

Research

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Combatting Trafficking In Persons Policy

Type of Policy: Administrative

Effective Date: 2016-02-00T00:00:00

Last Revised: 2016-02-00T00:00:00

Policy Owner: Sponsored Programs, Office of

Contact Name: Duane Hutchison

Contact Title: Executive Director, OSP

Contact Email: duane.hutchison@osp.gatech.edu

Reason for Policy: The United States Government has adopted a zero tolerance policy regarding trafficking in persons. These statutes and regulations require federal grant recipients and contractors to prohibit the use of research funds received from federal sources for promotion of prohibited activity.

Policy Statement:

Georgia Institute of Technology opposes prostitution, forced labor and any related activities contributing to the phenomenon of trafficking in persons. Trafficking in persons is a violation of U.S. Law and recognized as a violation of human rights.

Related Regulations

[18 USC Section 1581](#)

[45 CFR Section 52.222-50](#)

Applicability

This policy applies to all researchers at Georgia Tech and all employees or students who assist these researchers or participate in performing tasks related to such research activities.

Definitions

Trafficking in Persons

The United States government considers trafficking in persons to include all of the criminal conduct involved in forced labor and sex trafficking, essentially the conduct involved in reducing or holding someone in compelled service. [\[More\]](#)

Procedures:

Report any violations via Ethics Point which can be found online at <https://secure.ethicspoint.com/domain/media/en/gui/7508/index.html>.

Responsibilities:

Report any violations via Ethics Point which can be found online at <https://secure.ethicspoint.com/domain/media/en/gui/7508/index.html>.

Enforcement: Non-compliance with this policy would be a violation of U.S. law. Georgia Tech will take action for violation of this policy including, but not limited to, removal from the contract, taking disciplinary action up to and including termination of employment.

Policy History:

Revision Date	Author	Description
02/15/2016	OSP	

Contracting Services for other Georgia Tech Affiliated Non-Profit Entities

For Information about Contracting Services for other Georgia Tech Affiliated Non-profit Entities, please see [Office of Sponsored Programs website](#):

- BOR Agreements
- GATV Agreements
- GCMI Agreements

Environmental Health and Safety

The Environmental Health and Safety (EHS) Office at Georgia Tech consists of the following department units: Fire and Life Safety, General Safety, Chemical/Lab Safety, Radiation Safety, Biosafety, and Hazardous Materials.

"EHS develops programs and provides oversight, consultation, training, and other specialized services to assist the Institute community in meeting its public health, safety, environmental protection, and compliance responsibilities.

For more information please visit, [Environmental Health and Safety](#).

Industry Contracts

For Information on Industry Contracts, please see [Office of Sponsored Programs website](#):

- Advance Payments
- Contract Templates
- Establishing Relationships
- IP and Licensing
- International Collaboration
- STTR/SBIR

Intellectual Property Assignment Agreement

For information on the Intellectual Property Assignment Agreement, please see:

- [Intellectual Property Assignment Agreement](#)

International Agreements

For Information on International Agreements, please see [Office of Sponsored Programs website](#):

- Compliance Requirements in International Agreements and Subagreements
- Export Controls Policy
- F&A on International Agreements
- Foreign Corrupt Practices Act Policy
- Foreign Sponsors
- Internationally-Sourced Agreements Fee

Investigational New Drug (IND) Application

Type of Policy: Administrative

Last Revised: 2013-12-00T00:00:00

Review Date: 2016-12-00T00:00:00

Contact Title: Executive Vice President for Research

Reason for Policy:

An Investigational New Drug (IND) Application is submitted to U.S. Food and Drug Administration (FDA) if a drug not previously authorized for marketing in the US is intended to be used for the purposes of clinical investigation.

A clinical investigation is defined by the FDA as “an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. Such an experiment is any use of a drug [whether approved or unapproved] except for the use of a marketed drug in the course of medical practice.”

The Sponsor of an IND application is the party who submits the application to FDA. In the absence of any other sponsor (e.g. pharmaceutical company), the investigator conducting the proposed clinical investigation is the sponsor of the IND application.

When developing new drugs and devices in pre-clinical research to the point where they transition to investigations clinical applications, FDA approval is required and the Principal Investigator for the research serves as the Sponsor of the IND unless or until the further development and/or commercialization of the new drug or device is undertaken by a third party.

Consistency with Georgia Tech’s Strategic Plan, Other Institute Policies, and Related External Documents

21 CFR 11 (Electronic records and electronic signature)

21 CFR 54 (Financial Disclosure by Clinical Investigators) [FDA forms 3454 and 3455]

21 CFR 210 (Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding of Drugs; General)

21 CFR 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)

21 CFR 312 (Investigational New Drug Application)

21 CFR 314 (Drugs for Human Use)

21 CFR 320 (Bioavailability and Bioequivalence Requirements)

21 CFR 330 (Over-The-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and effective and Not Misbranded)

21 CFR 601 (Biologics Licensing)

Policy Statement:

The Principal Investigator for the project under which a new drug may become the subject of a clinical investigation and who is responsible for the initiation and conduct of the clinical investigation shall be responsible for developing the IND Application to be submitted to the FDA and will be a “Sponsor-Investigator” in accordance with 21CFR§312.53. Usually, the intent of the research in such a clinical investigation is to gain scientific knowledge without seeking market approval for the drug or device. This responsibility is generally part of the Principal Investigator’s research duties when it takes place in the course of sponsored or Institute-funded research. The Sponsor-Investigator is the source of the information for the relevant FDA filings and reports and is responsible for their content.

The Sponsor-Investigator’s responsibilities include:

- Selecting clinical investigators. Clinical investigations must be conducted in appropriate clinical setting under the direction of a physician (or dentist, when appropriate) qualified by training and experience as appropriate experts to investigate the drug who should be listed as a Sub-investigator for the trial and should be responsible for all trial-related medical (or dental) decisions. Clinical investigations will generally be conducted pursuant to an appropriate contract or subcontract with a Clinical Research Organization (CRO), most often an academic medical center, with the Sub-investigator generally serving as its Principal

Investigator. The negotiation and awarding of the contract or subcontract will follow all applicable Institute policies, guidelines, and applicable regulations.

- Selecting a Contract Manufacturing Organization (CMO) or other source to provide the drug for use in the study in compliance with applicable FDA requirements. The negotiation and awarding of the contract with the CMO or supplier will follow all applicable Institute policies, guidelines, and applicable regulations.
- Informing and qualifying investigators by obtaining their commitment to supervise the study, follow the protocol, and obtain consent.
- Monitoring the conduct of the study by auditing documentation and conducting site visits.
- Completing regulatory filings related to the IND or IDE, adverse events, amendments or revisions, progress reports, withdrawal of IRB approval, and final reports.
- Controlling the distribution, tracking, and dispensation of the regulated products.

Sub-investigator (Principal Investigator for Clinical Contract or Clinical Subcontract) Responsibilities Include:

- Ensuring IRB approval for the study is obtained before any subjects are enrolled.
- Ensuring that informed consent is obtained in accordance with FDA regulations.
- Ensuring that the investigation is conducted according to the investigational plan and applicable regulations.
- Administering the drug or using the device only in subjects under the investigator's supervision or under the supervision of a recognized sub-investigator.
- Maintaining adequate records of the dispensation of the drug or device.
- Returning unused materials at the end of trial.
- Preparing and maintaining adequate case histories and signed informed consent documents.
- Maintaining correspondence with the IRB and the sponsor to make sure that both have reviewed protocol amendments, recruitment materials, investigator brochures.
- Retaining records in accordance with regulations.
- Providing progress, safety, final and financial disclosure reports.
- Notifying the sponsor if IRB approval is withdrawn.
- Comply with International Conference on Harmonisation (ICH) guidelines, if applicable. Please see the module International Conference on Harmonisation, ICH for Investigators.
- Inspections and Audits
- Ensuring computer systems comply with 21 CFR Part 11.

Scope:

All units of the Institute must comply with this policy.

Procedures:

Faculty Investigator/Sponsor must complete IND Investigator Responsibility form and provide a copy to the Office of Research Integrity Assurance for review of any research study where an IND application will be filed by a Georgia Tech Investigator.

Joint and Dual Academic Agreements

Type of Policy: Administrative

Effective Date: 2014-08-00T00:00:00

Last Revised: 2014-08-00T00:00:00

Review Date: 2017-08-00T00:00:00

Policy Owner: Library Learning Excellence

Contact Name: Catherine Murray-Rust

Contact Title: Vice Provost Learning Excellence and Dean of Libraries, SACSCOC Accreditation Liaison

Contact Email: catherine.murray-rust@library.gatech.edu

Reason for Policy:

This policy is designed to ensure that Georgia Tech complies with applicable accreditation principles of SACSCOC and Policy and Procedures of the Board of Regents (BOR) of the University System of Georgia (USG) for academic programs offered via collaborative agreements between Georgia Tech and other institutions.

Policy Statement:

Georgia Tech is responsible for providing timely notification to SACSCOC and to the USG's BOR of agreements involving dual or joint academic agreements (awards), providing signed copies of the agreements and any other documentation or information required by SACSCOC or USG BOR policies and procedures for review.

This policy outlines the procedures Georgia Tech must follow to comply with SACSCOC's Agreement Involving Joint and Dual Academic Awards Policy and the USG's BOR Curriculum and Off-Campus Instructional Sites policy. Adherence to the policy will ensure Georgia Tech avoids sanctions and penalties associated with non-compliance.

Scope:

This policy applies to dual or joint academic agreements (awards) established for the purposes of awarding academic completions awards, e.g. certificates, diplomas or degrees.

Policy Terms:**Dual Academic Award**

Students study at two or more institutions and each institution grants a separate academic award bearing only its name, seal and signature.

Joint Academic Award

Students study at two or more institutions and the institutions grant a single academic award bearing the names, seals and signatures of each of the participating institutions.

Faculty Sponsor / Point of Contact

The Georgia Tech faculty employee responsible for developing and / or negotiating the terms and operational details of the dual or joint academic award on behalf of Georgia Tech and providing information and regular reports to every responsible person in his / her business unit responsible for oversight. The agreement must be signed by an authorized agent of Georgia Tech – this may or may not be the Georgia Tech Faculty Sponsor / Point of Contact.

Procedures:**5.1 Dual Academic Awards****SACSCOC: Dual Academic Awards**

Entering into an agreement with another institution involving a dual academic award is a substantive change that requires an institution to submit a letter of notification to SACSCOC six months prior to implementation of the agreement and a final signed copy of the agreement. Formal, written acceptance of that notification and agreement by SACSCOC is required before implementation of the provisions of the agreement.

The following should be submitted to SACSCOC:

- A notification letter that includes a statement of intent, the anticipated beginning date of the agreement, a description of the agreement, the complete address/location parties involved in the agreement and information for contact persons at each participating institution regarding the agreement
- A copy of the final signed agreement

If the joint or dual academic award involves offering 50 percent or more of a program at a previously unapproved off-campus site by a member institution or involves offering a new program which is significantly different from currently offered approved programs, notification is due six months prior to implementation date with a prospectus for approval due at least three months prior to implementation.

USG's BOR: Dual Academic Awards

Dual Degrees in the University System of Georgia are defined according to the SACSCOC Agreements Involving Joint and Dual Academic Awards: Policy and Procedures Policy. Notification to the Office of Academic Programs is

required at least two weeks prior to implementation. Only dual degrees comprised of academic programs that have been previously approved by the BOR either at a single University System institution or between University System institutions shall be forwarded as notification items. All new degree programs require Board approval.

Responsibilities:

8.1. Responsible Party

Faculty Sponsor / Point of Contact

- Notifies and receives approval from every responsible person/business unit noted in the Institute’s Graduate and Undergraduate Curriculum Committees Process for Approving Curricular Change – Steps 1-3 and 5 in the Approval Process. This can be found on the ICC website (information on website and location from Reta)
- Consults with SACSCOC Accreditation Liaison to determine if SACSCOC requirements and standards apply
- Provides final agreement to the SACSCOC Accreditation Liaison for submission to SACSCOC is applicable
- Completes and provides to the Substantive Change Standing Committee and the SACSCOC Accreditation Liaison all required SACSCOC and USG BOR documentation necessary for approval of any substantive change (i.e. a completed prospectus)
- Implements and submits annual assessment and periodic review report to every responsible party including the SACSCOC Accreditation Liaison

Enforcement:

Failure to comply with SACSCOC’s substantive change procedures, could result in the Institute’s loss of Title IV funding, the Institute’s reimbursement to the U.S. Department of Education money received for programs related to unreported substantive change, sanction or removal from membership with SACSCOC.

Optional: To report suspected instances of noncompliance with this policy, please visit Georgia Tech’s *EthicsPoint*, a secure and confidential reporting system, at:

https://secure.ethicspoint.com/domain/en/report_custom.asp?clientid=7508

Policy History:

Revision Date	Author	Description
08-2014	Library Learning Excellence	New Policy

Other Agreements

- Non-Disclosure Agreements, please see [Office of Legal Affairs.](#)
- For Information about Other Agreements, please see [Office of Sponsored Programs:](#)
 - [Intellectual Property Assignment Agreement](#)
 - [Intergovernmental Personnel Act](#)
 - [Material Transfer Agreements \(MTA's\)](#)
 - [Memoranda of Understanding](#)
 - [Software In-licenses](#)
 - [Teaming Agreements](#)
 - [Visiting Scholars](#)

Research Administration Policies

For additional information on Research Administration Policies & Procedures, please see the following:

- [1.0 Overview](#)
- [2.0 Pre-award Project Management and Proposal Development](#)
- [3.0 Regulatory Management and Research Risks](#)
- [4.0 Post-award Management - Financial Administration](#)
- [5.0 Subcontracts, Subawards, and Subrecipient Administration](#)
- [6.0 Post-award Management – Programmatic Administration](#)
- [7.0 Industry Contracts](#)
- [8.0 International Sponsored Projects](#)
- [9.0 Other Agreements](#)
- [10.0 Contracting Services for other Georgia Tech Affiliated Non-profit Entities](#)

Research Integrity Assurance

Review Date: 2015-01-00T00:00:00

Universities, as partners in the national research enterprise, are required by federal regulations to establish specific research committees to ensure the ethical and safe conduct of research and certain other scholarly activities. The Institutional Animal Care and Use Committee, the three Institutional Review Boards, and the Institutional Biosafety Committee have been established to oversee activities involving, respectively, vertebrate animal subjects, human research subjects, and recombinant DNA (rDNA). These federally mandated faculty committees are administered and supported by the Office of Research Integrity Assurance, which reports to the Vice President for Research. Procedures for obtaining committee approval can be found at www.researchintegrity.gatech.edu.

Conflict of Interest

For more information about Conflict of Interest, please see:

- [Faculty Handbook 5.6 Conflict of Interest and Outside Professional Activity Policy](#)
- [Conflict of Interest Management Office](#)

Export Control

Review Date: 2015-01-00T00:00:00

Research is a global endeavor and international experiences and opportunities are vital in preparing Georgia Tech's students to become leaders who meet the challenges of the future. It is sometimes challenging to conduct these programs in compliance with complex laws and regulations that change frequently.

Because you, as an individual, and Georgia Tech can be held liable for improperly transferring controlled technology it is important that you review these federal requirements.

What is Export Control?

"Exports" include:

- Verbal communication
- Transfer of written documents, and
- Transfer of U.S. computer software to a foreign national whether in the U.S. or abroad if the technology is controlled by export regulations.

The determination of whether a technology is controlled is critical in determining whether export control laws and regulations apply to the activity. To find out if technologies or data are controlled, check the Export Administration Regulations (EAR) and International Traffic in Arms Regulations (ITAR) control lists and contact the Office of Legal Affairs or by phone at 404.894.4812. Please refer to the both the EAR and ITAR web sites for a more general overview of the regulations regarding each of the above mentioned control lists.

As defined in these laws, technology includes information related to the design, development, or production of equipment or software. Transfers of listed technologies to non-U.S. persons or entities in the form of drawings, schematics, blueprints, research results, formulae, meetings, symposiums, classroom discussions, conversations, email, etc, are controlled.

If any controlled information, technology, software, or equipment will be transferred to another party overseas or to a foreign party in the United States, a license must be obtained prior to the transfer unless a valid licensing exception or exclusion applies.

For more information about Export Control, please see the [Export Control website](#).

Institutional Animal Care and Use Committee

Review Date: 2015-01-00T00:00:00

The Georgia Institute of Technology is committed to ensuring that vertebrate animals used in research and teaching activities receive humane care and treatment. The Institutional Animal Care and Use Committee (IACUC) is charged with reviewing all proposed use of vertebrate animals, regardless of where the work is performed and source of funding, if any. The IACUC has the responsibility and authority to review, approve, disapprove, or require changes in research activities involving vertebrate animals. This committee regularly inspects and monitors the animal care and use facilities and program at the Institute to ensure that all components are in compliance with regulations outlined in the federal Animal Welfare Act, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, and with the Eighth Edition of the Guide for the Care and Use of Laboratory Animals.

The animal facilities are registered with the U.S. Department of Agriculture and undergo frequent, unannounced inspections by that agency. Georgia Tech's Animal Welfare Assurance is approved by the Department of Health and Human Services. Committee membership is structured in accordance with federal requirements; members are appointed by the Vice President for Research, who also serves as the Institutional Official for matters related to vertebrate animal subjects.

The IACUC has set forth procedures for reporting, without fear of reprisal, concerns about the humane use and treatment of vertebrate animals used in research and teaching activities at Georgia Tech. The IACUC meets monthly to review research protocols which propose the use of vertebrate animal subjects; committee approval must be obtained prior to initiation of proposed activities.

For more information about the Institutional Animal Care and Use Committee, please see the [Institutional Animal Care and Use Committee website](#).

Institutional Biosafety Committee

Review Date: 2015-01-00T00:00:00

The Institutional Biosafety Committee (IBC) is responsible for reviewing all registrations for research, teaching, and training that involve the use of recombinant DNA by Georgia Tech faculty, staff or students and ensuring that the proposed activities comply with the federal *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and all other applicable regulations. All scholarly activities involving recombinant DNA, regardless of source of funding, must be reviewed by the IBC. The Committee has the responsibility and authority

to review, approve, disapprove, or require changes in research, teaching, and training activities involving recombinant DNA materials.

Georgia Tech's Institutional Biosafety Committee is registered with the National Institutes of Health's Office of Biotechnology Activities (OBA). IBC works closely with Georgia Tech's Biosafety Officer in the Office of Environmental Health and Safety. Committee membership is structured in accordance with federal requirements. Members are appointed by the Executive Vice President for Research, who is also the Institutional Official for matters related to the Biosafety Committee. The IBC holds meetings as needed to review registrations.

For more information about Institutional Biosafety Committee, please see the [Institutional Biosafety Committee website](#).

Institutional Review Board

Review Date: 2015-02-00T00:00:00

Georgia Tech subscribes to the basic ethical principles that underlie the conduct of biomedical and behavioral research involving human subjects as set forth in the Belmont Report, the timeless statement of ethical principles and guidelines for the protection of human subjects published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

The three Georgia Tech Institutional Review Boards are charged with protecting the rights and welfare of human subjects participating in research projects conducted by Georgia Tech faculty, staff, or students. These include the Central IRB, the Joint Georgia State University-Georgia Tech IRB for the Advanced Brain Imaging Center, and the Classified IRB. The IRBs have the responsibility and authority to review, approve, disapprove, or require changes in research activities involving human subjects. All proposed research activities involving human subjects, regardless of source of funding or study location, must be reviewed and approved by the appropriate Georgia Tech Institutional Review Board (IRB) prior to initiation of research. The IRBs hold regularly scheduled meetings to review research protocols involving human subjects.

Georgia Tech's Federalwide Assurance is approved by the Department of Health and Human Services, and the Institutional Review Boards are registered with the Department of Health and Human Services, Office for Human Research Protections.

Committee members are appointed by the Vice President for Research, who also serves as the Institutional Official for matters related to human subjects. Membership is structured in accordance with federal requirements set forth in *Title 45 Code of Federal Regulations Part 46*, Federal Policy for the Protection of Human Subjects• including *Subparts A, B, C, and D*, and in *Title 21 Code of Federal Regulations, Parts 50, 56, 312, and 812*.

For more information about the Institutional Review Board, please see the [Institutional Review Board website](#).

Protecting Sensitive Data

Protecting Sensitive Data in Electronic Format and Best Practices for Backing Up Sensitive Data

- The Office of Information Technology (OIT) provided this guidance for the Office of Research Integrity Assurance to share with faculty and other researchers who possess sensitive data, particularly those data that involve human subjects and for which confidentiality is essential. Detailed safeguard recommendations for protecting sensitive data are posted on [OIT's site](#).
- These safeguards are highlighted here:
 - Store data only on a laptop/desktop with whole disk encryption. This will protect the data in the event the machine is stolen.
 - Back up the data regularly to a professionally-managed file server that is protected and backed up on a routine schedule. Talk with OIT or a CSR for more information on options.
 - Back up data to a tape or drive that is managed by OIT or the researcher's unit. Back ups should

- be encrypted and stored in a physically secure location.
- Machines on which data reside should be fully patched with the latest security patches.
- Limit access to the data strictly to those with legitimate need. For example, do not store data on a public-facing web server or Prism account.

For more information about Protecting Sensitive Data, please see: "[Protecting Sensitive Data in Electronic Format and Best Practices for Backing Up Sensitive Data](#)"

Responding to Allegations of Scientific or Other Scholarly Misconduct

Please see [Faculty Handbook 5.7 Policy for Responding to Allegations of Scientific or Other Scholarly Misconduct](#)

Responsible Conduct of Research

Last Revised: 2013-08-00T00:00:00

Review Date: 2016-08-00T00:00:00

Policy Statement:

Georgia Tech students and trainees engaged in research at the undergraduate, graduate and post-doctoral levels shall receive formal instruction in ethical considerations and decision making in Responsible Conduct of Research that is appropriate for their disciplines and for the stages of their research careers. This policy is intended to comply with the requirements of the National Science Foundation’s (NSF) implementation of the requirements of Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act (42 U.S.C. 1862o–1) found in the NSF Award and Administration Guide, Chapter IV, and National Institutes of Health (NIH) requirements found in NOT-OD-10-019*.

Responsible Conduct of Research (RCR) is defined by NIH "...as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research."

For more information about Responsible Conduct of Research, please see: "[Responsible Conduct of Research](#)"

Policy History:

Revision Date	Author	Description
08-2013	Policy Library	Fixed Responsible Conduct of Research external link

Responsible Conduct of Research Compliance Policy

Type of Policy: Administrative

Effective Date: 2016-01-00T00:00:00

Last Revised: 2016-06-00T00:00:00

Review Date: 2019-06-00T00:00:00

Policy Owner: Sponsored Programs, Office of

Contact Name: Duane Hutchison

Contact Title: Executive Director, OSP

Reason for Policy: Georgia Tech’s RCR Compliance Policy is intended to comply with the requirements of the National Science Foundation’s (NSF) implementation of the requirements of Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act (42 U.S.C. 1862o–1) found in the NSF Award and Administration Guide: Chapter IV, the National Institutes of Health (NIH) requirements

found in NOT?OD?10?019, and the U.S. Department of Agriculture (USDA) National Institute of Food and Agriculture (NIFA) program’s RCR training requirements. The applicability criteria contained within this Policy (see below) may expand to cover other groups of researchers and sponsors in the future. RCR is defined by the NIH “...as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.”

Policy Statement: It is the policy of the Georgia Institute of Technology that trainees engaged in research at the undergraduate, graduate, and postdoctoral levels shall receive formal instruction in ethical considerations and decision-making in Responsible Conduct of Research (RCR) that is appropriate for their disciplines and for the stage of their research careers. Faculty, staff, and other members of the Georgia Tech community will need to complete RCR training if the sponsor of their research imposes that requirement. It is the responsibility of the Principal Investigator/Project Director (PI) of covered projects (see Applicability below) to ensure that all applicable research team members are informed of the requirement and that the requirement has been met. (In the case of the NSF Graduate Research Fellowship Program (GRFP), these responsibilities will be shared between the graduate advisor and the Coordinating Official in the Fellowship Office.) Moreover, it is the PI’s responsibility to provide appropriate mentoring through discussions of RCR topics and through oversight of the research project.

Scope:

The RCR Compliance Policy requires that students, postdoctoral researchers, faculty, and staff receiving research funds or who participate in research activities funded by Georgia Tech’s President’s Undergraduate Research Award Program (PURA) and certain covered awards (see Applicability below) shall engage in a program of study in RCR that includes some or all of the following elements:

- Conflicts of interest (personal, professional, and financial)
- Policies regarding the use of human subjects in research
- Policies regarding the use of vertebrate animals in research
- Laboratory safety, biohazard management, chemical safety, and polices regarding the use of radioisotopes and radiation sources in research
- The responsibilities and relationships of mentors and mentees
- Collaborative research
- The peer review process
- Data acquisition and laboratory tools; management, sharing and ownership of data and research tools
- Research misconduct and policies for handling research misconduct
- Authorship and publication
- Science and engineering in society: the scientist and engineer as responsible members of society and ethical issues in research and the environmental and societal impacts of scientific research

Applicability

This Policy is intended to meet the RCR training requirements of federal funding agencies and other sponsors. This Policy covers:

GT PURA – This Policy applies to all students who participate in Georgia Tech’s President’s Undergraduate Research Award (PURA) Program.

NSF – This Policy applies to all undergraduate students, graduate students, and postdoctoral researchers, whether as an employee, GRA, or other trainee, funded by new proposals submitted, or due, on or after January 4, 2010, to conduct research; it excludes, for example, conference, symposium, workshop, or travel proposals. The Policy also applies to NSF GRFP Fellows funded by Fellowship Offers effective with the 2010 Competition.

NIH – This Policy applies to all undergraduate students, graduate students, and postdoctoral researchers funded by the following NIH programs: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2, and U2R. Trainees funded by an NIH training grant, a career development award (individual or institutional), a research education grant, or a dissertation research grant must receive RCR instruction.

USDA NIFA – This Policy applies to all researchers funded by the USDA National Institute of Food and Agriculture (NIFA) program, **including the principal investigator, other faculty members, students, postdocs, and any**

staff participating in the research project.

The applicability criteria contained within this Policy may expand to cover other groups of researchers and sponsors in the future.

RCR Responsible Conduct of Research

Procedures:

5.1 Training Requirements by Funding Source

**President's
Undergraduate
Research Awards
(PURA) Program**

All undergraduate students participating in Georgia Tech's **PURA Program** must complete an online CITI RCR course (<http://www.rcr.gatech.edu/pura>).

The mentors of students funded by the PURA Program are strongly encouraged to provide discussion-based training opportunities for these students as well.

**Undergraduate
Students Funded by
NSF or NIH**

All undergraduate students paid in whole or in part from covered projects funded by **NSF** or **NIH** must complete both: (1) online RCR training and (2) in-person RCR training.

Undergraduate Online Requirement

The online training requirement involves successfully completing a CITI RCR course (<http://www.rcr.gatech.edu/online-training>).

Undergraduate In-Person Requirement

Applicable **NSF**-funded undergraduates must complete at least 1 hour of discussion-based RCR instruction; it is strongly encouraged that this instruction be focused on the topic of research misconduct. **NIH**-funded undergraduates must complete at least 8 hours of discussion-based (“in-person”) RCR instruction. At the discretion of the PI or School, applicable undergraduate students shall fulfill the discussion-based (“in-person”) RCR training requirement by either:

- Participating in OSP approved RCR training events (www.rcr.gatech.edu/workshops); or

5.1 Training Requirements by Funding Source

- Participating in educational events that the PI or School has deemed appropriate for RCR training, which can include regularly scheduled meetings or discussions involving the research team that address RCR topics; or it can involve a class, seminar, or other interactive approach developed by the School or PI that addresses RCR topics.[‡]

UNDERGRADUATE IN-PERSON RCR TRAINING REQUIREMENT	Funding Source and Hours Required	Training Options
	NSF - 1 HOUR	<ul style="list-style-type: none"> • OSP approved RCR Training Events • Research Team Meetings[‡] • Other events approved by the PI or School[‡]
	NIH - 8 HOURS	

[‡] Documentation of this form of in-person training must be maintained in the project file by the PI. All other training will be documented in either the Research Administration Education & Compliance training system or in Banner.

NSF-Funded or NIH-Funded Master's Students

All master's students paid in whole or in part from covered projects funded by **NSF** or **NIH** must complete both: (1) online RCR training and (2) in-person RCR training.

5.1 Training Requirements by Funding Source

Master's Online Requirement

The online training requirement involves successfully completing a CITI RCR course (<http://www.rcr.gatech.edu/online-training>).

Master's In-Person Requirement

Applicable **NSF**-funded master's students must complete at least 2 hours of discussion-based RCR instruction. **NIH**-funded master's students must complete at least 8 hours of discussion-based RCR instruction. At the discretion of the PI or School, applicable master's students shall fulfill the "in-person" requirement by either:

- Participating in OSP approved RCR training events (www.rcr.gatech.edu/workshops); or
- Registering through Oscar and successfully completing an approved RCR course (<http://rcr.gatech.edu/rcr-courses>); or
- Participating in educational events that the PI or School has deemed appropriate for RCR training, which can include regularly scheduled meetings or discussions involving the research team that address RCR topics; or it can involve a class, seminar, or other interactive approach developed by the School or PI that addresses RCR topics.[‡]

MASTER'S STUDENT IN-PERSON RCR TRAINING REQUIREMENT	Funding Source and Hours Required	Training Options
	NSF - 2 HOURS	<ul style="list-style-type: none"> • OSP approved RCR Training Events • Approved RCR course

5.1 Training Requirements by Funding Source

	NIH - 8 HOURS	<ul style="list-style-type: none"> • Research Team Meetings[‡] • Other events approved by the PI or School[‡]
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[‡] Documentation of this form of in-person training must be maintained in the project file by the PI. All other training will be documented in either the Research Administration Education & Compliance training system or in Banner.

**NSF-Funded or
NIH-Funded Doctoral
Students**

Doctoral students paid in whole or in part from covered projects funded by **NSF** or **NIH** must adhere to the training requirements delineated within the GT RCR Academic Policy for Doctoral Students (<http://www.rcr.gatech.edu/doctoral-policy/>).

While the same form of online training (a CITI RCR course) is required for all applicable doctoral students, those who began their graduate program prior to Fall 2011 should check with OSP if they need to discuss other options for satisfying the in-person training requirement.

**NSF-Funded or
NIH-Funded
Postdoctoral
Researchers**

All postdoctoral researchers paid in whole or in part from covered projects funded by **NSF** or **NIH** must complete both: (1) online RCR training and (2) in-person RCR training.

5.1 Training Requirements by Funding Source

Postdoctoral Online Requirement

The online training requirement involves successfully completing a CITI RCR course (<http://www.rcr.gatech.edu/online-training>).

Postdoctoral In-Person Requirement

Applicable **NSF**-funded postdoctoral researchers must complete at least 4 hours of discussion-based RCR instruction and **NIH**-funded postdoctoral researchers must complete at least 8 hours of discussion-based RCR instruction in order to satisfy the in-person training requirement. At the discretion of the PI or School, applicable postdoctoral researchers shall fulfill the “in-person” requirement by either:

- Participating in OSP approved RCR training events (www.rcr.gatech.edu/workshops); or
- Receiving permission to attend and participating in the RCR course (PHIL 6000) offered by the Ivan Allen College
(

); or
- Participating in educational events that the PI or School has deemed appropriate for RCR training, which can include regularly scheduled meetings or discussions involving the research team that address RCR topics; or it can involve an interactive approach developed by the School that addresses RCR topics.†

POSTDOC TORAL IN-PERSON RCR TRAINING REQUIRE MENT	Funding Source and Hours Required	Training Options
	NSF - 4 HOURS	<ul style="list-style-type: none"> • OSP approved RCR Train

5.1 Training Requirements by Funding Source

	NIH - 8 HOURS	ing E vents <ul style="list-style-type: none"> • Rece ive p ermis sion to att end PHIL 6000 • Rese arch Tea m M eetin gs[‡] • Othe r eve nts a ppro ved by the PI or Scho ol[‡]
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[‡] Documentation of this form of in-person training must be maintained in the project file by the PI. All other training will be documented in either the Research Administration Education & Compliance training system or in Banner.

**USDA NIFA-Funded
Students, Postdoctoral
Researchers, Faculty,
and Staff**

All researchers funded through the National Institute of Food and Agriculture (NIFA) program, including the principal investigator, other faculty members, students, postdocs, and any staff participating in the research project (defined as those who are funded by the project), must complete an online CITI RCR course (<http://www.rcr.gatech.edu/online-training>).

The PIs of projects sponsored by NIFA are strongly encouraged to provide discussion-based training opportunities for their research team as well.

Responsibilities:

The Principal Investigator (PI)

The PI is responsible for:

- filling out the RCR Project Plan Addendum to the Sponsored Programs/Research Proposal Authorization (as described in 5.4);
- notifying the research team of any applicable RCR training requirements;
- ensuring that the research team completes the RCR training;
- retaining records in the project file (as described in 5.5);
- certifying to OSP on an annual basis that the RCR training has been completed (as described in 5.5); and
- if a covered NIH project, preparing a plan to address the re-training requirements (as described in 5.3).

Office of Sponsored Programs (OSP)

The OSP is responsible for:

- notifying PIs about the RCR training requirements via terms and conditions in the project initiation package;
- retaining records of online (CITI) RCR training completions;
- notifying trainees, staff, and/or PIs of any non-compliance of online (CITI) RCR training; and
- retaining records of attendance at OSP-approved RCR workshops and events.

Coordinating Official (Fellowship Office)

The Coordinating Official for the Fellowship Office is responsible for:

- advising NSF GRFP Fellows on RCR policies and training requirements;
- working with the GRFP Fellow’s graduate advisor to ensure that the training is completed;
- working with the GRFP Fellow’s graduate advisor to obtain the necessary verifications required by NSF which confirm that all responsibilities have been fulfilled;
- certifying Satisfactory Academic Progress;
- working in coordination with the PI to ensure that the annual RCR certification to OSP can be submitted; and
- retaining records of in-person training completed outside of OSP approved events or approved RCR courses.

Enforcement:

Penalties for Non-Compliance

Students and Postdoctoral Researchers

Non-compliance on the part of any employed student or postdoctoral researcher may result in the termination of employment and shall result in the disallowance of salary and any associated expenses charged to the sponsored project. Cases of student non-compliance may also be referred to the Dean of Students for additional disciplinary action.

Non-compliance on the part of any NSF Graduate Research Fellow shall result in the failure to certify the Fellow’s Satisfactory Academic Progress and may result in the termination of the Fellowship.

Faculty and Staff

Non-compliance by faculty or staff on a USDA NIFA project shall result in the disallowance of salary and any associated expenses charged to the sponsored project.

Non-compliance by the PI on a USDA NIFA project may also result in the removal of the PI from the project and the appointment of a replacement PI.

Policy History:	Revision Date	Author	Description
	01-01-2016	OSP	Compliance Updates

Substantive Change Policy

Type of Policy: Administrative

Effective Date: 2014-08-00T00:00:00

Last Revised: 2014-08-00T00:00:00

Review Date: 2017-08-00T00:00:00

Policy Owner: Library Learning Excellence

Contact Name: Catherine Murray-Rust

Contact Title: Vice Provost Learning Excellence and Dean of Libraries, SACSCOC Accreditation Liaison

Contact Email: catherine.murray-rust@library.gatech.edu

Reason for Policy:

Georgia Tech is required to have policies and procedures to ensure that all substantive changes are reported to the Southern Association of Colleges and Schools Commission on Colleges (SACSCOC) in a timely fashion.

This policy outlines the procedures Georgia Tech must follow to comply with the SACSCOC Substantive Change Policy, in adherence with U.S. Department of Education regulations. Adherence to the policy will ensure Georgia Tech avoids sanctions and penalties associated with non-compliance.

Policy Statement:

As a member of the SACSCOC, Georgia Tech is required to notify SACSCOC of changes in accordance with the substantive change policy and when required seek approval prior to the initiation of changes.

Substantive change is a significant modification or expansion of the nature and scope of an accredited institution. The reporting and review of substantive change ensures that the scope of programs offered by Georgia Tech have undergone appropriate review by SACSCOC.

Required substantive change materials will be submitted by Georgia Tech's SACSCOC Liaison to SACSCOC for approval only after required Institute and University System of Georgia approvals have been obtained.

Scope:

Substantive change is defined by SACSCOC as a significant modification or expansion of the nature and scope of an accredited institution. Under federal regulations, substantive change includes:

- Any change in the established mission or objectives of the institution
- Any change in legal status, form of control, or ownership of the institution
- The addition of courses or programs that represent a significant departure, either in content or method of delivery, from those that were offered when the institution was last evaluated
- The addition of courses or programs of study at a degree or credential level different from that which is included in the institution's current accreditation or reaffirmation
- A change from clock hours to credit hours
- A substantial increase in the number of clock or credit hours awarded for successful completion of a program
- The establishment of an additional location geographically apart from the main campus at which the institution offers at least 50% of an educational program
- The establishment of a branch campus
- Closing a program, off-campus site, branch campus or institution
- Entering into a collaborative academic arrangement that includes only the initiation of a dual or joint academic program with another institution
- Acquiring another institution or a program or location of another institution
- Adding a permanent location at a site where the institution is conducting a teach-out program for a closed institution
- Entering into a contract by which an entity not eligible for Title IV funding offers 25% or more of one or more

of the accredited institution's programs

Policy Terms:

Substantive Change

A significant modification or expansion of the nature and scope of an accredited institution.

Branch Campus

A location of an institution that is geographically apart and independent of the main campus of the institution. A location is independent of the main campus if the location is: permanent in nature; offers courses in educational programs leading to a degree, certificate or other recognized educational credential; has its own faculty and administrative or supervisory organization and has its own budgetary and hiring authority.

Contractual Agreement

Typically is one in which an institution enters an agreement for receipt of courses / programs or portions of courses or programs (i.e. clinical training internships, etc.) delivered by another institution or service provider.

Consortial Relationship

A consortial relationship typically is one in which two or more institutions share in the responsibility of developing and delivering courses and programs that meet mutually agreed upon standards of academic quality.

Correspondence Education

A formal educational process under which the institution provides instructional materials, by mail or electronic transmission, including examinations on the materials, to students who are separated from the instructor. Interaction between the instructor and the student is limited, is not regular and substantive, and is primarily initiated by the student; courses are typically self-paced.

Degree completion program

A program typically designed for a non-traditional undergraduate population such as working adults who have completed some college-level course work but have not achieved a baccalaureate degree. Students in such programs may transfer in credit from courses taken previously and may receive credit for experiential learning. Courses in degree completion programs are often offered in an accelerated format or meet during evening and weekend hours, or may be offered via distance learning technologies.

Distance Education

A formal education process in which the majority of the instruction (interaction between students and instructors and among students) in a course occurs when students and instructors are not in the same place. Instruction may be synchronous or asynchronous. A distance education course may use the internet; one-way and two-way transmissions through open broadcast, closed circuit, cable, microwave, broadband lines, fiber optics, satellite, or wireless communications devices; audio conferencing; or video cassettes, DVD's and CD-ROMS if used as part of the distance learning course or program.

Dual Degree

Separate program completion credentials each of which bears only the name, seal, and signature of the institution awarding the degree to the student.

Educational program

A coherent course of study leading to the awarding of a credential (i.e. a degree, diploma or certificate).

Geographically separate

An instructional site or branch campus that is located physically apart from the main campus of the institution.

Joint degree

A single program completion credential bearing the names, seals, and signatures of each of the two or more institutions awarding the degree to the student.

Modified prospectus

A prospectus submitted in lieu of a full prospectus for certain designated substantive changes. When a modified prospectus is acceptable, SACSCOC specifies requested information from the institution.

Notification

A letter from an institution's chief executive officer, or his/her designated representative, to SACSCOC President summarizing a proposed change, providing the intended implementation date, and listing the complete physical address if the change involves the initiation of an off-campus site or branch campus. The policy and procedures for reporting and review of institutional substantive change are outlined in the document "Substantive Change for SACSCOC Accredited Institutions."

Significant departure

A program that is not closely related to previously approved programs at the institution or site or for the mode of delivery in question. To determine whether a new program is a "significant departure," it is helpful to consider the following questions: What previously approved programs does the institution offer that are closely related to the new program and how are they related? Will significant additional equipment or facilities be needed? Will significant additional financial resources be needed? Will a significant number of new courses be required? Will a significant number of new faculty members be required? Will significant additional library/learning resources be needed?

Teach-out agreement

A written agreement between institutions that provides for the equitable treatment of students and a reasonable opportunity for students to complete their program of study if an institution, or an institutional location that provides 50% or more of at least one program offered, ceases to operate before all enrolled students have completed their program of study. This applies to the closure of an institution, a site, or a program. Such a teach-out agreement requires SACSCOC approval in advance of implementation.

Teach-out plan

A written plan developed by an institution that provides for the equitable treatment of students if an institution, or an institutional location that provides 50% or more of at least one program, ceases to operate before all students have completed their program of study and may include, if required by the institution's accrediting agency, a teach-out agreement between institutions. This applies to the closure of an institution, a site, or a program. Teach-out plans must be approved by SACSCOC in advance of implementation.

Procedures:**5.1 Internal Reporting to SACSCOC Accreditation Liaison****Notification to SACSCOC Liaison of Proposed Changes**

If a change is substantive, SACSCOC must be notified as long as 12 months in advance of implementing the change. Upon becoming aware of a proposed change that may be substantive, Vice Provosts, Vice Presidents, Deans and Directors of the unit proposing the change should notify the SACSCOC Liaison as early as possible so that the information required by SACSCOC is prepared appropriately by the College and submitted by the SACSCOC Liaison to SACSCOC according to the SACSCOC specified timeline with the appropriate internal review and approvals.

Late Notification – After Program Implementation – to SACSCOC Liaison of Proposed Changes

If it is discovered that a program that may be considered a substantive change has been implemented without notification to the SACSCOC Liaison, the appropriate Vice Provost, Vice President, Dean or Director has the responsibility to notify the SACSCOC Liaison immediately. It is then the responsibility of the SACSCOC Liaison to notify SACSCOC as provided in the SACSCOC Policy. To minimize the possibility that proposals that may be considered substantive changes do not go unreported, it is expected that Vice Provosts, Vice Presidents, Deans and Directors participate or send a designee to the quarterly Substantive Change Standing Committee meetings.

Responsibilities:**8.1. Responsible Party**

Responsibilities of Vice Provosts, Vice Presidents, Deans, Directors, Curricular Committee Chairs, Registrar and the Substantive Change Standing Committee

Vice Provosts, Vice Presidents, Deans, Directors, Curricular Committee Chairs, Registrar and the Substantive Change Standing Committee have the responsibility to be aware of the substantive change policy, inform the Institute’s SACSCOC Liaison at the earliest point possible of proposals that may be considered a substantive change for the Institute and provide the SACSCOC Liaison with any data or information necessary to comply with SACSCOC policy when requested.

Additionally, the Substantive Change Standing Committee shall meet quarterly to discuss proposed or upcoming academic changes consulting with the SACSCOC Liaison on what, if any, communication is required to SACSCOC and when. This standing committee shall consist of the Registrar; Undergraduate and Graduate Curriculum Committee Chairs; Vice President of Legal Affairs & Risk Management; Vice Provosts of Undergraduate and Graduate Education; All College Deans or their designee; Associate Vice Provost of Learning Excellence; Director Office of Assessment; the SACSCOC Liaison and a Secretary appointed by the SACSCOC Liaison. Members of this committee shall ensure that academic changes are presented and discussed to provide sufficient advance time for internal approval and notification and / or approval by SACSCOC in advance of program changes in accordance with SACSCOC policy and procedures.

Colleges are responsible for completing and providing to the Substantive Change Standing Committee and the SACSCOC Liaison all required SACSCOC documentation necessary for approval of any substantive change (i.e. a completed prospectus)

The SACSCOC Liaison is the chair of the Substantive Change Standing Committee.

Enforcement:

Failure to comply with SACSCOC’s substantive change procedures, could result in the Institute’s loss of Title IV funding, the Institute’s reimbursement to the U.S. Department of Education money received for programs related to unreported substantive change, sanction or removal from membership with SACSCOC.

Optional: To report suspected instances of noncompliance with this policy, please visit Georgia Tech’s EthicsPoint, a secure and confidential reporting system, at:

https://secure.ethicspoint.com/domain/en/report_custom.asp?clientid=7508

Policy History:

Revision Date	Author	Description
08-2014	Library Learning Excellence	New Policy