. co-program directors) from the institution or affiliate sites.
 - The plan should define the relationships between the CTSA Principle Investigator and the directors of all the key functions that include all involved parties internal and external to the CTSA.
 - The plan should clearly state the vision and mission of the program.
 - The plan should identify short-term and long-term goals and objectives stated in terms of measurable outcomes.
 - The plan should define the methods and timing of assessment.

Research Environment and Infrastructure

- IC-2 The institution shall have the infrastructure to support intellectual exploration and innovation.
- Faculty members could pursue their funded research in areas that might include, for example, new translational methodologies, developing new phenotyping methods that are more objective and quantifiable, the development of biomarkers for research purposes, research into clinical trial designs, clinical informatics for longitudinal studies, home based research devices and methods, predictive toxicology in human populations, and ethics research specific to populations rather than specific trials.
- IC-3 The institution must provide opportunities and resources for original research on novel methods and approaches to translational and clinical science.
- The provision of resources should be available to support researchers, trainees, and research projects across multiple health conditions studied by a wide range of NIH Institutes and Centers
- IC-4 The institution must provide regulatory support to act as a sounding board for potential research participants, advocate for research participants, and work with investigators, trainees, and research teams to ensure that research involving human subjects accords the highest priority to human subject protections.
- Regulatory Support should include an individual independent of the Institutional Review Board or compliance office.
 - Regulatory Support for research teams must include systems that promote and assure the protection of human subjects, and facilitate regulatory compliance.
- IC-5 The institution must provide the translational technologies and knowledge base that covers the spectrum of clinical and translational science, including all types and sizes of studies and specialties.
- IC-6 The institution must be able to describe how it promotes the protection of human subjects and facilitate regulatory compliance by describing the following:
- provision of services, their selection and implementation;
 - interaction with institutional review boards and regulatory entities, such as FDA;
 - assessment of function and effectiveness; and
 - operation of the human-subject advocacy resources.
- IC-7 The institution shall demonstrate its experience in working with multi-site trials and with the FDA with respect to studies involving investigational new drug application procedures, etc.
- IC-8 The institution should have a process in place that develops best practices.
- These best practices should be targeted to reducing or removing institutional impediments to clinical and translational research.
 - These best practices should be disseminated with the goal to enhance inter-institutional collaborations.

IC-9 The institution should demonstrate innovation at all levels of clinical research regulation. Areas to consider are:

- Provision of integrated training
- Provision of services
- Provision of tools for protocol and informed consent authoring and translation
- Adverse event reporting
- Safety and regulatory management and compliance

IC-10 The institution should provide regulatory support through the CTSA to assist investigators in their documentation requirements.

- This regulatory support should not replace the institution's compliance or enforcement office, nor shall it be responsible for Institutional Review Board activities.
- Innovative processes should be operating to develop the regulatory support interactions with the Institutional Review Board and the compliance office to promote and facilitate clinical and translational science research without loss of participant protections.

IC-11 The institutions Institutional Review Board personnel should interact with regulatory support personnel at other CTSA institutions through the National CTSA Regulatory Support Steering Committee to ensure that collaborative clinical and translational research activities are facilitated by policy, procedures, best practices, or other means of facilitation.

IC-12 Participant and Clinical Interactions resources should promote participation in clinical and translational research and provide clinical resources for cost-effective human subject interactions. Examples could include:

- Recruitment of research participants
- Provision of in-patient, out-patient, or community-based exam rooms
- Provision of services, e.g., scheduling, specimen collection and shipping
- Provision of medical vans
- Temporary research participant recruitment/enrollment sites
- Research nurses, research coordinators, phlebotomists, etc.

Governance and Administration

IC-13 The governing board responsible for oversight of the CTSA must provide evidence that formal policies and procedures are in place and followed to avoid the impact of conflicts of interest in the operation of the school or any related enterprises.

IC-14 The institution must have available funds with an accompanying organizational structure that supports full compliance with regulatory requirements.

IC-15 The institution must show it has sufficient resources and grants that can be integrated into any CTSA activity and plans.

IC-16 The institution must show how CTSA will transform clinical and translational research at their institutions with reference to the following:

- the faculty, staffing and direction of a proposed 'home' for clinical research;
- the goals of the CTSA and the benefit to clinical and translational;

- key functions will be conducted to achieve the goals, and how these functions will be coordinated to achieve the goals;
- existing institutional resources that could be subsumed into the proposed CTSA;
- specific institutional commitments to achieve the goals of the CTSA; and,
- a self-evaluation plan to document accomplishments anticipated within the award period.

IC-17 The institution must demonstrate a commitment to work with rural and underserved populations.

- A mechanism to access these populations shall be identified.
- A system that advances, transforms and supports health care in this population through research and education should be available to use in CTR.

IC-18 The institution shall explain how their CTSA communities contribute to the selection and allocation of key resources, and the implementation, self-evaluation and prioritization of key functions.

IC-19 The institution must have an External Advisory Committee that meets annually with the director to review the structure, the progress, and offer recommendations.

IC-20 The institution shall support the CTSA's principle investigator to participate on the National CTSA Consortium Steering Committee.

- There must be a documented commitment that shows active collaborative participation at the national level to share ideas, experiences, methods; address barriers and impediments; make decisions; etc.

IC-21 The institution should be represented at the National CTSA Consortium Steering Committee's sub-committee meetings established for each common theme identified by the National Institute of Health.

IC-22 The institution must explain its plan and describe its efforts to recruit, retain, and graduate individuals from underrepresented minority groups.

Physician Investigators

IC-23 The institution must have a plan to recruit investigators, especially those early in their professional careers, and make the availability of Participant and Clinical Interactions resources known throughout the institution and medical catchments area.

Research Portfolio

IC-24 The institution must show its strengths in research areas that are specific to those focused in the CTSA.

Centers

- IC-25 The institution must demonstrate how it promotes and supports collaboration between departments and schools of an institution, and between institutions and industry in an effort to integrate translational and clinical science.
- IC-26 The institution shall demonstrate it supports the development of innovative and creative research programs that bridge design, biostatistics, and clinical research ethics with other CTSA activities. Topics for research might include, for example, the following:
- Limiting risk to participants, preventing bias, improving enrollment, capturing appropriate data, developing design and analysis plans for studies of unique populations or very small numbers of subjects, informed consent, and issues in diseases with limited treatment options.
- IC-27 The institution must demonstrate a plan to create a networked environment in which clinical studies can be expedited and implemented across multiple institutions.
- IC-28 The institution must show its commitment to the participant and clinical interactions resources (PCIR) in the following manner:
- PCIR resources, their prioritization, availability, management and tracking;
 - the integration of PCIR resources with similar resources at the institution(s);
 - method to ensure that all studies utilizing these resources will meet the highest standards for quality of science, statistical rigor, ethical evaluation, robust design, participant safety, and strict implementation, analysis, and reporting;
 - how Good Clinical Practice will be implemented;
 - the process by which under-utilization or poor performance will be addressed;
 - how the institution(s) will anticipate and be responsive to changing needs of the clinical and translational research communities;
 - evaluation of studies to justify their continued access to resources; and
 - plans for cost recovery from funded investigators, where appropriate.

Community Involvement and Participation and Rural Health (CIP)

CTSA key function: Community Engagement

- CIP-1 The institution must partner with foundations, industry, community organizations, and public and community providers.
- The institution shall share data and public access with its partners.
 - The institution shall facilitate the recruitment of research participants from the community.
- CIP-2 The institution should have a community outreach program and provide the resources that promote collaborative partnerships and enhances the public trust in CTSA.
- CIP-3 The institution should be committed to community involvement and participation and demonstrate this in the following manner:
- show how the institution will involve the community in setting research priorities that directly affect patients;
 - explore innovative ways to engage community members in mentoring processes, partnerships in clinical and translational research, and collaborations to enhance research perspectives (e.g., health disparity research), public trust, and recruitment for clinical and translational research; and
 - develop outreach plans for community practitioners including means of engagement, possible incentives, application of research results (dissemination), and plans for training CTSA researchers, trainees and scholars in community outreach, cultural sensitivity, and population and community-based research methods.
- CIP-4 The institution shall make efforts to identify and overcome the barriers to and enhance the opportunities for public trust and participation in clinical and translational research.
- CIP-5 The institution must provide a point of contact for partnerships with industry, foundations and community physicians as appropriate.
- CIP-6 The institution should allocate resources that supplement opportunities for its scholars and researchers to enhance applications of science to the general community, and expose them to population- and community-based research methods.
- CIP-7 The institution should have developed long-term relationships with community-based groups such as voluntary and professional organizations, women's health groups, faith-based groups, housing organizations, etc.
- CIP-8 The institution should demonstrate effort in the promotion of community outreach, cultural sensitivity training for clinical and translational researchers, community and provider education and outreach, development of software to facilitate the collaboration of community practitioners, and communication strategies to improve the two-way communication with, and participation by community groups.

Core Facilities (CF)

CTSA key functions: Biomedical Informatics; Translational Technologies and Resources

- CF-1 Systems must be in operation to assure privacy and confidentiality of human subject data.
- CF -2 The institution must provide the resources for the biomedical informatics director to participate in the National CTSA Informatics Steering Committee.
- There must be a commitment by the institution to work towards adopting and implementing the standards and practices endorsed by the Steering Committee.
- CF -3 The institution must show it has the following structure in place to promote medical informatics in the CSTA:
- support for operations, administration, research and clinical/translational research activities;
 - a plan to establish communication with external organizations relevant to their mission;
 - the process by which standards and other mechanisms will be developed and used to maximize interoperability between internal systems and systems in outside organizations;
 - an assessment of informatics performance across the CTSA programs and with external partners; and
 - an plan for inter- and intra-organizational sharing of data, technology and best practices.
- CF -4 The institution must demonstrate that their biomedical informatics support is flexible, innovative, interoperable, secure, efficient, and usable.
- CF -5 The institution must employ applicable standards in biomedical informatics (e.g., identifiers, vocabularies, transactions, security measures) adopted by the Department of Health and Human Services for use in U.S. health care and public health operations.
- CF-6 The institution shall have a communication system in place (internal, intra-institution and external interoperability) that supports communication among sites and the necessary research partners of clinical and translational investigators (e.g. government, clinical research networks, pharmaceutical companies, commercial vendors, laboratories, and equipment manufacturers).
- CF-7 The institution shall be able to show their biomedical informatics support is interoperable; secure; usable in work and standards; and the biomedical research activity is innovative in the development of new tools, methods and algorithms.
- CF-8 The institution must show evidence that all human subject data is handled securely and ensures the privacy and confidentiality of the subjects.
- CF-9 The institution must have in place standard operating procedures for quality control and standardization efforts.

CF-10 The institution shall use advanced technologies that support local and regional needs. These resources could include mass spectrometry, imaging, ultrasound, positron emission tomography, gene expression, proteomics, and translational cell and gene therapies.

CF-11 The institution should describe the following as its commitment to translational technologies and resources:

- the resources that will be offered, with plans for their prioritization, availability, management and tracking;
- the integration of resources with similar resources at the institution and any affiliates;
- how the institution(s) will anticipate and be responsive to changing needs of the clinical and translational research communities;
- evaluation of studies to justify their continued access to resources; and
- plans for cost recovery from funded investigators, where appropriate.

Training (T)

CTSA key function: Research Education, Training, and Career Development

- T-1 The institution must provide research education, training and career development leading to an advanced degree (Masters or Ph.D.) for the next generation of clinical and translational researchers (including physicians, nurses, dentists, pharmacists, and other allied health professionals).
- T-2 The institution must provide one or more graduate degree-granting and post-graduate programs in clinical and translational science.
- T-3 The institution must demonstrate its commitment to education and training in the following areas:
- an existing higher degree-granting programs, such as Masters or Ph.D. in Clinical Research, on which they base their eligibility to apply;
 - plans to develop new educational programs in Clinical and Translational Science;
 - novel concepts, methodologies, and approaches that integrate the education, training, and career development environments;
 - plans to configure, operate and govern the K and T components of the proposal;
 - programs to enhance, shorten, and strengthen the training and career pathways for all clinical and translational research professionals;
 - guaranteed sufficient time for investigators to pursue clinical and translational research and mitigate the demands of providing patient care;
 - institutional incentives and rewards for new modes of team-based research that promote the academic mission;
 - criteria for certification and degree programs; and
 - a method to train, evaluate, and replace when necessary mentors.
- T-4 The institution shall make training available to key clinical research personnel (e.g., study coordinators, project managers, etc.) that teaches a range of topics that support their roles and responsibilities (e.g., research design, epidemiology, biostatistics, pharmacology, biomedical informatics, ethics, behavioral science, engineering, law).
- T-5 The institution shall demonstrate that research education, training, and career development permeates the CTSA program in the following:
- create a career development environment that offers a scope of training broad enough to meet the attention and needs of all those interested in careers in multi-disciplinary team-based clinical and translational science;
 - opportunities and support to develop and improve research methods that advance the discipline; and
 - novel and innovative instructional designs that focus on efficient, integrated and flexible approaches to research education and predoctoral training without risking the quality of the instruction.
- T-6 The institution must demonstrate that an interdisciplinary approach to their research education component is encouraged through various support mechanisms.

- The curriculum should be flexible to meet the needs of the institution and the participants.

T-7 The institution must have in place a Mentored Career Development Component-K-12 that fosters the discipline of clinical research by increasing clinical research capacity and the expedition of clinical and translational research.

- The mentor program will support the research career development of clinical researchers who have recently completed sub-specialty training and who are commencing basic, translational and/or clinical research.
- The mentor program bridges clinical training with research independence.

Clinical Trials (CT)

CTSA key function: Pilot and Collaborative Translational and Clinical Studies

- CT-1 The institution shall demonstrate the points of integration and the methods to integrate molecular medicine into the larger unit of CTR.
- CT-2 The institution shall make available the funds and organizational structure that 1) allow clinical and translational trainees or researchers to generate preliminary data for submission of a research grant application; 2) seek to improve clinical design, biostatistics, clinical research ethics, informatics, or regulatory pathways; 3) develop new technologies; or 4) others as defined by the applicant.
- CT-3 The institutions shall demonstrate an interest in promoting and encouraging applicants to develop innovative and creative research programs that bridge the functions of design, biostatistics, and clinical research ethics. For example, topics of interest could be the following:
- Limiting risk to participants
 - Preventing bias
 - Informed consent
 - Issues in diseases with limited treatment options
 - Improving enrollment
 - Capturing appropriate data
 - Development of design and analysis plans for studies using a small number of subjects
 - Development of design and analysis plans for studies in unique populations
- CT-4 Pilot and collaborative projects should, in general, be of sufficient scope to qualify as a stand-alone research effort and should be well integrated into the activities of the CTSA.
- CT-5 The institution shall provide an infrastructure that sustains intellectual exploration. For example, areas of interest could be in the following:
- New translational methodologies
 - New more effective and quantifiable phenotyping methods
 - Development of biomarkers
 - Research into clinical trials design
 - Clinical informatics for longitudinal studies
 - Ethics research specific to populations rather than specific trials
 - Predictive toxicology in human populations
 - Home-based research devices and methods

Outcomes/Population-based Studies (OS)

CTSA key functions: Clinical Trial Design and Methodology; Biostatistics

OS-1 The institution shall have the following in place to show key functions in clinical trial design and methodology:

- support that will be provided for clinical trial design and analysis;
- resources that will be available to develop tools or methods in these areas;
- approaches that will be taken to prioritize research topics or projects; and
- educational topics that will be available to instruct trainees.

Clinical Research Ethics (CRE)

CTSA key functions: Ethics

CRE-1 The institution shall have a department in position to study the ethical implications in the CRT topics.

CRE-2 The institution must have a system of policies and procedures in place that assures all human subject data is handled securely to ensure privacy and confidentiality.

CRE-3 The institution must teach medical ethics and human values, and require its investigators to exhibit scrupulous ethical principles (e.g. honesty, integrity, maintenance of confidentiality, and respect for human subjects, patients' families, other investigators and students, and other health professionals, etc.) in CTR activities, and in relating to patients', their families, and to others involved in the investigation.

- Each school should assure that researchers receive instruction in appropriate medical ethics, human values, and communication skills before engaging in CTSA. Adherence to ethical principles should be monitored and reinforced through formal systems.
- There should be a means for identifying possible breaches of ethics in research, either through investigator observation of the encounter, human subject reporting, or some other appropriate method as defined by the institution.

CRE-4 The institution's educational objectives should identify dimensions of ethical behavior.

- There should be a procedure in place to inform all investigators of the objectives.

CRE-5 The institution must show how clinical research ethics will be integrated into services.

Evaluation (Evl)

- Evl-1 The institution must describe an evaluation plan that assesses the administrative and scientific functioning and accomplishments of the CTSA.
- Evl-2 The institution must demonstrate that it has a structure in place to conduct self-evaluation activities of its Clinical and Translational Research and the CTSA.
- Evl-3 The institution must describe specific, well-defined objective criteria and concrete outcome measures to evaluate progress.
- Evl-4 The institution must explain their evaluation and tracking plan for all research education, training, and career development activities. This plan must include criteria to measure the effectiveness of all programmatic aspects (e.g. curriculum development, training faculty, program directors, etc.)

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