

POLICY MANUAL

VOLUME VIII

ACADEMIC RESEARCH

July 2022

GEORGIAN COURT UNIVERSITY

THE MERCY UNIVERSITY OF NEW JERSEY

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Academic Research Policies

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**Volume VIII
Research Policies**

8.1 Policy for Review of Research Involving Human Subjects

| POLICY FOR THE REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS | |
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| Effective Date: | [To be inserted by the University] |
| Policy Number: | VIII -8.1 |
| Supersedes: | Not Applicable. |
| Issuing Authority: | [TBD] |
| Responsible Officer: | [TBD] |
| Applicability: | All University employees and students engaging in human subject research. |
| History: | |

PURPOSE

Georgian Court University is responsible for safeguarding the rights and welfare of human subjects in any research, development, and related activity. See also Volume I, paragraph 1.7.4.3 of the *Georgian Court University Policy Manual* for information regarding the Research Standards Committee and Institutional Research Review Board (IRRB).

POLICY

Georgian Court University is committed to a policy of safeguarding the rights and welfare of all human subjects in research. As standards for the ethical treatment of human subjects, Georgian Court University accepts the principles set forth by the national Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in its report *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (commonly known as the Belmont Report) and Title 45, section 46 of the U.S. Code.

DEFINITIONS

Assent—an affirmative agreement by an individual not competent to give legally valid informed consent (e.g., a child or person who is cognitively impaired) to participate in research.

Human Subject—means a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual; and/or (b) identifiable private information (45 CFR 46.102 f).

Informed Consent—a person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information (purpose of study, methods used, risks and benefits involved from participation etc.), to participate in research.

Interaction—includes communication or interpersonal contact between investigator and subject.

Intervention—includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102 f.2)

Minimal risk—means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102 i)

Principal Investigator (PI)—means a person who has ultimate administrative and fiscal authority in conducting and coordinating a research project.

Private Information—includes 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 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 subject 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 subjects. (45 CFR 46.102 f.2)

Legally Authorized Representative—means an individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minor—generally means a person who is under the age of 18 who is not an emancipated minor except for certain purposes as specified by law.

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 these regulations, whether or not they are supported or funded under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities. (45 CFR 46.102 d)

Unanticipated or Unexpected Result—refers to an adverse event or other problem arising during the research the specificity or severity of which is not consistent with information already provided to the IRRB. Adverse events are categorized as follows:

Adverse Events—undesirable and unintended, though not necessarily unanticipated, injuries or physical or emotional consequences for the subject.

Serious Adverse Events—adverse events which are fatal or life-threatening; that result in significant or persistent disability; that require hospitalization, or represent a significant hazard or potentially serious harm to research subjects or the researchers and their staff.

Unanticipated Problems—specific events experienced by subjects or developments that occur during implementation of research protocols that suggest the potential for increased risk to research subjects or the researchers and their staff.

Vulnerable Populations—human research subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Vulnerable subjects must be afforded special safeguards in a study to protect their rights and welfare. See 45 CFR 46.111(b) 21 CFR 56.111(b)

PROCEDURES/GUIDELINES

I. Purpose and Responsibilities of the IRRB

The purpose of the IRRB, as stated in Volume I of the Georgian Court University Policy Manual, is to advise on the ethical standards of those conducting research using humans.

In this role, the IRRB is vested with the ethical imperative to safeguard the rights and welfare of human and animal subjects in research studies at Georgian Court University and has jurisdiction over any research project that involves or has the potential to involve human beings or animals as the subjects of research and that is proposed to be carried out by a member of the University community (including faculty, students, staff, and administrators), or proposed to be carried out on University property, or that involves members of the GCU community as subjects of the research.

The responsibilities of the IRRB include:

1. Formulating guidelines and policies that meet federal regulations, incorporating the ethical concerns for the entire Georgian Court University community, and reflecting the particular needs of Georgian Court University's researchers. These guidelines and policies are to be approved by the President of Georgian Court University in consultation with the Provost;
2. Providing information to researchers as to the appropriate means for protecting the rights and welfare of subjects, securing the effective, free, informed consent of human subjects, and fulfilling federal, local, and the standards of Georgian Court University regarding human research;
3. Reviewing all proposals for human research submitted to the IRRB by faculty, student, or administrative researchers to assure concordance with aforementioned guidelines. The guidelines shall specify which research is included and which is exempt from the IRRB's review; and
4. Maintaining adequate records and confidentiality and preparing a yearly report for the President on the research approved.

II. Human Subject Research Procedures and Guidelines

A. Statement of Principles

The following are the principles governing Georgian Court University in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research:

1. Research must be justifiable for its scientific or other meaningful purpose or value;
2. Even if an inquiry has scientific or other value, it must not be pursued if benefit is outweighed by risk to the subject;

3. The research must be conducted by sufficiently competent and knowledgeable people
4. The research must be conducted under a sound design, suited to the nature of the study;
5. Informed consent is a process ensuring ethical conduct of research. No person should serve as the subject of research unless he or she, or an authorized or legal representative, has given voluntary consent after being fully informed of the nature, risks, and benefits of the study and their rights as participants. Additional safeguards must be included in the study to protect the rights and welfare of subjects;
6. Participation as a subject in a research study should be voluntary, and care should be exercised to ensure that subtle pressures are not used to obtain participation;
7. Care must be taken throughout the duration of the research study (and sometimes beyond) to ensure against the risk of harm to subjects, either physical or emotional;
8. Research must be terminated if there arises a serious risk of harm to subjects, either physical or emotional;
9. The subject should be entitled to withdraw from participation in a research study at any time.

C. Criteria for IRRB Approval of Research

In order to approve human subject research covered by this Policy, the IRRB will determine that all of the following requirements are satisfied:

1. Risks to Subjects are Minimized

Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. Minimal risk implies that the likelihood and degree of harm or discomfort expected as a result of the research are not greater than the risks encountered during the course of daily activity or during the course of routine physical or psychological examinations. Such risk considerations should not be limited to physical risk alone, but should also consider emotional and psychological risk, personal risk, and possible insurability risk.

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

B. Selection of Subject is Equitable

In making this assessment, the IRRB will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as minors, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Investigators should detail any extra precautions taken to safeguard the rights and welfare of subject populations.

C. Informed Consent and Assent

Informed consent has been obtained and appropriately documented from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required set forth in the General Requirements for Informed Consent section of this Policy.

D. Subject Safety

Where applicable, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. The IRRB will review who has been identified as having the primary responsibility for analyzing individual events to determine whether the study should be modified to minimize risk to current or future research subjects.

E. Privacy of Subject & HIPAA Compliance

When appropriate, the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

For research activities involving Protected Health Information (PHI), which is defined as individually identifiable information maintained in any medium, the IRRB acts as the institution's Privacy Board (required by HIPAA) to review and approve the proposed access, use, and disclosure of the PHI. The IRRB is responsible for determining whether research subjects are required to sign an authorization for the use and disclosure of their PHI, or if one of the exceptions to the authorization requirements applies. Examples of these exceptions include waivers of authorization and the use of de-identified data or limited data sets.

F. Vulnerable Subjects

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as minors, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. A full description of safeguards to ensure the fair and equitable treatment of these subjects and protect their rights and welfare can be found in the Department of Health and Human Services Office for Human Research Protections Code of Federal Regulations (see <http://www.hhs.gov/ohrp/policy/populations/index.html>).

G. Required IRRB Training

The University offers an IRRB training course through the <https://phrp.nihtraining.com/users/login.php>. This training is up-to-date and meets the federal requirements for training in human subjects protections. Completion of

this training is required for individuals participating in the IRRB process, including investigators.

C. Submission of Applications for Research Involving Human Subjects

The Georgian Court University IRRB will review and have authority to approve, require modifications in, or disapprove all research activities covered by this document. Any person wishing to conduct research involving human subjects must submit a proposal to the IRRB. This includes faculty and staff research, graduate student projects, and undergraduate projects, including class projects. No involvement of human subjects may take place prior to formal, written notification from the IRRB.

The applicant must complete Request for Approval of Human Subjects Research Georgian Court University - Institutional Research Review Board (IRRB) Form and submit it to the applicant's departmental IRRB representative, or if no such representative exists, to the Chair of the IRRB. The form must be neatly typed and accurately completed. The IRRB review cannot be accomplished unless all of the sections are completed. Any application that is not completed properly will be returned, possibly resulting in a delay in the review process.

D. Levels of IRRB Review

1. Projects Exempt from Review

Exempt research activities involve no more than minimal risk and may include classroom studies, surveys, observation of public behavior, the non-invasive collection of physiological data, and the analysis of existing data that involves human subjects. Research that includes both exempt and non-exempt categories is not exempt. More detailed information regarding exempt research activities may be found at 45 CFR §46.101(b) (see also <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101>). Irrespective of whether a study is exempt from full review, it must meet accepted standards of protection of privacy and a subject's right to refuse participation without penalty.

IRRB exemption reviews may be carried out by the IRRB Chair, or at the discretion of the Chair, by one or more experienced reviewers designated by the Chair from among members of the IRRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in CFR 45§46.108(b).

Under normal circumstances, the Chair or another member is able to review protocols in this category by the next committee review meeting, assuming the application does not lack essential information or questions arise that cannot be promptly and fully answered by the investigator. In determining whether an IRRB application and research is exempt from full IRRB review, the IRRB Chair or other IRRB member will utilize the Office for Human Research Protections decision charts (see <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>). If the activity does not qualify for exemption, the IRRB Chair or a designee notifies the

investigator in writing or via email. If the IRRB Chair, or designee, determines that an application does not qualify for exemption, the application will be processed either through Expedited Review or by full IRRB review.

The IRRB reserves the right to request the investigator to provide additional information concerning applications or reports.

Note: Surveys conducted as a part of student life or student success assessment activities, as well as student life areas conducting surveys to measure academic student progress are exempt from IRRB review.

2. Expedited Review

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRRB. Federal regulations make provisions for certain categories of research to be reviewed through an expedited procedure if the research involves no more than minimal risk. Expedited review is intended to enable the University to conserve administrative resources, provide timely reviews and focus the convened meetings of the IRRB on those research activities involving greater risks or ethical complexities. In addition, the IRRB may also use the expedited review procedure to review minor changes in previously approved research during the period covered by the original approval.

Research protocols that qualify for expedited review must meet two conditions: (a) the research must be determined to be minimal risk; and (b) all proposed research activities must be included in the list of eligible categories of expedited research as established by the DHHS for this purpose (see <http://www.hhs.gov/ohrp/policy/expedited98.html>). See also the Office for Human Research Protections expedited review decision chart (see <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>).

Under expedited review procedures, reviews may be carried out by the IRRB Chair, or at the discretion of the Chair, by one or more experienced reviewers designated by the Chair from among members of the IRRB. The expedited reviewer possess all the same authorities as the full IRRB to approve, modify, or conditionally approve the proposed research activities, except the authority to disapprove a research activity. A research activity may be disapproved only after review in accordance with the ordinary, non-expedited procedure set forth in 45 CFR 46.108(b).

Under normal circumstances, the Chair or other assigned reviewer(s) is able to review protocols in this category within 10 business days after receipt of a substantively complete protocol.

3. Full IRRB Committee Review

A Full-Board Review occurs when the Request for Approval of Human Subjects Research Georgian Court University - Institutional Research Review Board Form and research protocols involve more than minimal risk to research participants or vulnerable populations of research participants (other than minors when the protocol qualifies for expedited review) and are reviewed by the IRRB at a

convened meeting. Full board review is required for studies that involve greater than minimal risk or vulnerable populations that require special protection by the IRRB. These populations include, but are not limited to: pregnant women, human fetuses and neonates, prisoners, and minors.

Examples of greater than minimal risk are:

- A clinical interventional study that randomly assigns human subjects to alternative experimental or placebo groups; and
- Studies involving sensitive information connected to personal identifiers.

Investigators intending to conduct research which will require full IRRB review should submit a Request for Approval of Human Subjects Research Georgian Court University - Institutional Research Review Board Form through the departmental representative (the “submitting representative”) or if no such representative exists, to the Chair of the IRRB. The submitting representative will send copies of the proposal to the other IRRB members. The IRRB members will read the proposal and return comments to the submitting representative either in writing or by electronic mail. The submitting representative will then summarize the comments of the committee and, given unanimous approval by IRRB members, approve the study using the Request for Approval of Human Subjects Research Georgian Court University - Institutional Research Review Board (IRRB) Form. The submitting member must have approval from a majority of IRRB members in order to approve a study.

In determining whether an IRRB application and research is subject to full IRRB review, the IRRB will utilize the Office for Human Research Protections decision charts (see <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>).

The IRRB will attempt to review any full-IRRB research proposal and respond with a decision within thirty (30) days of receipt of the proposal. When a proposal is submitted, it is checked for completeness. The IRRB will evaluate the proposal for the extent to which it provides for the protection of human subjects, demonstrates scientific merit and meets the criteria set forth in the *Criteria for IRRB Approval of Research* section above. A majority of the members of the IRRB must be present at a convened meeting, including at least one member whose primary concerns are in nonscientific areas. In order for the application to be approved, it must receive the approval of a majority of those members present at the meeting. The IRRB chair will notify the investigator of the outcome of the full review.

E. Conflicts of Interest

If a member of the IRRB wishes to conduct a study, that committee member may submit the study for expedited review to any other IRRB member, or for committee review through any other IRRB member; however, that member cannot participate in the evaluation.

F. IRRB Action & Length of Approval

The investigator will be notified in writing (print or electronic) of the IRRB's action on his/her research proposal. These actions include:

Full Approval: The IRRB approves the proposed purpose and design as described in the application for a period of one (1) year to conduct the approved research study. The investigator is responsible for informing the IRRB in writing of any change or modification made to the study after approval is secured and/or continuing progress reports may be required.

Contingent Approval: An application receiving contingent approval requires additional information or minor revision. When the requested changes have been made, the IRRB Chair has the authority to provide full approval.

Deferred: Applications that are deferred require significant revision and must be resubmitted for IRRB review.

Denial: This is a rare action and is taken only when, in the judgment of IRRB members, the risks of the research outweigh the benefits to study participants, or other, significant problems exist specific to the proposed study. All objections of the IRRB member(s) will be outlined on the form.

Suspension or Termination: The IRRB has the authority to suspend or terminate any research project, including projects with full approval, that is not being conducted in accordance with the IRRB's decisions, conditions, and requirements, or when unexpected serious harm to human subjects has been discovered. The investigator will receive a written explanation of the decision for suspension or termination. Any suspension or termination of approval will be determined by the committee as a whole, shall include a statement of the reasons for the IRRB's action and shall be reported promptly to the investigator and appropriate University officials.

G. Periodic Review of the Approved Research

The investigator must inform the IRRB in writing of the progress of the research one year after approval and, if necessary, apply for extension of the research.

H. Revisions and Resubmission of Rejected Research Proposals

If an application has been rejected, the applicant may revise the proposal and resubmit it to the IRRB Chair. If the submitting representative deems that all the objections outlined by the IRRB have been answered, the submitting representative may approve the study.

I. Unanticipated or Unexpected Results

In the event of an unanticipated or unexpected result, the investigator is required to submit a written report to the IRRB. It should contain sufficient information for the IRRB to judge whether or not the event raises new questions about either the risk/benefit ratio or the design of the research. Typically, the written report serves as IRRB notification; however, in the instance of a serious adverse event, the investigator must notify the IRRB immediately then file the report within the time frame noted below. The time frame for the submission of the report is determined by the type of unanticipated or unexpected event that has occurred.

- When an adverse event is serious and unanticipated, the investigator must notify the IRRB in writing within 24 hours or by the end of the next working day.
- When an adverse event is serious but not unanticipated, the investigator must notify the IRRB within five (5) working days.
- When an adverse event occurs which is not serious but is unanticipated, the PI must notify the IRRB within 10 working days.
- When an unanticipated problem (UP) occurs which does not meet the definition of an adverse event, the investigator must notify the IRRB within 10 working days.

The written report must contain the following information: IRRB study number; Title of Protocol; Name of Principal Investigator; Date of Event; Description of Event including nature of injury or other adverse occurrence, assessment of severity, and assessment of the relationship to the study; Handling/response of the researcher to the event; Proposed changes in either research protocol or consent form in response to the event; and Signature of the investigator.

J. Proposed Changes to Research Protocol

The investigator is responsible for obtaining prior approval for proposed changes to an approved research protocol. Expedited review procedures may be used for certain kinds of research involving no more than minimal risk, and for minor changes in approved research (see CFR 45 §46.110). Under an expedited review procedure, the review may be carried out by the IRRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in CFR 45 §46.108(b).

If the procedural change is judged to involve more than minimal risk, intentional deception, or questions pertaining to a protected population and does not meet the categories for exempt or expedited review it must be presented to a convened full review board for discussion and consideration of approval or non-approval. The IRRB reserves the right to request the investigator to provide additional information concerning the application for a procedural change. After review, the IRRB will send the applicant formal notification of IRRB actions.

K. Informed Consent

1. General Requirements for Informed Consent

Informed Consent must be obtained from all research participants, regardless of the level of IRRB review. In these instances, the investigator must ensure that the informed consent of each subject is documented.

The following are matters that must be communicated to a subject before Informed Consent is given:

1. A statement of the purpose of the Human Subjects Research, the expected duration of the subject's participation, a description of any procedures to be followed, and an identification of any procedures that are experimental;
2. A description of any treatment included in the research, and the probability of random assignment to each treatment;
3. A description of any foreseeable risks and benefits to the subject;
4. If the research involves a risk of harm to the subject, an explanation of whether any compensation or medical treatment is available if injury occurs to the subject and if so, what that compensation or treatment will be;
5. A statement of the subject's responsibilities with respect to the research;
6. A statement describing how confidentiality will be maintained or private information identifying the subject will be dealt with;
7. A statement concerning the access to the subject's records that the IRRB and any auditors will have for the verification of the procedures and data associated with the research;
8. The name and contact details of a person the subject may contact for further information regarding the research, a statement of the subject's rights, and the name and contact details of a person the subject should contact in the event of injury arising in conjunction with the research; and
9. A statement that the subject's participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may stop participating at any time without penalty or loss of benefits to which the participant is entitled.

To the extent that is relevant, the Informed Consent must also include a statement addressing any cultural or religious concerns of the subject; a description of any foreseeable risks to an unborn fetus carried by the subject or to an infant being nursed by the subject; a statement of any anticipated circumstances under which the subject's participation in the research may be terminated by the Investigator without the subject's consent; a statement of any costs to the subject that may result from participation in the research; a statement of the consequences of a subject's decision to withdraw from the research and a description of the procedures for an orderly termination of participation by the subject; and a statement that any significant new findings developed during the course of the research, if they may relate to the subject's willingness to continue participation, will be provided to the subject.

Vulnerable Subjects: A Principal Investigator who seeks to obtain informed consent from vulnerable individuals must provide additional elements of protection, both with regard to obtaining and documenting informed consent, where that is necessary for the welfare of the subject. In the case of vulnerable subjects, consent is typically obtained from parent(s) or legal guardian(s). However, an understandable explanation of the research procedures should also be given to the minors or other vulnerable participants (populations such as pregnant women, prisoners, those who lack the capacity to consent, non-English speaking individuals, etc.) for whom consent has been obtained,

and they should be given the chance to volunteer to participate in the proposed activity. This is called “assent.” Their wishes determine their participation.

2. Documentation of Informed Consent

Informed consent shall be documented by the use of a written consent form and signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be either of the following:

- A written consent document that embodies the elements of informed consent required by paragraph J above. This form may be read to the subject or the subject’s legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
- A short form written consent document stating that the elements of informed consent required by Paragraph J above have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

The IRRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRRB may require the investigator to provide subjects with a written statement regarding the research.

3. Internet-Based Human Subject Research

All internet-based research studies must incorporate the principles of voluntary participation and informed consent; maintain the confidentiality of information obtained from or about human subjects; and appropriately address possible risks to participants, including psychosocial stress and related risks.

Internet-based research may not be suitable for studies involving greater than minimal risk, particularly where the research involves vulnerable populations or data that:

1. Places subjects at risk of criminal or civil liability;
2. Could damage subjects' financial standing, employability, insurability, or reputation; or
3. Places subjects at risk for identity theft.

Exceptions to the minimal-risk standard may be made at the discretion of the IRRB, but may involve additional consent requirements as defined below.

Recruitment: Internet-based procedures for advertising a study and recruiting potential participants must follow the IRRB guidelines for recruitment that apply to any traditional media, such as newspapers and bulletin boards. Additionally, advertising and recruitment efforts must comply with the University's information technology policies.

Informed Consent Process for Internet-Based Research: Typically, internet-based research involving minimal risk to participants does not necessitate hard-copy documentation of consent. Instead, a variation of the following statement must be visible on the screen prior to entering the survey: "Confidentiality will be maintained to the degree permitted by the technology used. Your participation in this online survey involves risks similar to a person's everyday use of the internet. By clicking "submit" upon completion of the survey, you are granting consent for your responses to be included in the research study."

Internet-Based Research Involving Minors: Investigators are not permitted to collect personal information from a child without posting notices about how the information will be used and without obtaining parental permission. Written permission must be obtained via postal mail or scan. A face-to-face interview must be conducted to obtain parental consent for studies with minors that involve more than minimal risk.

Internet-Based Research Data Collection: Any data collected from human participants through the internet must be transmitted in encrypted format, using the highest level of encryption that is reasonable within limits of availability and feasibility. Encryption helps to ensure that any data intercepted during transmission cannot be decoded, and that individual responses cannot be traced back to an individual respondent. Investigators are cautioned that encryption standards vary from country to country.

It is recommended that internet-based survey instruments be formatted in a way that will allow participants to skip questions if they wish or provide a response such as "I choose not to answer." Also, at the end of the survey, researchers should consider adding two buttons: one to allow participants to discard the data and the other to submit it for inclusion in the study. Finally, consideration should be given to including a mechanism for withdrawal.

Research in Online Communities: Conducting research in online communities, such as chat rooms, blogs, social sites, and gaming sites, requires investigators to respect the privacy and right to consent of members of the communities. Joining an online community for the purpose of surreptitiously collecting information and quotes for a research study is unethical and would not be approved by the IRRB. Instead, an investigator may set up his or her own chat room. Each person who joins the chat room must be greeted with a statement about the research study as well as a statement of

informed consent, and must be offered the opportunity to exit the chat room if they do not wish to participate.

Internet-Based Research Software and Server Guidelines: For minimal-risk studies that do not involve the collection of sensitive data, online software and survey tools may be used, provided they meet the following guidelines:

1. SSL (Secure Sockets Layer) encryption is available;
2. At the completion of the survey, there should be two buttons: one to allow participants to discard the data and the other to submit it for inclusion in the study;
3. The software company has signed confidentiality agreements preventing them from improperly accessing or disclosing the information contained in their databases;
4. The system is capable of masking IP addresses and other identifying information from the investigator.

For full-committee studies that involve the collection of sensitive data, the IRRB recommends that surveys be housed on a GCU server. The server will be administered by the Office of Information Technology staff. In accordance with University policy, access to the server is limited to key project personnel and the server will receive frequent, regularly scheduled security audits.

Internet-Based Research Data Storage and Disposal: If a server is used for data storage, personal identifying information must be kept separate from data, and data must be stored in encrypted format. Proper data destruction methods and schedules must also be used to ensure that no data can be recovered from obsolete electronic media. ITS should be contacted with questions regarding data storage and destruction plans.

4. Georgian Court University Students as Research Subjects

It is the University's general position that teachers should not use their own students as subjects in their research if it can be avoided. The University recognizes, however, that in some research situations, use of one's own students is integral to the research. This is particularly true of research into teaching methods, curricula and other areas related to the scholarship of teaching and learning. The following are two models of research design that may be permissible to the IRRB:

- **Collection of Data by Third Party:** In situations where the activities to be undertaken by the students are not part of required class activities, and thus students may or may not choose to participate, the instructor/researcher should arrange to have the data collected by an independent third party, so that the instructor does not know who participated, and does not have access to the identifiable data or identity of participants for any purpose until grades have been assigned and entered.
- **Collection of Data by Instructor/Researcher:** In situations where the collection of data by a third party is not feasible, the IRRB may approve the research if

the student provides written consent to use his or her own data, e.g., test results, papers written, homework, etc., after grades are entered.

Note: The giving of course credit or extra credit to students who participate in research as part of a course requirement will be approved by the IRRB only when alternative means of obtaining credit is made available to students who do not wish to volunteer as research subjects. The IRRB will carefully review these alternatives to make sure that students are not being coerced into becoming subjects. The informed consent statement must make clear the consequences of withdrawing from a project prior to completion.

5. *Payment to Research Participants*

It is not uncommon for subjects to be paid for their participation in research. Payment to research subjects for participation in studies must not be considered a benefit. Financial incentives are often used when health benefits to a subject are remote or non-existent. The amount and schedule of payment must be presented to the IRRB at the time of the initial review. The IRRB will review both the amount of the payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence.

L. Completion

The investigator must inform the IRRB in writing when the research project has been completed, accompanied by study completion documents and archival records.

Research studies can be deemed completed for a number of reasons, each requiring a different degree of IRRB involvement. Most often, the investigator will close the study and the IRRB's role is passive, receiving study completion documents and archiving the records for the study. In some cases, the IRRB must perform in a supervisory or disciplinary fashion and require that a study be ended.

M. Non-Compliance

The IRRB is responsible for determining the validity of all allegations of noncompliance with respect to human subjects research activities conducted under the auspices of the University and, if found to be non-compliant, determining whether it constitutes non-compliance that is serious or continuing in nature. If it is determined that a research protocol is not in compliance with regulations, regardless of whether it received prior review and approval by the IRRB, it may direct corrective action to be taken.

There are two levels of noncompliance:

- *Serious:* non-compliance that may affect the rights and welfare of participants including: (i) conducting non-exempt human research without submitting an IRRB protocol; (ii) actions that compromise confidentiality of the participants or the integrity or validity of the research; (iii) actions that harm the participants either physically, psychologically or emotionally; (iv) the use of subjects from federally identified protected groups, which were not identified on the IRRB protocol; (v) failure to report serious events, unanticipated problems, or substantive changes to the proposed protocol to IRRB.

- *Continuing*: a pattern or multiple instances of non-compliance that: (i) indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others; (ii) compromises the scientific integrity of a study such that important conclusions can no longer be reached; (iii) suggests a likelihood that noncompliance will continue without intervention; or (iv) involves frequent instances of noncompliance or a failure to respond to a request from the IRRB to resolve an episode of noncompliance or a pattern of minor noncompliance.

All cases of non-compliance are to be reported to the IRRB Chair on an immediate basis. Reports can be made by research subjects, members of the research team or anyone else familiar with the research project.

The IRRB Chair will inform the principal investigator (and sponsoring agency if applicable) that a non-compliance report has been made. The IRRB Chair will also determine whether the report is serious enough to merit suspension of the research.

The IRRB Chair will investigate and determine whether the non-compliance is Serious or Continuing. In the case of Serious or Continuing non-compliance, the IRRB Chair will call a meeting of the full IRRB. The researcher will be given the opportunity to attend the meeting to present information, but may not be present while the IRRB makes its decisions. At this meeting the following will be determined:

- Whether action needs to be taken, and if so what form it will take. This can include requiring changes be made to the protocol, assigning a person to monitor the remainder of the research, requiring the researcher to undergo training, or suspension/termination of the research.
- A recommendation on whether any sponsoring federal agencies need to be informed.

For cases of Serious or Continuing noncompliance, the IRRB Chair will report to the Provost the non-compliance and the IRRB's decisions on remedial action. In cases of continuing non-compliance, the Provost may revoke the research privileges of the individual at the University or institute other disciplinary actions. Although the IRRB can suspend or terminate the research project only the Provost may suspend the researcher's ability to conduct research.

N. Confidentiality

An investigator must not disclose any personal information obtained for the purposes of Human Subjects Research without the express consent of the subjects or donor to whom it relates (or his or her legally authorized representative), except where: disclosure is necessary to eliminate any apparent immediate risk of harm to the or donor or to any other person; and the disclosure is the minimum necessary for the purpose of eliminating such harm.

If personal information relating to a subject or donor is, or is likely to be, disclosed without consent, the investigator must immediately inform that subject or donor (or his or her legally authorized representative): of the disclosure and of its purpose and extent; and that any person given access to the information will be required by the

researcher to be subject to a duty of confidentiality, and he or she must ensure that any 3rd parties to whom the information is disclosed will be subject to a legally binding duty of confidentiality.

II. Monitoring Authorized Research Proposals

A Principal Investigator must at all times:

1. Act in accordance with the terms of the authorized research proposal (including any revisions or conditions specified by the IRRB when approving the proposal);
2. Comply with federal, state and local laws and regulations, as well as University policies and procedures;
3. Permit the IRRB to observe, or have a third party observe on its behalf, the conduct of the research; and
4. Permit the IRRB to audit, or have a third party audit on its behalf, the research facilities, files, and progress reports.

A Principal Investigator must promptly notify the IRRB of any: material change in circumstances occurring after the approval of a research proposal; or inaccuracy, of which it has since become aware, in any information provided to the IRRB in support of the authorized research proposal. Additionally, a Principal Investigator must promptly notify the IRRB of any suspension or premature termination of its research, and of the reasons for that suspension or termination. Finally, a Principal Investigator must immediately restrict, suspend, or terminate research where it is directed by the IRRB to do so.

In carrying out an approved research project, a Principal Investigator must submit to the IRRB: (a) progress reports including written summaries of the progress of the research, as often as the IRRB may specify; (b) a safety report immediately upon the occurrence of any serious adverse event; and (c) a final report upon the completion of the research, to be submitted no later than 90 days following the date of completion.

III. Record-Keeping by the Institutional Research Review Board

An institution, or when appropriate an IRRB, shall prepare and maintain adequate documentation of IRRB activities, including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- Actions taken by the IRRB and separate deliberations for each action.
- Minutes of all convened IRRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. The recusal of any IRRB members because of a conflicting interest shall also be documented when recording votes on IRRB actions.

- Records of continuing review activities.
- Copies of all correspondence between the IRRB and the investigators.
- A list of IRRB members in the same detail as described in §46.103(b)(3).
- Written procedures for the IRRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).
- Statements of significant new findings provided to subjects, as required by §46.116(b)(5). CFR 45§46.116(b)(5) (Informed Consent). This is: A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
- Required determinations and protocol-specific findings justifying those determinations for:
 - Waiver or alteration of the consent process. [45 CFR 46.116(c) and (d)]
 - Justification for the waiver of the requirement for written documentation of consent [45 CFR 46.117]
 - Research involving pregnant women, fetuses, and neonates. [45 CFR 46.204]
 - Research involving prisoners. [45 CFR 46.306]
 - Research involving children. ^[L]_{SEP}[46 CFR 46.404-407]
 - The rationale for determining that risk associated with using a medical device in a study significant or non-significant (referred to as significant risk/non-significant risk device determinations). ^[L]_{SEP}
- When the expedited procedure for review is used, documentation of discussions, decisions, and findings will be included in the protocol file.

The records required by this Policy shall be retained for at least 3 years, and records relating to research, which is conducted, shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the federal department or Agency at reasonable times and in a reasonable manner when applicable.

IV. Duration of Approvals

Approvals shall be in force for a period of one calendar year from the date of approval. If the project is not completed in that period, the researcher may simply resubmit the original application with a letter indicating that the project is continuing. So long as there have been no changes in the study or in the ethical standards of Georgian Court University or of the relevant discipline, the IRRB member may approve the study using an Institutional Research Review Board Response to Proposal Form. At this point, the approval is extended for a period of one calendar year from the date of the new approval. If the study or the relevant research standards have changed, the study may be submitted for expedited or committee review.

RELATED POLICIES

- Grants Policy
- Principal Investigators Policy
- Research Ethics and Conduct Policy

8.2 Research Involving Vertebrate Animal Subject

At this time, Georgian Court University does not conduct animal research. If in a future time animal research is conducted, an Animal Welfare Committee and appropriate protocols will be developed.

8.3 Principal Investigators

| PRINCIPAL INVESTIGATORS | |
|--------------------------------|--|
| Effective Date: | [TBD] |
| Policy Number: | VIII -8.3 |
| Supersedes: | Not Applicable. |
| Issuing Authority: | [TBD] |
| Responsible Officer: | [TBD] |
| Applicability: | All University employees and students engaging in sponsored research activities. |
| History: | |

PURPOSE

The purpose of this policy is to define eligibility requirements and the rights responsibilities of principal investigators and co-principal investigators on externally supported (sponsored) projects at Georgian Court University.

POLICY

Grants, contracts, and other types of awards that support sponsored projects at Georgian Court University are legally binding agreements between external entities (sponsors) and the University. Although sponsors make awards based on projects proposed by investigators, the awards are made to the University.

When the University accepts a sponsored project award, it becomes legally responsible and accountable to the sponsor for compliance with terms and conditions of the award and with all applicable laws and regulations. The principal investigator, in turn, is responsible to the University for the overall management and conduct of the project. Thus, an individual’s participation as principal investigator is dependent on his or her relationship with the University. To ensure that it can meet its contractual obligations, the University limits eligibility of principal investigators and co-principal investigators to individuals with appropriately defined affiliations with the University.

DEFINITIONS

PI/PD–a research project is generally under the direction of a principal investigator (PI), while other types of projects are under the direction of a project or program

director (PD). For the purposes of this policy, the term principal investigator or PI is used to refer to both.

Principal Investigator—an individual designated by the University to have the appropriate level of authority and responsibility to direct a project or program supported by an external award. A PI participates on the project to a substantial degree and is responsible to the University for the overall proper management of the project (including fiscal management, compliance, and technical reporting) and the conduct of the project scope of work in compliance with the award terms and conditions and University policies and procedures. The PI also acts as the University’s contact with the sponsor for scientific or programmatic issues, and with the Grants Development Team for fiscal and award administration issues. The Office of Institutional Advancement is the University’s contact with the sponsor for all issues related to fiscal and award administration issues.

Co-Principal Investigator (Co-PI)—an individual involved with the PI in the development or implementation of a sponsored project. A Co-PI devotes a specific percent of his or her effort to the project and is responsible to the University and to the PI for the management and conduct of a specific segment or area of the project in accordance with sponsor requirements, award terms and conditions, and University policies and procedures.

Sponsored Project – a specific research, training, service, or similar activity for which funding or other support is provided by an external entity (sponsor) under a legally binding agreement with the University.

PROCEDURES/GUIDELINES

Eligibility

Eligibility to act as a Principal Investigator (PI) or Co-Principal Investigator (Co-PI) on research projects at Georgian Court University is a privilege typically limited to members of the full-time faculty. This limitation is in place because PI and Co-PI’s are responsible for determining the intellectual direction of scholarship and research, which in turn impacts the academic trajectory and public perception of the University as a whole. Given the critical role played by the PI, it is critical that only the true leader of a research effort is designated as a PI. The designation of “PI” or “Co-PI” requires approval by the Provost.

Requests for PI or Co-PI eligibility for researchers who are not members of the appointed faculty may be made on a case-by-case basis by the Provost. Non-faculty members seeking to be appointed as a PI or Co-PI must submit the following materials to the Provost: (a) a written request containing a full justification for the exception; (b) a copy of the recommended individual’s current curriculum vitae; (c) one-page abstract describing the research project; and (d) a budget.

Rights of Principal Investigators and Co-Principal Investigators

PI and Co-PI have the right to academic freedom in the pursuit and support of research in accordance with the University’s Academic Freedom Policy (see Volume IV of the *Georgian Court University Policy Manual*). Each PI/Co-PI has the right to know who

is sponsoring the research and supporting his or her salary or stipend (if applicable). PI/Co-PI's also have the right to disseminate the results and findings of their research without suppression or modification from external sponsors beyond those provisions explicitly stated in the sponsorship agreement.

Responsibilities of Principal Investigators and Co-Principal Investigators

Supervision of Staff and Students

PI/Co-PI's must be aware of their obligations to staff and students working as part of a research team. It is particularly important that at least annually, each PI/Co-PI review intellectual property rights and responsibilities (for management of data in all media, for proper authorship attribution, etc.), with all members of the group under his or her direction. Any disputes arising between a PI/Co-PI and a staff member or student will be mediated through the Provost.

Health and Safety

Each PI/Co-PI is responsible for training members of his or her team in appropriate health and safety procedures for that particular research area, and for management of those procedures in his or her laboratory or other workplace. PI/Co-PI's are also responsible to assure the periodic inspection of lab facilities, and to cooperate in any inspections by University staff personnel or external agencies.

Fiscal Obligations

Although certain projects may be "sponsored" or funded by an external entity, the overall responsibility for management of a sponsored project within funding limitations rests with the PI/Co-PI. Funds must be expended within the restrictions of the contract or grant, and if any overdraft should occur, it is the responsibility of the PI/Co-PI to clear the overdraft by transferring charges to an appropriate account.

Equipment Management

PI/Co-PI's are responsible for securing necessary approvals for the purchase of the equipment, and for proper tagging, inventory, and disposal of equipment in accordance with University policy.

Proposal Preparation

The cost of proposal preparation activities in support of new directions in research may not be charged to sponsored projects. The Provost will endeavor to ensure that non-sponsored project funds via faculty development grants are available to offset the portion of the PI/Co-PI and appointed staff's salaries from sponsored projects for effort spent preparing proposals to support new directions in research. If there are concerns that a proposal may be costly, the PI must contact the Provost in advance to ascertain availability of funds beyond the normative amounts.

Research Protocols

PIs also need to ensure that approved research protocols for the use of human subjects and/or animals in research are obtained and followed.

RELATED POLICIES

Academic Freedom Policy
 Grants Policy
 Intellectual Property Policy Regarding Ownership of Works Created by Faculty
 Policy for Review of Research Involving Human and/or Vertebrate Animal Subjects
 Property Administration Policy
 Research Ethics and Conduct Policy

8.4 Research Ethics and Misconduct

| RESEARCH ETHICS AND MISCONDUCT | |
|--------------------------------|--|
| Effective Date: | |
| Policy Number: | VIII -8.4 |
| Supersedes: | Not Applicable. |
| Issuing Authority: | |
| Responsible Officer: | |
| Applicability: | All University employees and students engaging in research activities. |
| History: | |

PURPOSE

The purpose of this policy is to establish research ethics and conduct guidelines that apply to all individuals who conduct research at Georgian Court University (GCU).

POLICY

All members of the research community, including faculty, staff, students, fellows, adjunct faculty, and visiting faculty, are expected to adhere to the highest ethical and professional standards as they pursue research activities at the University.

The goal of the guidelines set forth in this policy is to offer a set of values, principles, and standards to guide decision-making and conduct throughout the research process. It is not intended to provide a set of rules that prescribe how researchers should act in all situations. Rather, the guidelines are intended to increase awareness of research integrity and outline the University's expectations for ethical behavior amongst all researchers.

DEFINITIONS

Principal Investigator (PI)—an individual designated by the University to have the appropriate level of authority and responsibility to direct a project or program supported by an external award. A PI participates on the project to a substantial degree and is responsible to the University for the overall proper management of the project (including fiscal management, compliance, and technical reporting) and the conduct of the project scope of work in compliance with the award terms and conditions and University policies and procedures. The PI also acts as the University's contact with the sponsor for scientific or programmatic issues, and with the Grants Development Team for fiscal and award administration issues. The Office of Institutional

Advancement is the University's contact with the sponsor for all issues related to fiscal and award administration issues.

Research—means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Scientific Misconduct—includes fabrication, falsification, plagiarism, misuse of research funds, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. In addition, the University reserves the right to require adherence to other definitions of scientific misconduct as required by contractual obligations with external sponsors of research.

PROCEDURES/GUIDELINES

The Duty of Honesty and Integrity

Researchers are expected to maintain the highest standards of honesty and integrity and otherwise refrain from research misconduct. Any form of research misconduct, including but not limited to the following, is a serious offence:

Falsification of Data: The gathering of data and research materials must be undertaken with honesty and integrity. Researchers should never publish data they know to be false or the result of deliberate acts of falsification.

Plagiarism: Plagiarism includes, but is not limited to, the taking over of the ideas, methods or written words of another individual, including those of students or other researchers, without acknowledgment and with the intention that they be taken as the work of the deceiver. Plagiarizing the work of another is the antithesis of the honest labor that characterizes true scholarship and without which mutual trust and respect among scholars is impossible. Accordingly, every researcher at GCU must scrupulously recognize all intellectual debts owed, be they in the form of ideas, methods or expressions, by means of an appropriate form of communication and acknowledgment. Moreover, researchers must make clear the respective contributions of colleagues on a collaborative project, and professors who have the guidance of students as their responsibility must exercise the greatest care not to appropriate a student's ideas, research, or presentation to the faculty member's benefit; to do so is to abuse power and trust.

Misuse of Research Funding: Where a granting agency provides guidelines on the use of research funds, researchers and PI's must follow those guidelines scrupulously. Researchers and PI's must also follow all GCU guidelines on the management and disbursement of funds. Regardless of the source of research funding, it is not permitted to divert any of the research resources for personal or any other use, except in cases where the grant or contract specifically provides otherwise. Nothing in the provisions of this section is intended to impugn the actions of a person who has made an honest error, or who exercises judgment or interprets data or designs experiments in a way which may reasonably be the subject of honest differences of opinion.

Serious Deviations from Accepted Practices: Serious deviation from accepted practices includes but is not limited to:

1. Abusing confidentiality, including the use of ideas and preliminary data gained from: (a) access to privileged information through the opportunity for editorial review of manuscripts submitted to journals; and (b) Peer review of proposals being considered for funding by agency panels or by internal committees, such as the Institutional Review Board;
2. Stealing, destroying, or damaging the research property of others with the intent to alter the research record; and
3. Directing, encouraging, or knowingly allowing others to engage in fabrication, falsification, or plagiarism.
4. Coercing a research subject to participate in research study.

Ethical Guidelines on Authorship

Multi-Authored Research Papers: GCU encourages collaboration between faculty, staff and students on research projects and papers, particularly in instances where it is particularly useful to draw upon diverse disciplinary knowledge. However, research collaborators must be aware of the unique challenges inherent in producing collaborative work.

In general practice, research collaborators are encouraged to establish as early as possible in the timeline of a project how the attribution of authorship and how the allocation of copyright are to be divided between them. However, in the absence of an agreement between the researchers, the following guidelines governing the attribution of authorship apply:

Authorship is attributed to all those persons who have made significant scholarly contributions to the conceptualization, design, execution, or interpretation of the work and who share responsibility and accountability for the results.

Lesser contributions, such as providing advice, analyses, subject material, or general support, must be acknowledged in footnotes or an Acknowledgements section. In addition, GCU and the sponsor (if applicable) must be acknowledged.

An administrative relationship to the investigation does not of itself qualify a person for co-authorship.

The order of the names in publication is decided according to the quality of the contribution, the extent of the responsibility and accountability for the results, and the custom of the discipline.

The attribution of authorship is not affected by whether researchers were paid for their contributions or by their employment status.

Student-Faculty Collaborations: The rules set forth above apply to the case where the collaborators are professor and student. Further to those rules, a student should be granted prominence in a list of co-authors of any multiple-authored article that is based primarily on the student's own dissertation/thesis, according to the practice in the discipline.

Duties of a Principal Author: In a collaborative project, the principal author assumes the ultimate responsibility for ensuring compliance with the guidelines enumerated above. In addition, the principal author is expected to: (a) Accept the responsibility of having included co-authors all persons who are entitled to co-authorship, and none that are inappropriate; (b) Send each co-author a draft copy of the manuscript and should make a reasonable attempt to obtain consent for co-authorship, including the order of names; (c) Accept responsibility for acknowledging other contributions (including GCU and applicable sponsors) in either a footnote or the “Acknowledgements” section; (d) Assume responsibility for ensuring the overall validity and cohesiveness of the work.

Duties of Each Collaborative Author: Every author and co-author is responsible for reviewing and verifying those portions of a manuscript, publication, or presentation that represent the author’s contribution. Additionally, all authors in a collaborative effort have a shared responsibility for the complete, published result and will be provided the opportunity to review all sample preparation procedures and data, as well as all data acquisition and analysis procedures. Each author will be expected to sign a standard form or statement of verification attesting to the authenticity of the manuscripts. The signatures must be appended to the final manuscript. All co-authors are entitled to make appropriate copies of a manuscript, including figures and appended documents.

Resolving Disputes Between Co-Researchers

Where disputes between co-researchers arise, they should be resolved amicably and in a respectful and collegial fashion. Where a dispute cannot be resolved by the parties themselves, the parties must initially seek the advice of the appropriate authorities in their division, who may help the parties to resolve the dispute in any way to which the parties may agree, including conciliation, mediation, and binding and non-binding arbitration. To this end, the parties may agree that other persons become involved in the dispute in order to help facilitate its resolution. The parties may stipulate that their own involvement in any dispute resolution process is without prejudice to their rights in any subsequent process.

GCU has a duty to investigate disputes to help facilitate their resolution, in accordance with the following provisions. However, GCU has no obligation to ensure that disputes are resolved, since the resolution of disputes is ultimately subject to the will of the parties to the dispute.

If the dispute is between individuals working under the PI, the PI will investigate and attempt to resolve the matter. If the PI is involved in the dispute or if any party shall object to this process, then disputes will be resolved by the Provost.

Allegations of Research Misconduct

Any individual who believes an act of unethical or research misconduct has occurred or is occurring must notify the Provost, who, after preliminary assessment indicating grounds to proceed, will immediately notify the President that an inquiry is being conducted. Reporting such concerns in good faith is a service to GCU and to the larger

academic community, and will not jeopardize anyone’s employment or status at the University.

If an individual is not sure whether or not a particular incident or practice constitutes Research Misconduct or a violation that is covered by this policy, then the individual may call the Provost to discuss the matter confidentially and obtain guidance. Such calls may be made anonymously.

Upon receipt of an allegation, the Provost will assess the information presented to determine whether it constitutes alleged research misconduct as defined by this policy, and whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If both of these criteria are met, the Provost will refer the case to the appropriate process for formal review. Allegations made against students will be addressed through the formal resolution section of the GCU Academic Honesty Policy; allegations against faculty will be addressed through the *Volume IV of the Georgian Court University Policy Manual*.

RELATED POLICIES

- Grants Policy
- Intellectual Property Policy Regarding Ownership of Works Created by Faculty
- Policy for Review of Research Involving Human and/or Vertebrate Animal Subjects
- Property Administration Policy

8.5 Retention of and Access to Research Data

| RETENTION OF AND ACCESS TO RESEARCH DATA | |
|---|--|
| Effective Date: | [TBD] |
| Policy Number: | VIII -8.5 |
| Supersedes: | Not Applicable. |
| Issuing Authority: | [TBD] |
| Responsible Officer: | [TBD] |
| Applicability: | All University employees and students engaging in research activities. |
| History: | |

PURPOSE

The purpose of this policy is to describe the University’s policy regarding research data ownership and the standards for the collection, retention, and access of data, as well as to provide guidelines with respect to transfer of research data in the event a researcher leaves Georgian Court University (GCU). The policy also addresses compliance issues with respect to federal laws that govern the export of sensitive technologies, equipment, software, biological agents, and related data and services to foreign nations.

POLICY

It is GCU policy for principal investigators to bear primary responsibility for the overall conduct of the research or scholarly activity. In this role, principal investigators have the right and authority to control the appropriate use-of and access- to their research data, including the use of data and materials in scholarly publications and presentations. They are also responsible for retaining or ensuring retention of the data and materials and complying with all applicable federal regulations, including but not limited to those addressing the export of sensitive technologies, equipment, software, biological agents, and related data and services to foreign nations. Complex projects with multiple investigators require that principal investigators assert responsibility for access and retention for all components of the project at all performance sites as applicable.

Students, employees, program participants, and visiting researchers who are involved in the research endeavor are required to make research data and materials obtained at the University, or using University resources or funds, readily available upon request to the principal investigator.

Under federal regulation, however, tangible research property, including the data and other materials of research conducted under the auspices of GCU, belongs to the University. Where research is funded by a sponsored contract that includes specific provision(s) regarding ownership, retention of and access to technical data, the provision(s) of that agreement will supersede this policy.

DEFINITIONS

Foreign Person—any person who is not a U.S. citizen and not a lawful permanent resident is considered to be a foreign person, regardless of where that person resides, works or studies.

Principal Investigator (PI)—an individual designated by the University to have the appropriate level of authority and responsibility to direct a project or program supported by an external award. A PI participates on the project to a substantial degree and is responsible to the University for the overall proper management of the project (including fiscal management, compliance, and technical reporting) and the conduct of the project scope of work in compliance with the award terms and conditions and University policies and procedures. The PI also acts as the University's contact with the sponsor for scientific or programmatic issues, and with the Grants Development Team for fiscal and award administration issues. The Office of Institutional Advancement is the University's contact with the sponsor for all issues related to fiscal and award administration issues.

Research Data—means scientific data including, but not limited to, materials contained in laboratory notebooks or other media such as computer disks and machine printouts. Data also includes both intangible data (statistics, finding, conclusions, etc.) and tangible data (notebooks, printouts, etc.).

PROCEDURES/GUIDELINES

Ownership and Stewardship of Research Data

GCU's ownership and stewardship of the scientific record for projects conducted at the University, under the auspices of GCU, or with University resources are

based on federal regulation (OMB Circular A-110, Sec. 53) and sound management principles. GCU's responsibilities in this regard include, but are not limited to:

1. Complying with the terms of sponsored project agreements;
2. Ensuring the appropriate use of animals, human subjects, recombinant DNA, etiological agents, radioactive materials, and the like;
3. Protecting the rights of students, postdoctoral scholars, faculty, and staff, including, but not limited to, their rights to access to data from research in which they participated;
4. Securing intellectual property rights; and
5. Facilitating the investigation of charges, such as scientific misconduct or conflict of interest.

Data Collection and Retention

PIs are responsible for adopting an orderly system of data organization and to communicate the chosen system to all members of a research group and to the appropriate administrative personnel, where applicable. Particularly for long-term research projects, PIs are responsible for establishing and maintaining procedures for the protection of essential records in the event of a natural disaster or other emergency. Additionally, PIs have the obligation to discuss the responsibilities of data management and retention with other members of the research team.

Research data must be archived in accordance with the University's Record Retention Schedule after the final project close-out, with original data retained wherever possible. Data, however, must be kept for as long as may be necessary to protect any intellectual property resulting from the work. Moreover, if any charges regarding the research arise, such as allegations of scientific misconduct or conflict of interest, the data must be retained until such charges are fully resolved. If a student is involved, the data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work.

Beyond the period of retention specified in the Retention Schedule, the destruction of the research record is at the discretion of the PI and his or her department.

Records will normally be retained in the department where they are produced. Research records must be retained on the GCU campus, or in facilities under the auspices of GCU, unless specific permission to do otherwise is granted by the Provost.

Transfer of Data in the Event of Researcher Mobility

When individuals engaged in research projects leave GCU, they may take copies of research data for projects on which they have worked. Original data, however, must be retained at GCU by the PI.

If a PI leaves GCU, and a project is to be moved to another institution, ownership of the data may be transferred with the approval of the Provost, and with written agreement from the PI's new institution that guarantees: (a) its acceptance of custodial responsibilities for the data; and (b) GCU's access to the data, should that become necessary.

Trade Control

GCU is committed to open and shared learning, and encourages the dissemination of research results. At the same time, GCU recognizes that some of the research it conducts may be subject to “trade controls”, or federal laws that govern the export of sensitive technologies, equipment, software, biological agents, and related data and services to foreign nations.

Federal trade control laws also encompass the disclosure of controlled information to foreign persons, and access to controlled equipment and technology by foreign persons visiting GCU. Any person who is not a U.S. citizen and not a lawful permanent resident is considered to be a foreign person, regardless of where that person resides, works or studies. Possession of a valid student or work visa does not qualify an individual for exemption from trade controls.

Typically, trade controls restrict the export of technology or data related to military operations or defense. Although most research conducted at GCU will be deemed exempt from trade controls, all GCU community members engaging in research should be knowledgeable about federal guidelines. National Security Decision Directive (NSDD) 189 states that fundamental research is not subject to trade controls. Fundamental research is defined as basic or applied research in science or engineering at an accredited institution of higher learning in the United States, where the resulting information is not restricted in the form or content of its release to the public and is ordinarily published and shared broadly in the scientific community. The following types of research are not deemed to be fundamental, and thus they are subject to trade controls: (a) research wherein GCU has accepted any restrictions on the publication of the information resulting from the research, other than limited prepublication reviews by research sponsors to prevent accidental dissemination of proprietary information or to ensure that the results will not compromise patent rights of the sponsor; and (b) research that is federally funded and wherein specific access and dissemination protocols for handling resulting information have been accepted by GCU or the researcher.

Trade controls for non-fundamental research should not be confused with trade sanctions. When the federal government has issued a trade sanction against a foreign nation, provision of any information, goods or services to that nation will be restricted, regardless of the classification of research as fundamental. Violation of trade controls and sanctions may result in criminal charges, institutional fines, and imprisonment.

Any questions regarding trade controls should be directed to the office of sponsored research. Additionally, all instances of non-fundamental research being conducted at GCU must be immediately reported to the Provost upon conception of the research objective.

RELATED POLICIES

Grants Policy

Intellectual Property Policy Regarding Ownership of Works Created by Faculty

Policy for Review of Research Involving Human and/or Vertebrate Animal

Subjects

8.6 Surveys

| SURVEYS | |
|-----------------------------|------------------------------------|
| Effective Date: | |
| Policy Number: | VIII – 8.6 |
| Supersedes: | Not Applicable. |
| Issuing Authority: | [TBD] |
| Responsible Officer: | Director of Assessment |
| Applicability: | All departments of the University. |
| History: | |

PURPOSE

The purpose of this policy is to ensure that University surveys of prospective students, current students, alumni, employees, board members, community members, and other stakeholders are designed, administered, analyzed, and reported in a coordinated, methodologically sound and strategic manner.

POLICY

Unless specifically exempted by this policy, the Director of Assessment must approve all surveys intended for distribution to any members or prospective members of the Georgian Court University community (e.g., prospective students, current students, alumni, employees, board members, community members, and other stakeholders) by using the procedures described herein. A copy of all approved surveys, datasets, and associated reports that are generated by the surveyor(s) will be provided to the Director of Assessment electronically for retention in a survey archive.

Surveys administered as part of research projects involving human subjects requires review and action by the University's Institutional Research Review Board (IRRB). Only the IRRB may determine if a project is exempt from review. The Director of Assessment and IRRB Committee will work collegially to make sure surveys follow applicable University procedures and protocol.

Policy 8.6 does not cover (a) faculty-supervised survey research that contributes toward students' academic progress, (b) evaluation of an event by participants, (c) feedback from clients at the point of service, (d) teaching evaluation forms, (e) forms used to collect information for administrative purposes (e.g., scheduling), (f) feedback instruments used in the evaluation of employee performance, and (g) systems for electing students, faculty, or staff to leadership positions within University committees or organizations.

DEFINITIONS

Survey—any instrument, whether administered online, via e-mail, on paper, or in an interview format, specifically designed to elicit information for analysis.

Respondent—prospective students, current students, alumni, employees, board members, community members, and other stakeholders.

PROCEDURES/GUIDELINES

Approval Procedures

Individuals and offices wishing to conduct a survey that is covered by this Policy must complete and submit a written application, to the Director of Assessment. Information required includes but is not limited to: a description of the survey project, including the purpose and intended use of results; the specific respondent population receiving the survey; the method of survey distribution (e.g. online or hard copy, via email, in class, at event, etc.); the time frame for administering the survey, including beginning and end dates; evidence of IRRB approval (if necessary); description of any planned incentive program for respondents; and a current draft of the survey and all invitation and cover letters.

Applicants must submit the written application to the Director of Assessment or via email. If a recurring survey has been approved in an earlier year, it will be necessary only to submit information about the proposed administration dates. Surveys that had been approved in prior years, but which have been significantly changed, must be re-approved. If a survey is approved by the IRRB, the Director of Assessment will accept the IRRB protocol in lieu of the survey application.

The Director of Assessment will review the survey application and provide a response to the applicant. The answer to the following questions will be used by the Director of Assessment when making decisions about approving the administration of surveys to the prospective respondents:

- Does the survey comply with University policy and not violate of federal, state or local laws?
- Is the purpose of the survey clear and is it explained to the prospective participants?
- Does the survey provide information pertaining to the mission, goals, and future planning of the University?
- Is the survey well-designed and of an appropriate length? Does it follow sound survey methods and practices? Are the questions easily understood and interpreted?
- What is the target population? Will the entire population or a sample be surveyed?
- Are the rights of prospective respondents clearly explained?
- What actions are being taken to ensure the confidentiality of the responses?
- When will the survey be conducted? What is the optimal timing to ensure it does not compete with other surveys and activities?
- How will the results be used?
- Will the findings be disseminated to appropriate University audiences?

- Who will have access to the information and will it help them make better decisions as a result?
- Has the IRRB approved the project (if necessary)?
- Can the proposed survey be combined with other planned surveys?
- Are there other data available that will allow the survey to be avoided?

The Director of Assessment will provide feedback to the applicant, either approval of the survey project as is or a change notice with feedback regarding specific changes needed for approval.

Guidelines for Conducting a Survey

All surveys conducted at Georgian Court University must adhere to the following guidelines:

- The survey form must clearly identify the group or person who is conducting the survey and include contact information (name, email address, telephone number) should the respondents have any questions about the content of the form or about the use and/or publication of survey results.
- All respondents must be notified that their participation is voluntary.
- Respondents must be notified in advance if data collected will not be anonymous.
- Respondents must be protected from risk of unreasonable harm, including any risks regarding confidentiality or privacy.
- A summary of the survey will be made available on request to all respondents.
- Information from surveys conducted by administrative offices, faculty committees, and other University committees are the property of the University. The researcher, department, or committee responsible for conducting the survey must be consulted prior to the release and distribution of the survey's findings.
- The use of mass e-mailing lists to promote or distribute a survey to university employees, staff, students, trustees, or alumni is limited to official surveys approved by the Director of Assessment in consultation with the Office of Information Technology.

Confidentiality

Personal identification information may be collected only as required in relation to the expressly stated purpose of research or a project.

Data Security

The researcher assumes the full responsibility for the security and privacy of the data. The investigator must ensure that the host system provides security in both data transfer and storage (e.g., disassociation of responses from the ISP address, SSL encryption, and firewall and intrusion prevention technology).

The person conducting a survey is responsible for managing and releasing the data collected. Raw data from surveys are typically not shared with people outside of the University except under special circumstances. If survey data are shared, the use of the data must be approved by the appropriate President's Cabinet member and conform to applicable University policies and laws pertaining to privacy matters (i.e., Student Record Confidentiality (FERPA), HIPAA, Information Security, Identity Theft Prevention).

Sanctions

Failure to adhere to the policies, procedures and guidelines relating to the use of surveys will result in a written notification to the data collector and the President's Cabinet member who is responsible for their department. Violators of this policy must receive clearance from the Cabinet member to administer any future surveys for a period determined by the President's Cabinet member. Violations of University policies pertaining to privacy matters (i.e., Student Record Confidentiality, HIPAA, Information Security, Identity Theft Prevention) may result in appropriate disciplinary measures.

RELATED POLICIES

Institutional Data Requests Policy
Policy for Review of Research Involving Human and/or Vertebrate Animal Subjects
Student Record Confidentiality (FERPA) Policy
HIPAA Policy
Information Security Policy
Identity Theft Prevention Policy

8.7 Research Grants

RESEARCH GRANTS

Effective Date: [TBD]
Policy Number: VIII – 8.7
Supersedes: Not Applicable.
Issuing Authority: [TBD]
Responsible Officer: [TBD]
Applicability: All University employees engaged in sponsored grant research activities.
History:

PURPOSE

The purpose of this policy is to provide a set of policies, procedures and guidelines by which grants are procured and administered by Georgian Court University (GCU).

POLICY

Grants Procurement and Administration

The grant procurement and administration functions of the University are broad and complex, involving personnel with expertise in varied subject areas and located in many different University organizational units. Personnel involved in the administration of extramural awards are responsible for the grant administration function from proposal development and submission through periodic and final reports and project closeout. Administration of external awards shall be in accordance with this policy.

For GCU, a grant is any unrestricted or restricted cash award of \$1,000 or more, or an in-kind gift of instructional equipment or software worth at least \$1,000 made to the University by an organization, that is a foundation, a family foundation, a corporate foundation, a corporation or a government agency. For the CASE definition of a grant see Appendix A. A grant may be funneled through a consortium such as Independent College Fund of New Jersey (ICFNJ). Corporate matching gifts, event sponsorships, non-instructional in-kind gifts and gifts smaller than \$1,000 from organizations are not included in this definition. Grants are distinguished from contracts (exchange transactions) by applying the NACUBO checklist for classifying revenue as a contribution or exchange transaction derived from FASB SFAS 116 and 117.

Regardless of the size of the grant request, no individual or department of the University is authorized to solicit any organization or government office for a grant in the name of the University without clearance in advance, in writing, from the Dean, Provost, Director of Marketing, and Communications & Grants Specialist. It is in the University's best interest to coordinate these efforts and to prioritize the cultivation and solicitation efforts.

Grant proposals for research, as well as programmatic grant requests, must be coordinated through the Advancement Communications and Grants Specialist in the Office of Marketing and Communications. This coordination is in addition to any planning or program development requirements of the provost or vice president of the division.

All grants activities of the University are coordinated specifically by the Advancement Communications and Grants Specialist. The CGS works with the Executive Director of Marketing and Communications, the grant sponsors (PI/PD's), and the grants accountant to ensure the smooth development and operation of grant activities. The CGS provides research on funding organizations and the funders' requirements for submission of grant proposals.

The Grants Development Team is an advisory body chaired by the Provost, to aid in coordinating the grants process. It meets frequently, is aware of all initial and continuing grants, suggests grant opportunities related to the priorities of the annual grants strategy, advises on grant development projects, coordinates multiple applications for the same program or funder, and reviews proposals and reports as need for coordination. The Grants Development Team consists of the Provost, Vice President of Finance and Administration, Executive Director of Marketing and Communications, and the Advancement Communications and Grants Specialist. Approval of grants rests with the members of the administration, specifically the Dean of the appropriate school, Provost, Vice President of Finance and Administration, Executive Director of Marketing and Communications, and the Advancement Communications and Grants Specialist and ultimately with the University president.

Every grant must have a grant sponsor (PI/PD). The grant sponsor is the primary individual who takes responsibility for the design of the project, for creating the proposal, for ensuring that the project is completed and for drafting all interim and final reports.

DEFINITIONS

Grant—any unrestricted or restricted cash award of \$1,000 or more, or an in-kind gift of instructional equipment or software worth at least \$1,000 made to the University by an organization, that is a foundation, a family foundation, a corporate foundation, a corporation or a government agency. A grant may be funneled through a consortium such as Independent College Fund of New Jersey (ICFNJ). Corporate matching gifts, event sponsorships, non-instructional in-kind gifts and gifts smaller than \$1,000 from organizations are not included in this definition. Grants are distinguished from contracts (exchange transactions) by applying the NACUBO checklist for classifying revenue as a contribution or exchange transaction derived from FASB SFAS 116 and 117.

PI/PD—a research project is generally under the direction of a principal investigator (PI), while other types of projects are under the direction of a project or program director (PD).

Principal Investigator—an individual designated by the University to have the appropriate level of authority and responsibility to direct a project or program supported by an external award. A PI participates on the project to a substantial degree and is responsible to the University for the overall proper management of the project (including fiscal management, compliance, and technical reporting) and the conduct of the project scope of work in compliance with the award terms and conditions and University policies and procedures. The PI also acts as the University's contact with the sponsor for scientific or programmatic issues, and with the Grants Development Team for fiscal and award administration issues. The Office of Institutional Advancement is the University's contact with the sponsor for all issues related to fiscal and award administration issues.

RESPONSIBILITIES/PROCEDURES

Grant Officers

Those persons involved in grants take responsibility for ensuring that funders' policies and procedures, as accepted under an award document, are in accordance with University policies. Through appropriate coordination and follow up, these individuals will inform the responsible University personnel of funder requirements. To exercise such responsibility successfully, these individuals must possess broad knowledge of and familiarity with current University policy, the organization and operation of academic departments and a wide range of related administrative offices, and functions such as, purchasing, facilities management, risk management, grants accounting, human resources, and compliance review. In addition, these individuals must possess a broad knowledge of current governmental and private sector procurement and assistance policies, regulations, and practices.

More specifically, these individuals are responsible for the following:

- Review of all proposals to extramural sponsors for consistency with University policy and with funder terms and conditions and assurance of proper acceptance or execution of legally binding proposals on behalf of the University.
- Negotiation of contract, grant, or cooperative agreement awards for scopes of work and terms and conditions acceptable to the PI/PD, the academic or administrative department, and the University, that are reasonable and consistent with University policy;
- Obtaining the approval of General Counsel when required; and assure proper acceptance or execution of such awards.
- Advising PI/PD's, other academic officials, and appropriate or participating administrative offices of the commitments they are undertaking in the name of the University under accepted or executed awards.
- Providing appropriate assistance and follow up to PI/PD's, academic departments, and administrative offices to assure full compliance with the terms and conditions of the award, including deadlines and reporting requirements.
- Taking other actions as necessary for the proper implementation of all grant administration policies as are set forth in this policy.

Institutional Advancement, Office of Marketing & Communications and Office of the President

IA, the Office of Marketing and Communications, and the President are responsible for assisting, as appropriate, the campus grant officers to ensure the adequate implementation of University policy and discharge of campus grant procedures.

More specifically, these offices are responsible for:

- Formulating University grant administration policies to meet internal University needs as well as to address externally imposed sponsor requirements; coordinating approval of such policies by appropriate University officials; and disseminating such policies and information.
- Providing ongoing feedback and analysis to governmental and private sponsors concerning the sponsor's policies and requirements in order to establish optimum consistency between externally imposed sponsor requirements and University policies. Such information is transmitted through direct personal contact and negotiation, through formally proposed regulation review and comment, and through cooperation and coordination on issues and policies with the higher education community.
- Recommending University-wide master contracts and grants and basic agreements for use by all divisions. Assisting the grant officers in carrying out contract and grant administration responsibilities for those projects involving multiple University divisions, involving internal University wide funding programs or involving trustee approval, as necessary.

- Conducting analyses of long-range problems and preparing plans for improvement of the University's grant administration function.
- Setting standards and requirements for individual eligibility as a PI/PD for any grant proposal.

Principal Investigator/Project Director (PI/PD)

Although formal legal obligations related to solicitation and acceptance/execution of extramural funding ultimately rest with the President, and although responsibility for reviews and negotiation, coordination, guidance, and follow-up rests with a grant officer, a principal investigator or project director is the individual with primary responsibility for:

- The scientific integrity and/or quality management of the sponsored project;
- The financial management of project funds
- Adherence to all internal University policies; and
- Adherence to externally imposed sponsor terms and conditions including reporting and record keeping requirements contained in the award document.
- Obtaining approval for human subject research if applicable.

The University may require all PI/PD's to attend informative meetings for guidance on grant administration.

Provost, Vice-Presidents, School Deans, Academic Department Chairs and Administrative Department Directors

The Provost, Vice-Presidents, school deans, academic department chairs and administrative department directors are accountable for the performance of PI/PD's within their units. Specific responsibilities related to this accountability vary among and within University divisions. Basic responsibilities, however, include:

- Certifying an individual's eligibility for PI/PD status;
- Determining the consistency of the proposed project with the mission, goals and objectives of the organizational unit;
- Determining the appropriateness and acceptability of faculty or other personnel time, space, equipment, and University financial commitments contained in proposals for sponsored projects;
- Assuring that project scope of work is consistent with internal University policies, with externally imposed sponsor terms and conditions, and with the organizational department's educational, training, and/or other objectives; and

Identifying appropriate funding sources to cover project costs not covered by the project sponsor's funds or by other funds available to the PI/PD.

Grant Submission and Reporting Procedure

There are five steps to the successful solicitation and implementation of a grant at GCU.

Step 1: Preliminary Grant Form

The preliminary grant form is a required document that ensures that the appropriate college sponsors are informed of the intent to apply for a grant and have been given opportunity to comment on:

- The appropriateness of the plans for GCU in the context of the grants strategy and priorities;
- The appropriateness of the budget and financial requirements within the University's abilities; and
- Any potential conflict with other grants in process or with the funder.

Before making any contact with a funding organization, a PI/PD must complete a preliminary grant form supplied by the Advancement Communications and Grants Specialist. A call or e-mail to the Advancement Communications and Grants Specialist, ext. 2276, will start the process. The grant sponsor obtains the necessary signatures and comments and forwards the completed form to the Advancement Communications and Grants Specialist, who will track outstanding forms. The form should be submitted to the Advancement Communications and Grants Specialist at least six weeks before the grant submission deadline. The PI/PD is responsible for continuing follow-up communication with all the individuals who signed the form. The PI/PD is responsible for the approval of the Research Standards Committee and Institutional Research Review Board for any proposal that uses human subjects.

Step 2: Proposal Development

Grant proposal development is the process of planning, budgeting, writing and obtaining internal authorization for the activities included in a grant proposal. This process is the responsibility of the PI/PD with the Advancement Communications and Grants Specialist responsible for providing the institutional profile, required attachments and for compiling and submitting the application. The grants staff is also available for assistance in drafting and must review the final draft proposal.

Step 3: Proposal Approval and Submission

All completed grant or project proposals must be read and certified as appropriate for submission to the funder when applicable by the Dean, the Provost, the CFO/Vice President for Finance and Administration, the Executive Director of Marketing and Communications, the Advancement Communications and Grants Specialist, the FGR Director, the VPIA, and the President. The grant proposal sign-off is obtained from the grant office and must be completed 5 business days before the grant submission deadline to ensure timely submission through the President's office. Ordinarily, grants are submitted under the signature of the University President. In the case that the President is not available, the final sign off will be the responsibility of the VPIA vice President's appointed representative. The Advancement Communications and Grants Specialist will keep a list of all active and pending grant proposals.

Step 4: Notification of Grant Decision

In addition to the grant sponsor's name, the Advancement Communications and Grants Specialist's name will be listed as a contact on all grant proposals. In the case that the notification of funding is sent to any other office, the University policy is that any person who receives notification of a grant approval or denial in writing, or by phone or e-mail must copy that information to either the Advancement Communications and Grants Specialist or Executive Director of Marketing and Communications in a timely way. The Advancement Communications and Grants Specialist will take responsibility for communicating the information to all those involved in the proposal. The Advancement Communications and Grants Specialist prepares and submits an award acknowledgement and contacts the funder to implement the grant. The actual receipt of all grant monies is reported to the advancement office for entry into the database regardless of the office of receipt.

Step 5: Tracking and Reporting

Because the University also has a responsibility to monitor the project and maintain good relationships with the funders, the Advancement Communications and Grants Specialist will be involved with reporting. Grants are recorded and required report deadlines are tracked through the Advancement Communications and Grants Specialist. Every granting agency or funder requires or expects a report on the project either throughout the implementation or on completion or both. The grant sponsor works with the grant directors to write and submit all grant reports to the funder in a timely manner.

Grant Proposal Funding Procedures and Guidelines

The University has specific procedures and guidelines related to grant funding. These are concerning salaries, released time, benefits, F&A, other agreements, consulting, etc. It is the responsibility of the PI/PD and the Provost and Vice Presidents to be aware of these following guidelines:

Salary rate and raises, faculty or staff: Funds requested in proposals for salary cannot exceed the individuals' established salary rates paid by the University, regardless of the source of funding. Salaries for years in which the exact salary rates are not known will be projected at rates determined by the finance office based on expected salary increases and past experience. Increases for projected years may be above the established rate under special circumstances, such as promotion. Salary charges to grants or contracts, including raises on multi-year proposals, must be at a rate no higher than that paid by the University.

Faculty Release Time: Funds requested for faculty course release time should be included in the proposed budget based on a faculty member's academic year salary and the percentage of his/her time that will be devoted to the project. This percentage of time will be determined by the PI/PD in consultation with the chair or dean and then approved by the Provost. Full fringe benefits should also be included. The funds provided for the PI's salary and benefits may be used to hire replacement faculty and any remainder may be recovered by the University. Funds for course release may be requested at a lower rate than the faculty members' salaries and benefits with the approval of the Provost.

Externally paid employment on grants or contracts: Faculty on nine-month contracts requesting additional salary from external sponsors during the academic year and twelve-month personnel requesting additional salary at any time must have a written approval by the Provost. The external paid employment must not interfere with the obligations of the faculty or staff member to the University or create any financial conflicts of interest. Approval for an external paid employment must be sought in advance of the beginning date of the commitment. Final approval need not be obtained prior to the submission of a proposal; however, approval must be obtained before any salary payment can be made.

Benefit Rates: Fringe benefits should be included in proposal budgets as shown below at rates determined by the finance office in conjunction with the Human Resources Office, subject to federal and state laws and policies and other University policies.

Faculty, summer salary – Social Security only.

Faculty, academic year – Full benefits (unless above and beyond regular duties and proposed as external paid employment in which case only Social Security benefits would be applicable).

Students, summer salary – Social Security only (unless enrolled in classes at least half-time in which case no benefits are applicable).

Students, academic year – No benefits.

Part-time personnel – Social Security only.

Full-time non-tenure-track personnel, and postdoctoral researchers – Full benefits.

Annual and/or sick leave for grant-funded full-time employees: Annual or sick leave for grant-funded full-time employees will not accrue during the life of the grant; however, leave can be granted to employees at the discretion of the Provost or appropriate Vice President during the grant-funded employment period.

Facilities & Administration Costs and Rate (F&A – formerly “indirect costs” or “overhead”): The University includes funds for F&A costs in all proposal budgets submitted to external funding sources at the rates negotiated with the federal government, unless the sponsor has an officially published policy that states F&A costs are not allowed or that they are permitted at a reduced rate, or if a waiver or partial waiver of these costs has been approved by the Provost or vice President. The University’s federally negotiated F&A rates in force at the time of proposal submission (or that would be in force at the time of award, if known) will be used to calculate the appropriate level of F&A costs to request in proposal budgets. After awards are made, the F&A costs will be charged to grants as stipulated in the approved budgets.

F&A rates may be waived or reduced by the Provost or appropriate vice President only in exceptional circumstances in writing. The conditions for and duration of F&A waivers or partial waivers are determined by the Provost or vice President. A

waiver must be renegotiated with the Provost or vice President after the duration of the previous waiver has expired.

The F&A rates in force at the time of proposal submission (or that would be in force at the time of award, if known) will be used in proposal budgets throughout the requested project period, which is usually up to five years. When an award is made, the rate used at the beginning of a grant or contract will remain the same throughout the project period stated in the award. If a proposal that will compete for funding is submitted to continue the work (sometimes referred to as a "competitive renewal" or a "competing continuation"), the rate in force when the new application is submitted (or that would be in force at the time of award, if known) should be used in the proposed budget for the new project period. F&A recoveries are deposited 100% to the general use of the University.

Consulting Agreements: Individual agreements made directly between GCU faculty and external sponsors for consulting services will not be administered by the Advancement Communications and Grants Specialist.

Over-expenditures: While the finance office provides management support, ultimately the fiscal responsibility for sponsored programs resides with the PI/PD, the department chair, the dean of the school and the Provost or vice president. These individuals will review project expenditures regularly and may consult with the grants accountant at any time. Unresolved over expenditures on accounts administered by the University will, at the direction of the President, be recovered from the school or department of the PI/PD.

Faculty affiliation of non-tenure-track investigators: For purposes of submitting a proposal, each PI/PD not currently employed with the University must be affiliated with the department or school most compatible with his/her research or educational project. The chair or school dean must approve the proposal before submission.

Reporting Responsibilities to Grant Sponsors: The PI/PD must ensure that ongoing fiscal management is accomplished in accordance with sponsor requirements, including necessary notifications to the sponsor about project status. Remaining in communication with sponsors and with GCU administrative offices is an important part of project management. To keep all involved parties aware of project status, it is good practice to maintain communications with the sponsor's technical office and the sponsor's grant or contract officer. In all cases, required notifications or requests for prior approval of contract or grant status must be made in writing to both the administrative and technical officials in the sponsoring agency. Such notifications must be coordinated through the Advancement Communications and Grants Specialist.

Changes in Funding Status: The PI/PD has a duty to provide the sponsor with periodic research progress and funding status updates, as agreed upon in the initial project proposal. The duty to notify sponsors in a timely manner is of particular importance when changes in funding status may affect the ultimate viability of the project. Such notifications must be made in a timely manner, in coordination with the Advancement Communications and Grants Specialist in order to allow sufficient time to arrange for and process additional funds, or for the reduction in

spending and effort in order to phase out the program in an orderly fashion if additional funds are not available. The PI/PD's dean must also be informed, in advance, of potential funding problems.

Changes in Principal Investigator Status: In addition, sponsors often request the right to notification or prior approval of changes in availability of the PI/PD. A significant change in the availability of a PI/PD is designated as a reduction in time devoted to the project of 25% or more from the proposed and awarded level, or an absence from the project for more than three months.

In either of the above cases, the PI/PD must contact the [Director of Foundation and Government Relations and Director of Grants Development] to coordinate securing required approvals. If, in the original award, GCU had committed to fund some of the PI/PD's effort as cost sharing and the PI/PD reduces the overall committed level on the project, the Advancement Communications and Grants Specialist will also negotiate reductions in levels of the cost-shared component of effort, as appropriate.

In addition, when a PI/PD's faculty appointment will terminate prior to or during a project's period of performance, the sponsor must be informed immediately by the Advancement Communications and Grants Specialist.

Closeout Procedure: The successful closeout of a sponsored project relationship is critical to maintaining long-term positive contacts with donors. The PI/PD, with support from the Director of Grants Development, assumes primary responsibility for ensuring the completion of all closeout procedures. Sponsors must be provided with the following documents within a reasonable period (typically within one month) following the completion of the research project: a technical report, a financial report, a property report, and an invention report (if applicable). The PI/PD must also adhere to ethical standards and any specifically agreed-upon provisions for recognition of the sponsor in any publications resulting from the project.

Disposition of University-owned grant-purchased (GP) equipment: Unless policies of the funder dictate otherwise, GP equipment will remain with the University and be subject to Information Technology policies as per the CIO. Any GP equipment relocated to a PI/PD's home (e.g., computer equipment) must be cleared first by a memorandum to the finance and administration office informing them of the relocation.

Proposal Preparation Expenses: Expenses related to proposal preparation outside of Georgian Court University Marketing or Advancement offices will be covered by the school or department of the PI/PD. These may include travel to proposal preparation workshops offered by the grantor, additional pay for time in proposal writing, or travel to meetings to prepare multi-institutional collaborative projects as well as other items.

These procedures and guidelines will be reviewed annually and updated as necessary.

RELATED POLICIES

Policy for Review of Research Involving Human Subjects

8.8 Export Control

| EXPORT CONTROL | |
|-----------------------------|------------------------------------|
| Effective Date: | |
| Policy Number: | VIII – 8.8 |
| Supersedes: | Not Applicable. |
| Issuing Authority: | [TBD] |
| Responsible Officer: | [TBD] |
| Applicability: | All departments of the University. |
| History: | |

PURPOSE

Georgian Court University is committed to full compliance with the laws and regulations of the United States addressing the export of certain goods, information, technology and services that are restricted for reasons relating to U.S. national security, economic interests, and foreign policy goals. This policy is designed to provide guidance to University employees, students and other applicable members of the University community in the application of and compliance with the various complex U. S. Export Control laws.

POLICY

It is the responsibility of all University employees, students and applicable community members to be familiar with this policy and aware of export control laws that might apply to their activities, and to comply with those laws and University policy and procedures.

DEFINITIONS

“*Export*” means (a) an actual shipment or transmittal of items (such as equipment, hazardous material, or technology) controlled under the Export Administration Regulations (EAR) or International Traffic in Arms Regulations (ITAR) to persons and entities outside of the U.S.; or (b) any written, oral or visual release or disclosure of controlled technology, information or software to a Foreign Person either in the U.S. or outside the U.S.; or (c) any actual use or application of controlled technology on behalf of or for the benefit of any foreign entity or person anywhere.

“*Foreign Person*” means any person, corporation, business association, partnership, trust, society or any other entity or group that is not incorporated or organized to do business in the U.S. as well as international organizations, foreign governments and any agency or subdivision of foreign governments (e.g., diplomatic missions), and anyone who is not a U.S. citizen, a lawful permanent resident of the U.S. (i.e., a green card holder) or who does not have refugee or asylum status in the U.S.

EAR means the Export Administration Regulations written and promulgated by the Bureau of Industry and Security (BIS), Department of Commerce. See <http://www.gpo.gov/fdsys/pkg/FR-2013-04-16/pdf/2013-08352.pdf>

ITAR means the International Traffic in Arms Regulations written and promulgated by the Directorate of Defense Trade Controls (DDTC), Department of State. See https://www.pmdt.c.state.gov/regulations_laws/itar.html

OFAC Regulations means regulations promulgated by the Office of Foreign Assets Control (OFAC), Department of the Treasury. See <http://www.treasury.gov/resource-center/sanctions/Pages/default.aspx>

PROCEDURES/GUIDELINES

The export of certain technologies, software, and hardware is regulated and controlled by federal law for reasons of national security, foreign policy, prevention of the spread of weapons of mass destruction, and for competitive trade reasons. Export control laws require that a license be obtained prior to providing controlled technologies to foreign nationals from restricted countries. The following is a non-exhaustive list of situations that might trigger export control regulations:

- Shipping tangible items internationally;
- Sharing proprietary, confidential, or otherwise restricted information or software code with foreign nationals at a University or destinations outside the U.S.;
- Interactions with countries or organizations/individuals from a country currently subject to sanctions or embargo (see <http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>);
- Hand carrying laptops, cell phones containing microprocessors and equipment while traveling to a foreign destination; and
- Exporting or importing items that have been designed, developed, configured, adapted or modified for a military application.

In addition, the trade sanctions/embargo regulations have additional requirements restricting transferring of “items of value” to sanctioned countries.

Many of the activities conducted by a University’s employees, students or community members are exempt from these complex regulations. The federal regulations generally provide an exemption from export controls for basic or applied academic research that is published in the public domain and shared with the general research community. This broad exemption is commonly referred to as the “Fundamental Research Exemption”. This exemption provides that the conduct, products and results of fundamental research are to proceed largely unfettered by deemed export restrictions. Research that carries access, participation, or dissemination restrictions, however, will typically not qualify for the fundamental research exemption.

Notwithstanding research exemptions, in any of the circumstances listed above, or under other circumstances where there is a question whether export control laws might apply, the University requires its employees, students, and other applicable members of the University community to confer with the University’s Office of the General Counsel to determine the applicability of export control laws and regulations (including the applicability of any exclusion or exemption) prior to the export, traveling to the country, and/or entering into any negotiations or agreements with the country, entity or person.

Failure to comply export control laws and regulations may result in criminal and civil penalties (incarceration and fines), as well as sanctions (fines, loss of research funding and/or export privileges) for the University. In addition, the failure to comply with this policy may result in University discipline for the affected employee, student or University community member.

Additional Information

The three main export control regulators are:

- The Department of Commerce, through BIS, for “dual-use” (i.e., used both in military or commercial applications) and commercial goods, information and technology under the EAR. Dual-use items are listed on the Commerce Control List (CCL), which can be found in the EAR: <http://www.gpo.gov/fdsys/pkg/FR-2013-04-16/pdf/2013-08352.pdf>
- The Department of State, through the DDTC, for defense technologies and services under the ITAR. Defense technologies are listed on the U.S. Munitions List (USML), which can be found in the ITAR: https://www.pmddtc.state.gov/regulations_laws/itar.html
- The Department of the Treasury through the Office of Foreign Assets Control (OFAC) for economic sanctions and embargoes, under Executive Orders and OFAC Regulations: <http://www.treasury.gov/resource-center/sanctions/Pages/default.aspx>
- Other agencies involved in export regulation include the Bureau of Customs and Border Protection, Department of Energy, Nuclear Regulatory Commission, Department of Justice, Department of Defense, Environmental Protection Agency, and Patent and Trademark Office.

In addition, a helpful tool for analyzing exclusions under the EAR for publicly available information is the Questions and Answers – Technology and Software Subject to the EAR which is found in Supplement 1 to part 734 of the EAR (<http://law.justia.com/cfr/title15/15-2.1.3.4.22.0.1.13.23.html>).