MAIN ACRONYMNS GLOSSARY				
Acronymn	**Full Term**	**Definition**	**Unit or Level**	**Website**
CPIRA	Council of Principal Investigators and Research Administrators	CPIRA consists of individuals elected to represent Principal Investigators and Research Administrators from members of the TAMUCC research community. CPIRA serves as a conduit between the administration and the research community; identifies and provides solutions to issues affecting the research enterprise; meets regularly with administrators via an executive committee; and serve on committees, task forces. and advisory groups addressing issues affecting the research community.	TAMUCC	https://www.tamucc.edu/research/cpira/
DRA	Departmental Research Administrator	Personnel assigned to assist a PI with the sponsored program administration at the Department Level	TAMUCC Department, Program, College, Institute, and/or Center	Varies
EVPR	Vice President for Research and Innovation	The VPR leads the planning, coordination, and implementation of programs of excellence in research. The VPR facilitates the pursuit of major research, scholarly and creative advancements, and multidisciplinary and interdisciplinary initiatives involving, as appropriate, major external funding and industries.	TAMUCC Research and Innovation Office	https://www.tamucc.edu/research/about/vpr/index.php
IRB	Institutional Review Board	The TAMU-CC IRB provides oversight and institutional reviews of research activities involving human subjects to ensure compliance with federal, state, and institutional regulations.	TAMUCC Office of Research Compliance in the TAMUCC Research and Innovation Office	https://www.tamucc.edu/research/compliance/irb/index.php
OEC	TAMUCC Office of Risk, Ethics and Compliance			
OGC	Office of General Counsel	The office provides legal services for the System Office and the A&M System member institutions, and coordinates and assists in litigation representation provided by the Office of the Attorney General of Texas. The office also secures and coordinates outside legal counsel services throughout A&M System. (Each university also has an Ethics and Compliance Officer.)	TAMU System	https://www.tamus.edu/legal/
ORC	Office of Research Compliance	ORC ensures that TAMUCC employees, faculty, staff, and students remain in compliance with regulations applicable to research activities.	TAMUCC Research and Innovation Office	https://www.tamucc.edu/research/compliance/index.php
OREC	Office of Risk, Ethics, and Compliance	OREC provides training and services to promote a culture of compliance campus-wide while mitigating significant risks, investigaiting and resolving allegations, and reducing the consequences of non-compliance with federal and state laws.		https://www.tamucc.edu/president/compliance/index.php
OSRA	Office of Sponsored Research Administration	OSRA facilitates and supports the research endeavors of TAMUCC constituents by providing administrative assistance in the preparation of research proposals through budget preparation, assembly, approval and submission of proposal documents, as well as in the negotiation and acceptance of research awards. OSRA provides the fiscal framework necessary to receive, disburse, and administer project funds.	TAMUCC Research and Innovation Office	https://www.tamucc.edu/research/osra/index.php

MAIN ACRONYMNS GLOSSARY				
Acronymn	**Full Term**	**Definition**	**Unit or Level**	**Website**
PI	Principal Investigator	The holder of an independent sponsored program and the lead researcher for the sponsored program. The PI is the person who takes direct responsibility for completion of a funded program, directing the research, and reporting directly to the funding agency. Sometimes also referred to as a Project Director (PD) for non-research projects.	TAMUCC Department, Program, College, Institute, and/or Center	Varies
SPA	Sponsored Program Administrator	OSRA personnel at TAMUCC provide high-level support to Principal Investigators and their staff with regard to management and oversight of awarded sponsored programs.	TAMUCC Research and Innovation Office	https://www.tamucc.edu/research/about/directory/index.php
SRS	Texas A&M Sponsored Research Services	TAMU SRS provides TAMUCC expertise and assistance with the process of proposal submissions for external funding.	TAMU System	https://srs.tamu.edu/

ADDITIONAL ACRONYMS GLOSSARY

AAHRPP – Association for the Accreditation of Human Research Protection Programs, Inc.
AAALAC – American Association for the Accreditation of Lab Animal Care
ADA – Americans with Disabilities Act
AID – Agency for International Development
AFOSR – Air Force Office of Scientific Research (DOD)
AO – Administrative Official
AOR – Authorized Organization Representative
ARRA – American Recovery Act
ATDSDR – Agency for Toxic Substances and Disease Registry (CDC Partner Agency)
BBA – Broad Agency Announcement
CAS – Cost Accounting Standards
CCR – Central Contractor Registration
CDC – Center for Disease Control
CFDA – Catalog of Federal Domestic Assistance
CFR – Code of Federal Regulations
2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
CITI- Collaborative Institutional Training Initiative
COGR – Council on Governmental Relations
COI – Conflict of Interest
CRA – Certified Research Administrator
CRADA or CRDA – Cooperative Research and Development Agreement
CRO – Contract Research Organization
CSR – Center for Scientific Renew (National Institutes of Health)
CV – Curriculum Vitae
DAR – Defense Acquisition Regulations
DARPA – Defense Advanced Research Projects Agency (DOD)
DCAA – Defense Contract Audit Agency
DFARS – Defense Federal Acquisition Regulation Supplement
DHHS – Department of Health and Human Services (also known as HHS – Health and Human Services
DOC – Department of Commerce
DOD – Department of Defense (includes Air Force, Army, ARPA, and NAVY)
DOE – Department of Energy
DOED – Department of Education
DOI – Department of Interior
DOT – Department of Transportation
DUNS – Data Universal Number System
EA – Expanded Authority
EAGER – NSF Early-concept Grant for Exploratory Research
iEDISON – Interagency Extramural Invention Information Management System
EPA – Environmental Protection Agency

MAIN ACRONYMNS GLOSSARY				
Acronymn	**Full Term**	**Definition**	**Unit or Level**	**Website**
F&A – Facilities and Administrative Costs*				
FACA- Federal Advisory Committee Act				
FAR – Federal Acquisition Regulations				
FCOI – Financial Conflict of Interest				
FDA – Food and Drug Administration				
FDP – Federal Demonstration Partnership				
FERPA – Family Educational Rights and Privacy Act				
FFATA – Federal Funding Accountability and Transparency Act				
FIC – Fogarty International Center (NIH)				
FOA – Federal Opportunity Announcement				
FOIA – Freedom of Information Act				
FTE – Full Time Equivalent				
FWA – Federal-wide Assurance				
GPG – Grant Proposal Guide (National Science Foundation)				
GSA – General Services Administration				
IAA – Inter-Agency Agreement				
IACUC – Institutional Animal Care and Use Committee				
IBC – Institutional Biosafety Committee				
IC – Informed Consent				
IDC – Indirect Costs*				
IGA – Inter-Governmental Agency				
IO- Institutional Official				
IRB – Institutional Review Board				
MOA – Memorandum of Agreement				
MOU – Memorandum of Understanding				
MTA – Material Transfer Agreement				
MTDC – Modified Total Direct Costs				
NACUBO – National Association of College and University Officers				
NASA – National Aeronautic and Space Agency				
NCATS – National Center for Advancing Translational Sciences (NIH)				
NCCIH – National Center for Complementary and Integrative Health (NIH)				
NCE – No Cost Extension				
NCI – National Cancer Institute (NIH)				
NCURA – National Council of University Research Administrators				
NEI – National Eye Institute(NIH)				
NHLBI – National Heart, Lung, and Blood Institute (NIH)				
NIA – National Institute on Aging (NIH)				
NIAAA – National Institute on Alcohol Abuse and Alcoholism (NIH)				
NIAID – National Institute of Allergy and Infectious Diseases (NIH)				
NIAMS – National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIH)				
NIBIB – National Institute of Biomedical Imaging and Bioengineering (NIH)				
NICHD – National Institute of Child Health and Human Development (NIH)				
NIDA – National Institute on Drug Abuse (NIH)				
NIDCD – National Institute on Deafness and Other Communication Disorders (NIH)				
NIDDK – National Institute of Diabetes and Digestive and Kidney Diseases (NIH)				
NIDCR – National Institute of Dental and Craniofacial Research (NIH)				
NIEHS – National Institute of Environmental Health Sciences (NIH)				
NIGMS – National Institute of General Medical Sciences (NIH)				
NIH – National Institutes of Health				
NIMHD – National Institutes on Minority Health and Disparities (NIH)				
NHGRI – National Human Genome Research Institute (NIH)				
NHLBI – National Heart, Lung, and Blood Institute				
NIMH – National Institute of Mental Health				
NINDS – National Institute of Neurological Disorders and Stroke (NIH)				
NINR – National Institute for Nursing Research (NIH)				
NIOS – National Institute for Occupational Safety and Health				

MAIN ACRONYMNS GLOSSARY				
Acronymn	**Full Term**	**Definition**	**Unit or Level**	**Website**

NLM – National Library of Medicine
NOFA – Notice of Funding Availability
NSF – National Science Foundation
OFPP – Office of Federal Procurement Policy
OHRP – Office for Human Research Protections
OGC – Office of General Counsel
OMB – Office of Personnel Manage and Budget
ONR – Office of Naval Research
OPAS – Organizational Prior Approval System
OPRR – Office for Protection from Research Risks (DHHS)
ORC – Office of Research Compliance
OSRA – Office of Sponsored Research Administration
PHS – Public Health Service
PHS 2590 – Application for Continuation of a PHS Grant (NIH)
PHS 398 – Application Form for a PHS Grant (NIH)
PI – Principal Investigator
PRDA – Program Research and Development Announcement
PWA – Partial Waiver of Authorization
RAPID – NSF Grants for Rapid Response Research
QA – Quality Assurance
RFA – Request for Applications
RFP – Request for Proposal
RFQ – Request for Quotations
S&W – Salary and Wages
SBA – Small Business Administration
SBIR – Small Business Innovative Research
SOP – Standard Operating Procedures
SOW – Scope of Work
SRAI – Society for Research Administrators International
SRS –Sponsored Research Services
SR – Significant Risk
STTR – Small Business Technology Transfer
T&C – Terms and Conditions
TTC – Texas A&M Technology Commercialization
USACE – United States of America Corps of Engineers
USFWS – US Fish and Wildlife Service (DOI)
WA – Waiver of Authorization

DEFINITIONS

1 Abstain. Refrain from voting.

2 Access. A method of obtaining data or information through either hard copy or electronic medium review.

3 Active Study. A study in which any of the following activities are ongoing: (1) advertisement and/or recruitment of participant(s), (2) interaction or intervention with current or potential research participant(s), (3) acquiring or recording identifiable private information for research purposes, and/or (4) analysis of identifiable data.

4 Administrative Hold. A voluntary interruption of research enrollment and/or ongoing research activities by an appropriate official, such as the IO, IRB Chair, IRB, Investigator, or Sponsor. This does not apply to interruption due to research related concerns for the safety, rights or welfare of human research participants, Investigators, staff or others.

5 Advertising. Any outreach effort intended to be seen or heard by a potential human research participants and designed, wholly or in part, to encourage them to contact the Investigator or study team for further information about a specific study.

6 Allocable Costs. Costs that actually benefit the grant or contract to which they are being charged.

7 Allowable Costs. Costs that can be charged to a grant, such as salaries and equipment. Certain types of costs, such as the cost of alcoholic beverages are not allowable and may not be charged to a contract or grant.

8 Assurance. An agreement between an organization and a federal agency that stipulates the organization will comply with regulatory requirements. A Federal-wide Assurance (FWA) is the organization's assurance with Office of Human Research Protections (OHRP). 45 CFR 46.103 (1/19/2017).

9 Basic Research. A fundamental research designed to answer a scientific question with the primary objective to advance the knowledge and theoretical understanding of the relations between variables. It is exploratory and often provides the foundation for the applied science or clinical research that follows. Laboratory researchers conduct these investigations in laboratories designed and equipped to withstand chemical hazards, to contain biological hazards, to accommodate physical hazards, and to provide emergency response. Basic and applied research may utilize or examine human or mammalian tissues, recombinant DNA, cell lines, or specimens; microorganisms, viruses, or toxins; or advanced technologies for evaluation. This science follows sound scientific principles, best safety practices, and is compliant with local, state, federal, and industry laws and procedural processes applicable to the conduct of research.

10 Challenge Grant. A grant that provides monies in response to monies from other sources, usually according to a formula. A challenge grant differs from a matching grant in at least one important respect: the amount of money that the recipient organization realizes from a challenge grant may vary widely, depending upon how successful that organization is in meeting the challenge. Matching grants usually award a clearly defined amount and require that a specified sum be obtained before any award is made. This form of grant is common in the arts, humanities, and some other fields, and less common in the sciences.

11 Certification. The official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance. 45 CFR 46.102(a)(1/19/2017).

12 Compensation. Cash, check, gift cards, gift certificate, or merchandise given in exchange for participating in a research study.

DEFINITIONS

13 Compliance. Adhering to the research protocol, federal regulations, relevant guidelines and/or the requirements and determinations of the Board. See also non-compliance.

14 Confidential Records. Documents to be kept with limits on access and/or restrictions on certain types of information to be disclosed, include but are not limited to: all memoranda; letters; notes; analyses; compilations; minutes of meetings, protocols and other submissions related to research studies; regulatory data; financial data; computer programs; e-mail; IRB members' curricula vitae; procedures; voice mail messages; manuals; documents; audio- and video-tapes; regulatory documents; reports; or other proprietary information created, possessed or obtained in the course of the IRB's business.

15 Confidentiality. Refers to the protection of an individual's private information once it has been communicated to another party and recorded as data.

a. ICH 1.16. Confidentiality Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

16 Conflict of Interest. A situation in which an individual or entity have financial or other personal considerations that may compromise or have the appearance of compromising his/her professional judgment in conducting his/her duties, conducting or reporting research, teaching, or performing other obligations as a professional.

a. For the purposes of an IRB member, a conflict of interest occurs when financial or other personal considerations may compromise, or have the appearance of compromising, a IRB member's deliberation in reviewing research protocols for the protection of human research subjects.

b. For purposes of an Investigator (Researcher and Research Staff- defined as anyone involved in the design, conduct or report of the research) - a conflict of interest occurs whenever an investigator at a site has personal or financial interests which compromise, or appear to compromise, the investigator's independent professional judgment in any aspect of the conduct of a clinical research study, including the protection and rights of the human subjects involved.

c. For the purposes of PHS funded research, a Financial Conflict of Interest is a Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS funded research.

17 Collaborative Agreement. A type of federal assistance; essentially, a variation on a discretionary grant, awarded by the sponsor when it anticipates having substantial involvement with the recipient during the performance of a funded project.

18 Consortium Agreement. Collaboration of investigators/institutions; arrangement can be formalized with specified terms and conditions.

19 Consultant. An individual with competence in a special area who assists the review of the research project.

20 Continuation Project. A project approved for multiple-year funding, although funds are typically committed only one year at a time.. At the end of the initial budget period, progress on the project is assessed. If satisfactory, an award is made for the next budget period, subject to availability of funds.

21 Continuing Review. A periodic review of ongoing research study conducted by an IRB at intervals appropriate to the risk of the study but not less than once per year to evaluate whether the study continues to meet regulatory requirements. 45 CFR 46.109(e); 21 CFR 56.109(f).

DEFINITIONS

22 Contract. A mechanism for procurement of a product or service with specific obligations for both sponsor and recipient.

23 Contributing Investigator. For repository protocols, an Investigator who deposits biomaterial/data into an established repository.

24 Contract Research Organization (CRO). A person or organization (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's study-related duties and/or functions. ICH 1.20.

25 Cooperative/Collaborative Research. The conduct of a joint research project in which one or more institutions meet the criteria for being engaged in human subjects research as described by PHS.

26 Covered entity. "Covered entities" are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) medical care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Covered entities can be institutions, organizations, or persons.

27 Department or Agency Head. The head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated. 45 CFR 46.102(c)(1/19/2017).

28 Deviation. Any unplanned instances of noncompliance with the protocol, Board requirements, federal regulations, or GCP.

29 DHHS (Department of Health and Human Services). The principal federal agency responsible for protecting the health of all Americans.

30 Direct Costs. Costs that can be specifically identified with a particular project or activity. Direct costs include those obtained through a sub-award.

31 Documentation. All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a research study, the factors affecting research, and the actions taken.

32 Electronic or Digital signature. An electronic signature is an electronic way or paperless method of documenting the identity of the signer and documenting an indication that the person adopts the intentions in the document.

33 Electronic record. Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

34 Engagement in Research.

a. In general, an organization is considered "engaged" in a particular human subjects research project when its employees or agents for the purposes of the research project obtain: (a) data about the participants of the research through intervention or interaction with them; (b) identifiable private information about the participants of the research; or (c) the informed consent of human participants for the research. OHRP, Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008).

DEFINITIONS

b. Personnel engaged in research. Personnel or persons engaged in research shall mean a person, whether designated as a principal investigator, sub-investigator, collaborator, fellow/resident, research coordinator, laboratory personnel or other support staff, who is involved in performing, assisting with, or supervising: (1) study procedures not typically performed for non-research purposes; (2) recruitment/enrollment of potential study participants; (3) informed consent or permission/assent process; (3) collecting, interpreting, or contributing to the analysis of research data; (4) communicating the results of research through scientific presentation or publication of abstracts and/or manuscripts; or (5) any other important study-related decisions. The term personnel engaged in research shall be used interchangeably with researcher or investigator.

35 Exception. A planned event that is to take place when performing a process or task using a specification, method, protocol or policy and procedure. The potential harm, outcome, or effect on quality is determined prior to the exception.

36 Expedited Review. A review carried out by the Board Chair or by one or more experienced reviewers designated by the Board Chair that involves either:

a. Some or all the research appearing on the list published in the Federal Register and found by the reviewer to involve no more than minimal risk or

b. A minor change in previously approved research. 21 CFR 56.110; 45 CFR 46.110.

37 Experienced IRB member. An IRB member who has participated in [define institutional policy on how to determine who is an "experienced IRB member", i.e., at least 10 meetings and has served as a primary presenter for at least 4 protocols (or who the IRB Chair determines has equivalent level of participation in convened meeting experience)], and who the IRB Chair has determined has sufficient knowledge of the regulatory requirements and Standard Operating Procedures.

38 Expiration Date. The first date that the protocol is no longer approved.

39 Facilitated Review. The review process used by local IRBs as they make a determination about whether to accept the review of a central IRB or another institution's IRB. The local IRB provides review for local context.

40 Fair Market Value. Retail cost of Tangible Property at the time of purchase.

41 Federalwide Assurance (FWA) or "Assurance of Compliance". A formal, written, binding commitment submitted to a federal agency by an institution conducting research involving human subjects.

42 Federal department or agency. A federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency). 45 CFR 46.102(d)(1/19/2017).

43 Federal Educational Rights and Privacy Act (FERPA). The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

44 Final Peer Reviewed Manuscript. The final, peer-reviewed manuscript is defined by NIH as: "The Investigator's final manuscript of a peer-reviewed article accepted for

DEFINITIONS

45 Final Report. Study information received after the study is completed or discontinued.

46 Finding of Noncompliance. A proven assertion of noncompliance.

47 Food and Drug Administration (FDA). An agency of the Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription, and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), and veterinary products. Among other responsibilities, the FDA regulates the process through which evidence of product safety and efficacy are developed, with particular emphasis on research involving human subjects.

48 Full IRB member. A person appointed by the Institutional Official and assigned as a full member.

49 Future Research. Research not covered by the protocol under which the data/biomaterial are originally collected.

50 Generalizable Knowledge. A general conclusion based on understanding acquired through experience that can be applied to a broader population.

51 Handwritten Signature. The scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

52 Hazardous. Dangerous, especially to people's health or safety. As used herein includes biohazards, chemical hazards, and physical (including radiation) hazards.

53 Health Insurance Portability and Accountability Act (HIPAA). Passed by Congress in 1996, this legislation resulted in regulations (the "Privacy Rule") which provide protections for individually identifiable health information.

54 Human Subject or Human Participant.

a. DHHS. Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

1 Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

2 Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 45 CFR 46.102(e)(1/19/2017).

b. FDA-regulated studies.

i. Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. 21 CFR 56.102(e).

ii. A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or a disease. 21 CFR 812.3(p)

iii. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

c. ICH 1.57 Subject/Trial Subject. An individual who participates in a clinical study, either as a recipient of the investigational product(s) or as a control.

55 Human Research Protection Program (HRPP). A general term to describe the program to administer the research involving human subjects research.

56 Incentive. Anything offered to participants, monetary or otherwise, to encourage participation in research.

57 Incidental findings. Findings that are abnormalities observed during the research study which are unrelated to the disease or condition being studied, but which may have clinical implications.

58 Identifiable private information. Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. 45 CFR 46.102(e)(5) (1/19/2017).

59 Informed Consent. A process whereby an adult (defined as the age of majority by state law, typically 18 years of age or older) is given sufficient information about planned research so that he/she can make an informed decision about whether or not to participate. Consent is considered "informed" when the required elements, as defined by reference regulations, have been exchanged and the study staff has ascertained to the best of their ability the participant has exercised their decisional making capacity. (See Assent, Children and Legally Authorized Representative).

a. ICH 1.28. A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form document.

60 Institution.

a. 45 CFR 46.102(f)(1/19/2017). Any public or private entity or agency (including federal, state, and other agencies).

b. 21 CFR 56.102(f). Any public or private entity or agency (including federal, state, and other agencies). The term facility as used in section 520(g) of the act is deemed to be synonymous with the term institution for purposes of this part.

61 Institutional Official (IO). An individual authorized to act for Schulman IRB and to assume, on behalf of the company, the obligations imposed by federal, state, and international law, as applicable, regarding human participants. This position is directly involved in the allocation of resources to the HRPP.

62 Institutional Review Board (IRB). For purposes of this SOP, "IRB" refers to the Texas A&M University-Corpus Christi Institutional Review Board, unless otherwise noted.

a. An institutional review board established in accord with and for the purposes expressed in the Common Rule. 45 CFR 46.102(g)(1/19/2017).

b. 21 CFR 50.3(i). An independent committee comprised of scientific, non-scientific, and non-affiliated members established according to the federal regulations which

DEFINITIONS

c. 21 CFR 56.102(g). Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

d. ICH 1.31. An independent body of medical, scientific and non-scientific members, whose responsibility it is to help protect the rights, safety and well-being of human subjects involved in a study by, among other things, reviewing, approving, and providing continuing review of studies, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the study subjects.

e. 45 CFR 46.102(g). An institutional review board established in accord with and for the purposes expressed in 45 CFR 46.102(g)(1/19/2017).

63 IRB Chair (also known as Chairperson). An individual responsible for leadership and oversight of all aspects of IRB review. Maintains superior level knowledge of, and ensures IRB compliance with regulatory requirements and HRPP Standard Operating Procedures. This position works with the Institutional Official (IO) to ensure the IRB effectively fulfills its obligation to help protect human research subjects.

64 IRB Member. A person sufficiently qualified to review research according to federal regulations and ethical guidelines, appointed by the Institutional Official and assigned as a primary or full member or as an alternate member.

65 Interaction. Communication or interpersonal contact between investigator and subject. 45 CFR 46.102(e)(3)(1/19/2017).

66 Interim Report. Site submitted study information received at the midway point of the study approval period that includes, but is not limited to, a completed form designated by Schulman for Interim Reporting, changes to the protocol, IC, investigator(s), and study location, and issues concerning compliance, unanticipated problems involving risks to human subjects or others, and subject safety. The Board may choose to require interim reporting if it determines that more frequent reporting is required during the approval period.

67 Investigator or Study Staff (aka study team).

a. Includes anyone engaged in research. Examples of study staff include persons who perform, assist with, or supervise the performance of: (1) study procedures, (2) informed permission/assent/consent process, and/or (3) collecting, interpreting, or contributing to the analysis of research data. OHRP does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. Note that if the individuals who provide coded information or specimens collaborate on other activities related to the conduct of this research with the Investigators who receive such information or specimens, then OHRP would consider such additional activities to constitute involvement in the conduct of the research.

b. For the purposes of PHS funded research "study team" includes the Project Director (PD) or Principal Investigator (PI) and any other person regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, which may include, collaborators or consultants. This includes, but is not limited to, Senior/Key Personnel.

c. 21 CFR 56.102(h). An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject) or, in the event of an investigation conducted by a team of individuals, is responsible leader of that team.

Note: DHHS, Guidance on Research Involving Coded Private Information or Biological Specimens (Oct. 16, 2008), http://www.hhs.gov/ohrp/humanparticipants/guidance/cdebiol.htm.

DEFINITIONS

68 IRB Approval.

a. 45 CFR 46.102(h)(1/19/2017). The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

b. 21 CFR 56.102(m). The determination of the IRB that the clinical investigation has been reviewed and ay be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

69 IRB Member. Appointed to the Board with voting privileges to include Primary Members, Alternate Members, Scientists, Non-Scientists, and Community Members.

70 IRB of Record. The IRB completing the initial review of human subjects research and the board responsible for continued oversight of the study.

71 IRS. Internal Revenue Service of the United States of America.

72 Joint Site. A location where research activities are being conducted when that research is being conducted by more than one institution.

73 Location. An additional physical address belonging to a site (i.e. same business entity) where research activities are being conducted.

74 Mass Media Advertising. Advertisement distributed through newspaper, radio, television, site or sponsor websites, social media websites, direct mail of letters/flyers/pamphlets, or broadcast emails.

75 Minimal risk. The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102(j)(1/19/2017); 21 CFR 50.3(k).

76 Miscellaneous Items. Any information that is obtained exclusive of typically required submissions or reporting to the review committee.

77 Monitoring. Monitoring may refer to either data monitoring or monitoring the conduct of research. Data monitoring means the systematic tracking of data from a research study with the intent to evaluate harms and benefits that accrue to participants. Monitoring the conduct of research means overseeing the progress of the study and ensuring that it is conducted, recorded, and reported in accordance with the protocol, Schulman policies and procedures, regulatory requirements, and IRB determinations.

78 National Institutes of Health (NIH). One of the world's foremost medical research institutions and the preeminent federal funder of medical research in the U.S. The NIH, comprised of 27 separate Institutes and Centers, is one of eight health agencies within the Public Health Service, which is an agency within the U.S. Department of Health and Human Services. The goal of NIH research is to acquire knowledge to help prevent, detect, diagnose, and treat disease and disability. The NIH mission is to uncover knowledge that will lead to better health for everyone.

79 NIH Guidelines for Research Involving DNA Molecules (generally referred to as NIH Guidelines). The NIH Guidelines detail safety practices and containment procedures for basic and clinical research involving recombinant DNA, including the creation and use of organisms and viruses containing recombinant DNA. The NIH Guidelines are a "living" document that was first drafted in 1976 as an outcome of a meeting of scientists concerned about addressing the potential public health and environmental risks associated with this developing technology. Since that time, the NIH Guidelines have been frequently amended to reflect evolving scientific understanding of recombinant DNA and its applications.

80 Non-compliance. Failure to comply with federal regulations, Schulman policies or procedures including those governing human research, or IRB determinations.

DEFINITIONS

a. Confirmed Non-compliance. An allegation of noncompliance that has been verified as a result of an investigation and/or monitoring.

b. Continuing Non-compliance. A repeated pattern of non-compliance or un-rectified instance of noncompliance that if unaddressed is likely to increase risks to research participants, adversely affect the rights, welfare and safety of research participants, or affect the scientific integrity of the study or the continued violation of Schulman policies, state and local laws, and/or federal regulations. The pattern observed may occur regardless of whether the non-compliance is a consequence of a lack of knowledge or a willful or intentional violation of the Schulman policies, state and local laws, and/or federal or international regulations, as applicable.

c. Serious Noncompliance. Any noncompliance that creates an increase in the risks to research participants, adversely affects the rights, welfare and safety of research participants, or adversely affects the scientific integrity of the study or results from a willful or intentional violation of Schulman policies, state and local laws, and/or federal or international regulations, as applicable.

d. [Define any locally used definitions of minor versus major noncompliance].

81 Noncompliance Committee. A committee composed of IRB members and Subject Safety Team representatives and designated staff formed to review noncompliance issues.

82 Non-Scientific IRB member. An IRB member whose primary expertise is in a non-scientific area.

83 Office for Human Research Protections (OHRP). Component of DHHS that provides leadership in the protection of the rights, welfare, and wellbeing of participants involved in research conducted or supported by the U.S. Department of Health and Human Services (DHHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.

84 OHRP Investigator. Representative of OHRP who has responsibility for conducting inspections of research investigators and Institutional Review Boards (IRBs).

85 ORI. Office of Research Integrity within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

86 Participant Non-Compliance. Variances from the IRB (and sponsor when one exists) approved protocol/protocol related materials by the research participant that have not been pre-approved and are not in the control of the researcher. They may or may not have increased risk to the participant and/or result in a negative consequence.

87 Payments. Cash equivalent given to research participants in exchange for their participation in research study. Previously labeled as compensation or stipend.

88 Permission. Agreement of parents or guardian to the participation of their child or ward in research.

89 Personal Identifiers. All the following direct identifiers of the individual: name, street name or address or post office box, telephone and fax numbers, email address, social security number, certificate/license numbers, vehicle identifiers and serial numbers, URLs and IP addresses, full-face photos or other comparable images, medical record numbers, health plan beneficiary numbers and other account numbers, device identifiers and serial numbers, and biometrics, including finger and voice prints.

DEFINITIONS

90 Plagiarism. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including plagiarism through the journal peer review process.

91 Private information. Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). 45 CFR 46.102(e)(4)(1/19/2017).

92 Public health authority. An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. 45 CFR 46.102(k)(1/19/2017).

93 Public Health Service (PHS). U.S. Public Health Service, an operating component of the DHHS.

94 Public health surveillance activities. The collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). 45 CFR 46.102(l)(2)(1/19/2017).

95 PHS Supported Research. Research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, agreement, or other form of PHS support. 42 CFR 93.102(b).

96 Principal Investigator (PI). The study team member responsible for the implementation of research. The PI bears direct responsibility for the management and supervision of the study team members and conduct of all research activities.

a. ICH 1.34. A person responsible for the conduct of the clinical study at a study site. If a study is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be called the principal investigator. See also "Subinvestigator"

b. ICH 1.35. An expression meaning "the investigator and/or institution, where required by the applicable regulatory requirements."

c. 21 CFR 56.102(h). An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

97 Private Information. Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is, or may readily be, ascertained by the Investigator or associated with the information) in order for obtaining the information to constitute research involving human participants. 45 CFR 45.102 (f).

98 Privacy. An individual's right to control access to him/herself i.e., controlling the dissemination of personal information and/or access to one's body.

DEFINITIONS

99 Protected Health Information (PHI). Any individually identifiable health information, maintained in any form or medium, including data elements specific to an individual from which the individual can be identified. Such data elements include but are not limited to the eighteen (18) data elements listed in 45 CFR 164.514(b)(2)(i).

100 Protocol. A research plan that governs the conduct of the research activity/experiment. A written study plan which includes, but is not limited to: study objective, design, methods, statistical methods and organization. This also includes amendments made to the original document.

a. ICH 1.44 Protocol. A document that describes the objective(s), design, methodology, statistical considerations, and organization of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guidance, the term protocol refers to protocol and protocol amendments.

b. ICH 1.45 Protocol Amendment. A written description of a change(s) to or formal clarification of a protocol.

101 Protocol File. The file where the protocol, any amendments, correspondence with the sponsor/CRO/SMO, and any study- related materials are stored. The Board reviews this file at least annually, or as otherwise directed by the Board, while a study is open.

102 PubMed Central. PubMed Central (PMC) (http://www.pubmedcentral.nih.gov/) is the U.S. National Institutes of Health (NIH) free digital archive of biomedical and life sciences journal literature.

103 Quality Assurance/Quality Improvement (QA/QI) Activities. Quality assurance/Quality improvement activities attempt to measure the effectiveness of programs or services. Such activities may constitute human participant research and require IRB review, if they are designed or intended to contribute to generalizable knowledge.

104 Reimbursement. Includes repayment to research participants and/or their family by proof of receipt, to cover out-of-pocket expenses they incur while participating in clinical research (e.g., reimbursement such as taxi fare or hotel).

105 Reportable Event Reports. Documentation of the event given by the study team to the sponsor, IRB, FDA or appropriate regulatory body.

106 Report to Board. Reports provided to IRB members to communicate determinations made outside of the convened meeting.

107 Repository (also known as Registry). A place or unit that procures, processes, stores and/or distributes human biomaterial and/or data expressly for future use in research. It may also store linked clinical and demographic data including individually identifiable health information.

108 Research.

a. 45 CFR 46.102(d)(1/19/2017). Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes unless the activities are deemed not to be research under 45 CFR 46.102(d)(1/19/2017).

b. When following Department of Education regulations, research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

DEFINITIONS

c. 21 CFR 56.102(c). Clinical investigation means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520 (g) of the act, or need not meet the requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by the FDA as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions for part 58, regarding nonclinical laboratory studies. The term research, clinical research, clinical study, and clinical investigation are deemed to be synonymous for purposes of this part.

109 Research Activity. All aspects of the conduct of a research study outlined in the scope of work protocol and reviewed and approved by the IRB (e.g., recruitment methods, consent process, research procedures, experiments, data collection, etc.).

110 Research Administration. A general term used to refer to the administrative and contractual obligations inherent to the conduct of research, including the following components: (1) budget development and approval; (2) contract review, negotiation and adherence; (3) securing research oversight committee approval and compliance with conditions of approvals; (4) patient billing practices; (5) funding guidelines; and (6) expenditure of funds.

111 Research Record. Any data, document, computer file, external computer device, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research created during the course of the research project. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; administrative records; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal participant protocols; consent forms; medical charts; and patient research files.

112 Research Site. The location where the research is to be conducted.

113 Resource. Refers to any book, periodical, journal or educational material that is part of the Schulman library (electronic or hardcopy) and available to employees and IRB members.

114 Research Misconduct (also known as Scientific Misconduct). Fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research or in reporting research results. Scientific misconduct is a significant departure from accepted practice of the relevant research community and is committed intentionally, knowingly, or recklessly. Misrepresentation of one's qualifications or ability to perform the proposed research in merit review applications or similar submissions falls within the definition of research misconduct. Scientific misconduct does not include honest error or honest differences in interpretations or judgments of data, nor does it include authorship disputes. 42 CFR 93.103. Also, it does not include improprieties such as conflicts of interest, misallocation of funds, sexual harassment, discrimination, and breaches of human research protections and animal welfare requirements. These improprieties are participant to other regulations, policies, and procedures.

115 Research Site. An organization associated with a study in which research activities will be conducted.

116 Risk. The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties.

DEFINITIONS

117 Scholarly and journalistic activities. Oral history, journalism, biography, literary criticism, legal research, and historical scholarship, including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. 45 CFR 46.102(l)(1) (1/19/2017).

118 Scientific IRB Member. An IRB member whose primary expertise is in a scientific area.

119 Serious Adverse Event (SAE). An SAE is an AE in human research that, in the view of the Investigator or Sponsor, results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions, congenital anomaly, or birth defect. An AE is also considered a serious adverse event when it does not result in one of the listed outcomes, but when, based upon appropriate medical judgment, may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

a. ICH 1.50. Any untoward medical occurrence that at any dose: Results in death; is life threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/ incapacity or; is a congenital anomaly/birth defect. (See the ICH Guidance for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.)

120 Short Form. A modified consent process that utilizes a general information summary and documents that the elements of informed consent have been presented orally.

121 Social and Behavioral Research. The goal of social and behavioral research is like biomedical research in establishing a body of knowledge and to evaluate interventions; however, the content and procedures often differ. Social and behavioral research involving human participants focuses on individual and group behavior, mental processes, or social constructs and usually generates data by means of surveys, interviews, observations, studies of existing records, and experimental designs involving exposure to some type of stimulus or environmental intervention.

122 Source Data. All information contained in original records or certified copies of original records of clinical findings, observations and other activities in the study required for the reconstruction and evaluation of the research that is contained in source documents.

123 Source Documents. The original documents, data, and records from which clinical trial case report forms (CRFs) are completed and medical information becomes available to the clinical investigator or his designee. Source documents can be, but are not limited to: site records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

124 Sponsor. A person who takes responsibility for and initiates a clinical investigation or research. The sponsor may be an individual or pharmaceutical company, governmental agency, academic hospital, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a Sponsor-Investigator. An entity that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators. 21 CFR 50.3(e); 21 CFR 56.102(j); 21 CFR 312.3.

DEFINITIONS

125 Sponsor-Investigator. This is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor. If an investigator is the developer of the drug, biologic or medical device, and no commercial manufacturer is involved, then the investigator is also the sponsor for the purposes of designing and organizing clinical trials. 21 CFR 50.3(f).

126 Sponsor Representative. A person working on behalf of the Sponsor to fulfill obligations of the Sponsor.

127 Stopping Rules. Stopping rules are predetermined guidelines that are used to determine that the study should be altered, placed on hold, or stopped, based on a review of study related events or analysis of collected data.

128 Study Related Supplies. Items that are required for the conduct of the study (i.e. study drug, thermometers, etc.) and are not considered to be Payment.

129 Study Staff/Study Team. A general term that designates any or all roles of PI, co-Investigator, sub-investigators, study coordinators, or other study staff roles.

130 Substantive Clarifications or Modifications. Where (1) the IRB's outstanding questions and/or required changes to the protocol, permission/assent/consent form(s), or other study documents do not allow the IRB to make the required determinations about research risks and benefits, the adequacy of privacy and confidentiality protections, or the adequacy of the informed consent process or (2) the IRB is unable to specify changes that would allow the IRB to make required determinations.

131 Suspension of Research. The temporary interruption of enrollment of participants or other research activities related to concerns regarding the safety, rights or welfare of human research participants, research Investigators, research staff or others. A protocol is suspended when the IRB or IRB Chair places a temporary halt on research that had been previously approved by the IRB so that no new research participants can be enrolled and no further research interventions on current participants, unless the IRB or IRB Chair decides that it is in the best interest of the research participants to have research interventions continued.

132 Tangible Property. Any item of value given to a research participant (e.g. a toy, a tote bag, a water bottle, etc.). May be reported as taxable income. This does not include Study Related Supplies.

133 Termination of Research. A permanent halt in the enrollment of new participants or other research activities related to concerns regarding the safety, rights or welfare of human research participants, research Investigators, research staff or others.

134 Translation. The process of converting a written document from one language into another, assuring that the language of the translated document has the same meaning as the written document in the first language.

135 Unaffiliated. A person who is not an employee or agent of Schulman currently receiving any benefits or payments from Schulman.

136 Waiver. A waiver …. or alteration, in whole or in part, of the authorization that is required by the.

137 Withdraw.

a. When a study participant discontinues his/her participation in research.

DEFINITIONS

b. A study team removes a pending application from IRB consideration by executing the "withdraw" activity.

RASCI System and Coding:

R = Responsible for the correct and thorough completion of the work to achieve the task

A = Accountable for the correct and thorough completion of the task, typically delegating the work to those responsible

S = Support for those who are responsible or accountable

C = Consulted as needed in order to complete the task (two-way communication)

I = Informed that task is underway/completed (one-way communication)

RESEARCH RELATED AGREEMENTS															
		College/Institute/Center				Research & Innovation							TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support Services	ORC	AVPR	AVPR2	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Requests material transfer, confidentiality agreements, data use agreements	A/R	C	I	I	C	S			I		I				
2	Reviews and negotiates material transfer, confidentiality agreements, data use agreements	S	C	I	I	A	R			I		I			C	
3	Signs material transfer, confidentiality agreements, data use agreements	S	I	I	I	C	S			C		A/R				

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REGULATORY COMPLIANCE															
		College/Institute/Center				Research & Innovation						TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support Services	ORC	AVPR	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Prepares and submits protocols for research involving human subjects, animal use, and biosafety hazards	A/R	I				I	S	S/C						
2	Verifies investigators are submitting protocols to appropriate compliance committee(s)	R	I				C	S	A						
3	Approves compliance protocols	S/C/I	I				I	I	A/R						
4	Verifies approval of compliance protocols (during award set up)		I				A/R	C	C						
5	Provides documentation of certification and representations to sponsor		I			R	S		S				A		
6	Verifies compliance with federal regulations regarding financial disclosure of potential conflicts of interest	R	C				R								OREC - A
7	Maintains export control documentation and clearances for faculty and staff	R	I				S		I						OREC - A
8	Completes and submits study extension for any terminating compliance protocols (if needed)	A/R	I				C/S	S	C						
9	Develop, draft, negotiate and establish compliance reliance agreements for subawards	C	S/C				C/I	A/R	S/C					C	
10	Issues compliance protocols to subrecipients relying on TAMUCC	S/C	I				S		A/R						
11	Maintains documentation to/from subawardees with reliance agreements to verify continuing review of expiring compliance protocols has been completed (if applicable)	C	I				A/R	I							

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PRE-AWARD: PROPOSAL PREPARATION AND SUBMISSION															
		College/Institute/Center				Research & Innovation					TAMUCC	TAMUS			
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support	ORC	AVPR	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Reviews requests for proposals for technical requirements	A/S	C/I										R		
2	Reviews requests for proposals for institutional compliance	A/S	C/I			S							R		
3	Prepares technical proposal	A/R	S										S		
4	Reviews proposed project to verify that it is in line with departmental and institutional mission	A	I	R	R								S/C		
5	Develops initial budget draft to accomplish proposed scope of work	A/S	C/I										R		
6	Reviews budget for appropriate salaries, fringes, tuition, indirects, and escalations	S/C	S/C/I	I	I	S							A/R		
7	Requests approval for cost share source account on mandatory and voluntary cost share (to department/center as applicable)	A/R	S/C	I/C	I/C								I		
8	Reviews and approves required cost sharing	C	C/I	A	A								S		
9	Reviews and approves voluntary cost sharing			A	A	S	S				A/R		I		
10	Request subaward commitment form and applicable documents from subrecipient	A	S/I										R		
11	Prepares final version of proposal as required by the sponsor and submits to SRS for institutional approval in advance of sponsor deadline in accordance with SRS submission deadline policy	A/R	S/C/I										I		
12	Completes and routes IDC waivers for college/department/R&I approval	A/R	S	I	I	S					I		S		
13	Approves IDC waivers			A	A						A/R		I		
14	Requests and documents university signature approvals of internal routing forms and, as appropriate, other attachments; and routes all forms for university approval	S/C/I	S/C/I										A/R		
15	Submits proposal to sponsor as dictated by sponsor instructions	S/C/I	S/C/I										A/R		
16	Maintains proposal pending files and database												A/R		
17	Maintains proposal status in Maestro	S	I										A/R		

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PRE-AWARD: PROPOSAL PREPARATION AND SUBMISSION															
		College/Institute/Center				Research & Innovation					TAMUCC	TAMUS			
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support	ORC	AVPR	EVPR	VP Finance / Comptroller	SRS	OGC	Other
18	Reviews and approves confidentiality agreements, data use agreements	A	C	I	I	S				C	A/R			C	

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AWARD AND AGREEMENT NEGOTIATION, ACCEPTANCE, AND ESTABLISHMENT															
		College/Institute/Center				Research & Innovation						TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support Services	ORC	AVPR	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Notify OSRA that a new project is anticipated to be awarded to TAMUCC, if new award notice is received	A/R-if notice is sent directly to PI	I				I						A/R-if notice is sent directly to SRS		
2	Submits additional requested documentation to the Sponsor (if applicable)	R	S/I			S	S						A/R		
3	Negotiate and approve project terms and conditions					A/R								C	
4	Accept award on behalf of University	S/C	I			R				A	A				
5	Reviews project terms and conditions with PI (upon receipt of SPS report)	I	A/R												
6	Establish project in Maestro system based on award documentation	I	I				A/R								
7	Establish account in FAMIS system based on award documentation. Send synopsis and a copy of award to PI and appropriate department support (e.g. business coordinator/manager)	I	I				A/R								

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AWARD TRANSFERS														
		College/Institute/Center				Research & Innovation						TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support Services	ORC	AVPR	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Notify OSRA that a new PI with existing awards is joining TAMUCC		I	A	A/R	I	I								
2	Notify OSRA that a PI with existing awards is leaving TAMUCC	A	A/R	C	C	I	I								
3	Sponsor notification for award relinquishment	A	C/I	C/I	C/I	S	R			C/I	C/I				
4	Conduct award transfer discussion meeting with Dean/Director & R&I	A/R	C/I	C/I	C/I	C/I	S			C/I	C/I				
5	Prepare inventory of equipment to be transferred	A	S	R	C/I	I	I				C/I				Property office-S
6	Approve inventory of equipment to be transferred	C	I	C/I	C/I	I	I				R				I
7	Prepare award reqlinquishing statement (or sponsor equivalent)	A	C/I	C/I	C/I	S	R				C/I				
8	Prepare sponsor required technical documentation or final technical report	A/R													
9	Prepare sponsor required financial documentation or prepares final report	I	S				A/R								
10	Termination of active subawards	C	C				A/R								
11	Request to close POs of subawards to be terminated		A/R				I								
12	submission of final invoice, if applicable	C	C				A/R								
13	Submission of final drawdown, if applicable	C	C				C					A/R			
14	Close out of existing award	C	C				A/R								

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AWARD FINANCIAL MANAGEMENT															
		College/Institute/Center				Research & Innovation						TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Preaward	OSRA Postaward	Research Support Services	ORC	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Request pre-award spending account (i.e., preliminary account) and approve costs from department fundingif not funded, if needed	R	A	C-Approve	C-Approve			S/I							
2	Request approval from sponsor for pre-award expenditures (if needed)	R	I					A							
3	Set up pre-award spending account in Maestro	I	I					A/R							
4	Prepare revised budget basd on changes in F&A applicable at the time of award, if needed	C/I	A/R					S/I							
5	Submit revised budget on new award to sponsor for approval (if applicable)	C/I	I					A/R							
6	Verifies allowability, allocability, reasonableness of expenditures as per Uniform Guidance	A/R	S/C/I					S/C/I							
7	Reviews expenditures in accordance with approved budget	A	A/R					R							
8	Provides oversight of sponsored project administration including the review and approval of cost transfers and effort reporting	S/C/I	S/C/I					A/R							
9	Determines effort allocation	R	A					I							
10	Initiates and encumbers personnel transactions	S/C/I	A/R												
11	Approval of allocating personnel expenses to sponsored project in HR systems	I	S/C/I					A/R							
12	Reviews and reports cost sharing to sponsor		S/C/I					A/R							
13	Initiates requests for rebudgeting on cost reimburseable projects throughout period of performance, as needed	A/R	S/C/I					I							
14	Internally approves and submits rebudget to sponsor for approval	S/C/I	S/C/I					A/R							
15	Initiates no-cost time extension to OSRA	A/R	S/C/I					I							
16	Submits request for no-cost time extensions to sponsor	A	S/C/I					R							
17	Approves payment of sub-recipient invoices (including certification on final invoice for agreement with completion of sub-recipient's work)	R/A	S					S/C/I							
18	Processes payment of sub-recipient invoices (Department receives and OSRA pays)		S					A/R							

19	Prepares and submits all invoices to sponsor	I/S	S					A/R							
20	Performs drawdowns (i.e., letters of credit)							S/C/I				A/R			
21	Monitors invoices and aging of receivables for sponsored projects	S/C	S					R/A							
22	Determines need for write-off of receivables	I		I	I	I		S/C/I				A/R		S/C	
23	Applies payment to proper fund							S/C				A/R			Bursar-AccRec
24	Reconciles accounts monthly and checks for errors	S/C	A/R					I							
25	Provide information for, prepare, and submit financial reports to sponsor, as required	s						A/R				C-Approval for Federal FFRs			

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AWARD NON-FINANCIAL MANAGEMENT														
		College/Institute/Center				Research & Innovation					TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support Services	ORC	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Conduct and oversee the execution of project aims or statement of work	A/R	S/C	I	I		I							
2	Hire research personnel for the project	A/R	S/C	I			I							
3	Assign research personnel for the project aims or statement of work	A/R	S/C	I			I							
4	Prepare technical reports and other deliverables to the sponsor as required	A/R	S/C				I							
5	Submit technical reports and other deliverables to the sponsor as required	A/R	S/C				S/I							
6	Provide oversight on the implementation of university, state, and federal policies and regulations	S/C/I	S/C/I	S/C/I	S/C/I	A/R	A/R		A/R	A/R				
7	Review programmatic changes to the project	A/R	S/C/I	C/I	C/I	C/I	C/I			C/I				
8	Notification to sponsor of programmatic changes to project	A/R	I	C		I	S							

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EFFORT REPORTING														
		College/Institute/Center				Research & Innovation					TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support Services	ORC	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Reviews effort report for personnel working on each award before release to certifiers (if applicable)		R/A											
2	Certify Time and Effort reports including approving certification of other personnel and communicates instances of potential errors for correction	R/A	S/C/I											
3	Monitor certification status and send notices regarding uncertified effort	S/C	S/I				R/A							
4	Manage time and effort reporting system					R/A								

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OUTGOING SUBAWARDS														
		College/Institute/Center				Research & Innovation					TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support Services	ORC	EVPR	VP Finance/ Comptroller	SRS	OGC	Other
1	Initiate request to OSRA for subaward agreement if not already initiated during project setup	R	A				I							
2	Completes risk assessment prior to awarding	C/I	I				R/A							
3	Completes visual compliance prior to issuance of subaward agreement is prepared (if applicable)	I	I			R	A							C-Wanese
4	Develop, draft, negotiate and establish sub-award	C	C			S	R/A						C	
5	Develop, draft, negotiate and establish compliance reliance agreement	S/C/I				S	A	R	C					
6	Issuance of compliance protocol to subrecipients relying on TAMUCC						R	C	C					
7	Requests documentation from subawardees to verify if IACUC, IRB, and/or IBC protocols are in place (if applicable)	C					A/R							
8	Create purchase order in Islander Buy for subaward (at time of award)	C/I	R/A				I							
9	Review and approve technical reports from subawardees	R/A	I				I							
10	Completes annual risk assessment for active subawards						R/A							
11	Reviews subrecipient invoices for fiscal compliance	R	S				A							
12	Requests documentation from subawardees to verify continuing review of						R/A	S						
13	Approves payment of subrecipient invoices (including certification on final invoice for agreement with completion)	R/A	S				S/C/I							
14	Processes payment of sub-recipient invoices (Department receives and OSRA pays)		S				R/A							
15	Confirm closeout of subaward including verification of receipt of final technical report(s) and final invoice	A/R	C/I				I							
16	Request liquidation of purchase order for subaward for closeout (email sent to Buyers and/or comment on the PO in Islander Buy)	I	R/A				I							

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CLOSEOUT														
		College/Institute/Center				Research & Innovation					TAMUCC	TAMUS		
#	Category	PI	DRA	Dept Head	Dean/ Director	OSRA Director	OSRA Postaward	Research Support Services	ORC	EVPR	VP Finance / Comptroller	SRS	OGC	Other
1	Confirms closure of award as scheduled	R/A	S/C/I				I							
2	Freeze account from all activity (i.e. 30 days after period of performance ends or final invoice is submitted, whichever is first)						R/A							
3	Prepares and submits final technical reports to sponsor	R/A	I				I							
4	Prepares and submits financial report and final invoice to sponsor, as required	I	S/C/I				R/A				C-Approves Federal FFRs			
5	Respond to Maestro closeout checklist		R/A				R/A							
6	Terminates project and account including cost share		C				R/A							
7	Initiates request to transfer residual balance		R/A				I							
8	File appropriate closeout documentation required by sponsor	C	C				R/A							
9	Request approval for deletion of closed files according to record retention schedule						R/A							
10	Approves request for deletion of closed files according to record retention schedule						I							R/A TAMU-CC Records Officer
11	Notifies stakeholders to destroy all project related records, per record retention schedule	I	I	I	I	I	R/A							
12	Destroys closed files	R/A	R/A				R/A							

Records Retention Schedule and Forms | record-retention-schedule-and-forms | Records Management | Research | Library | Texas A&M University-Corpus Christi (tamucc.edu)