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Introduction

Research Integrity is an umbrella term that describes a framework of core values and professional practices that collectively help to insure that all aspects of the research process are conducted in an honest and accurate manner¹. It encompasses the following shared values in scientific research²:

HONESTY - convey information truthfully and honoring commitments

ACCURACY - report findings precisely and take care to avoid errors

EFFICIENCY - use resources wisely and avoid waste

OBJECTIVITY - let the facts speak for themselves and avoid improper bias

In practice, research integrity is more commonly referred to as Responsible Conduct of Research (RCR). RCR is 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.

Responsible Conduct of Research (RCR)

As defined by federal agencies, RCR encompasses the following nine areas³⁴:

1. Research Misconduct: Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. See the Research Misconduct section below.


3. Welfare of Laboratory Animals: Visit City College’s Animal Research webpage for information about research with animals. Please note that as there is no animal facility or animal research conducted at CUNY SPS, individuals interested in animal research should contact the Institutional Animal Care and Use Committee (IACUC) staff of the respective college with the animal facility.

4. Conflicts of Interest and Commitments: See the Conflict of Interest section below.

5. Data Management Practices: Encompasses data acquisition, management, sharing and ownership. Visit The Health and Human Services Responsible Conduct in Data Management website for an introduction to integrity issues related to data management.

6. Mentoring: Visit the University of Wisconsin – Madison’s Research Mentoring website to learn about the central role of mentoring to the field of responsible conduct of research.

7. Collaborative Research: Visit Columbia University’s Responsible Conduct of Research – Collaborative Science website for a comprehensive examination of collaborative science. In addition, visit CUNY’s Research

¹ University of Pennsylvania. Research Integrity. Retrieved from http://www.upenn.edu/research/compliance_training/research_integrity/
⁴ Steneck Introduction to the Responsible Conduct of Research
Agreements webpage for information and links to instructions on how to enter into research agreements at CUNY, including:
- Signatory Authority for Research Agreements
- Data Transfer Agreements
- Unrestricted Data Use Agreements
- Restricted Data Use Agreements
- IRB Authorization Agreements
- Individual Investigator Agreements

8. Authorship and Publications: Visit the University of Southern California Responsible Authorship and Publication overview of the issues involving publication and authorship as well as a model academic policy on authorship.


While all of these areas are critical to research integrity, the remainder of this manual will focus on research misconduct, protection of human subjects, conflicts of interest and export control.
Research Misconduct

Research misconduct occurs when a researcher fabricates or falsifies data, or plagiarizes information or ideas within a research report.

- Fabrication - making up data or results and recording or reporting them.
- Falsification - manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism – the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

Reporting allegations, inquiry and investigation of research misconduct follow CUNY’s Policy Regarding the Disposition of Allegations of Research Misconduct. This Policy describes the procedures to be followed by the University in connection with any Allegation that University faculty, staff, post-doctoral associates, and/or students, whether paid by the University or through other funding sources, may have engaged in Research Misconduct. This Policy is also intended to comply with the requirements of applicable regulatory agencies and the sponsors of research.

Human Research Protection Program (HRPP)

The CUNY Human Research Protection Program (HRPP) is responsible for the protection of the rights and welfare of human subjects in research projects conducted at CUNY or by CUNY faculty, staff and students and Research Foundation of CUNY staff. The program provides oversight, administrative support and educational training to ensure that CUNY research complies with federal and State regulations, University policy and the highest ethical standards. The CUNY HRPP comprises of five University Integrated Institutional Review Boards (IRBs) and 19 on-site HRPP offices.

Each of the UI-IRB’s are comprised of members with varying expertise (e.g. scientists, nonscientists, prisoner representatives, etc.) representative of the diverse CUNY research subject areas. In addition to the diverse research expertise, each UI-IRB is comprised of members from across the 19 CUNY campuses to ensure the “local” context specific to each campus is sufficiently represented. Four of the UI-IRBs review human subject research that poses greater than minimal risk to the human subjects and/or does not meet the criteria for undergoing an expedited review process. The fifth UI-IRB is an Expedited Panel. As the majority of research conducted at the University falls into the expedited category, this panel exists in order to serve the high demand for expedited reviews.

Each campus has an HRPP office with an “HRPP Coordinator”, who serves as the primary point of contact for all human research concerns at their respective campuses. They will be able to further assist you with your concerns or route your concerns to the appropriate person.

The HRPP office for the CUNY SPS is supported by CUNY’s Central Office, and the Coordinator is Faith Forgione (faith.forgione@cuny.edu, 646.664.8919).

When is HRPP or IRB Review Required?

CUNY HRPP or IRB review is required when ALL of the following criteria are met:
1. The investigator is conducting research or clinical investigation;
2. The proposed research or clinical investigation involves human subjects; AND
3. CUNY is engaged in the research or clinical investigation involving human subjects.

The CUNY HRPP Guidance document When is CUNY HRPP or IRB Review Required? provides additional information on this topic.
HRPP/IRB Requirements for Course Research Projects

1. A student engaging in research solely for the purpose of fulfilling a course requirement, where the data will be destroyed when the project is complete, and where the information will not be published, presented or otherwise distributed outside of the course, does not need HRPP/IRB approval.

2. A student engaging in research involving human subjects where the data and/or conclusions WILL be used beyond fulfilling a course requirement (e.g., publications, presentations, future scholarly work), must submit an application to the HRPP/IRB. In such cases, the student is the PI. In order to submit to the HRPP/IRB, the student must share the protocol with his/her faculty advisor for their approval. (See Application for Approval to Involve Human Research Subject in Research below for instructions.)

3. A student PI must have a faculty advisor who complies with the faculty advisor responsibilities.

   In cases where there is ambiguity about the student’s role and/or if the research constitutes human subject research, contact Faith Forgione to discuss.

Application for Approval to Involve Human Research Subjects in Research

All human research protocols must be submitted through Ideate (https://ideate.cuny.edu/home/), an electronic system for the development, submission, review, and management of research protocols involving human subjects.

Ideate log-in and password are identical to CUNY Portal Log-In credentials. Additional information is available at the CUNY HRPP Policies, Procedures & Guidelines webpage.

Once the protocol is submitted through Ideate, the HRPP Coordinator will determine if the research study qualifies for exemption under federal regulations. Exemption determinations of human subject research activities will be made by the HRPP Coordinator. Human subject research protocols that qualify for “expedited review” will be submitted to the Expedited Panel for review.

If a protocol does not qualify for exempt status or an expedited review, it must be reviewed by a fully convened Institutional Review Board. The HRPP Coordinator will submit the protocol to the CUNY IRB Administrator who will place it on the agenda of the UI-IRB meeting according to the submission deadlines. The submission deadlines are available via CUNY’s HRPP webpage.

Review Process

In order to facilitate approval of the application for use of human subjects in research, it is necessary for all relevant information to be included in the application. It is of equal importance that the application presents a clear and concise explanation of the proposed research project. The review process will be slowed down when applications are incomplete (including all possible required attachments, consent forms, CITI training certificates, etc.) and/or that do not clearly explain the research project.
**Exempt and Expedited Reviews**
The initial Administrative Review is approximately 2 to 5 days. If the protocol does not require any changes it is forwarded to the IRB for review. Protocols that require changes and/or additional information will be sent back to the PI to address. The review typically takes 3 to 5 business days. Questions or concerns raised during this stage of review will be communicated to the PI by the HRPP Coordinator via Ideate. Final determination will be communicated to the PI via Ideate.

**Full Board Reviews**
The initial Administrative Review is approximately 2 – 5 days. If during this stage of review it is determined that the protocol requires full board review it is submitted to the CUNY IRB Administrator. The IRB Administrator will review the protocol then reach out to the PI if additional information or changes are required before it can be sent to the full board. Once complete, the protocol is put on the agenda of the UI-IRB meeting according to the submission deadlines.
**Decision**
The PI will receive a notification email from Ideate with the decision. The PI will need to log into Ideate to retrieve a copy of the decision letter, which can be found in the “Details” section of the “Submission Details” page.

*Please note: Research may not begin until approval has been granted in writing.*

**Continuing Review, Final Report and Modifications**

**Continuing Review**
The IRB grants approval for a defined period of time, is communicated to the PI when a study is approved. To continue the study or to continue using human subject data beyond that period of time, PIs must submit a Continuing Review application via Ideate.

**Modifications/Amendments**
Any change for any reason to the research protocol requires filing a request for approval of an amendment to the study prior to implementation. You are responsible for submitting your proposed amendment(s) to the IRB via Ideate.

**Final Report**
When a research study is complete the PI must submit a final report (via Ideate). The final report will alert the HRPP Coordinator and the CUNY IRB Administrator that the research has been finalized and therefore will not require continuing review.

*Researchers should visit the CUNY Human Research Protections Program Policies and Procedures website regularly for updates.*
Conflict of Interest (COI)

CUNY's Conflict of Interest policy establishes standards to ensure that there is no reasonable possibility that any conflicting interests will bias the design, conduct, reporting or review of research projects at the University, regardless of the source of funding or the commercial exploitation of the results of such projects.

To comply with this policy, investigators are required to disclose to the College Conflicts Officer (CCO) at his or her college any Significant Financial Interest (as defined in the Policy) relating to the investigator's institutional responsibilities. Disclosure is made via the CUNY Significant Financial Interest (SFI) Disclosure Form for Research Projects Not Funded by the Public Health Service or via the CUNY Significant Financial Interest Disclosure Form for PHS Funded Research submitted by the investigator to the college Grants Officer and CCO at the time that the Principal Investigator submits a grant proposal or application. An updated form must also be submitted to the college Grants Officer and CCO at the time that the Principal Investigator submits an annual progress report. In addition, each investigator is required to submit an updated CUNY SFI Disclosure Form to the college Grants Officer and the CCO within 30 days of any material change in the previously disclosed SFI, discovery or acquisition of a new SFI, or when the investigator joins an ongoing research project at CUNY.

These forms are accessible at http://www.cuny.edu/research/compliance/conflictofinterestpolicy.html.

If the University’s Conflicts Committee determines that a Financial Conflict of Interest exists (i.e., that the Significant Financial Interest could directly and significantly affect the design, conduct, reporting, or regulatory review of the investigator's research), the Committee determines whether the conflict is manageable, and if so, issues a conflict management plan for the research project.

Export Control

Export controls regulate the shipment or transfer, by whatever means, of controlled items, software, technology, or services out of U.S or within the US to non-US individuals. As this is a complex and complicated topic, it is recommended that researchers visit CUNY’s Export Control website for a detailed explanation of Export Control regulations how they affect research activities, international collaborations, and export-related transactions at CUNY. This website will provide links to key sections of the regulations, CUNY’s procedures addressing the types of items that the government controls, and CUNY contacts for export control administration.
Required Training

CUNY subscribes to the Collaborative Institutional Training Initiative's (CITI) research compliance courses to fulfill CUNY's educational requirements. The following details the training requirements.

General Guidelines

All CUNY faculty members, staff, administrators, postdoctoral scholars, graduate and undergraduate students involved in research are required to complete the CITI Responsible Conduct of Research (RCR) training within six weeks of initiating their research. RCR training certificate will be valid for five years. CUNY researchers are required to take a refresher CITI RCR training course every five years.

Researchers will also be required to take additional trainings based on the type of research being conducted.

- **Human Subjects Research**: All researchers involved in human subjects research as key personnel must complete the CITI Basic Course in the protection of human subjects prior to Institutional Review Board (IRB) approval of their protocol. Key personnel are defined as the Principal Investigator, co-investigators and research personnel who interact directly with human subjects or who have access to private information related to human subjects during the course of a research project. Key personnel also include faculty sponsors /advisors who provide direct oversight of research with human subjects or research using private information about human subjects. Certificate of completion of the basic course is valid for three years. Key personnel of human subjects research protocols must complete a refresher course every three years.

- **Conflict of Interest**: All investigators engaging in research related to any Public Health Service (PHS) funded grant or contract, and all CUNY Conflict of Interest Officers are required to complete the CITI training in Conflict of Interest (COI). In addition, a CUNY Conflict of Interest Officer may require individuals to complete this course on a case-by-case basis. Individual training requirements may be based on the nature of an existing conflict; non-compliance with CUNY’s Conflict of Interest Policy; or non-compliance with a Conflict of Interest management plan. COI training certificate will be valid for four years. CUNY researchers are required to re-take the CITI COI training course every four years.

- **Care and Use of Animals**: All CUNY faculty members, postdoctoral scholars, graduate and undergraduate students involved in animal care, use or treatment must complete the CITI training in the care and use of animals prior to Institutional Animal Care and Use Committee (IACUC) approval of their protocol.

Instructions for Completing Training

1. Log into CITI at [https://www.citiprogram.org/](https://www.citiprogram.org/). (First time users will need to create an account. Instructions are available here).

   *Note: Select "City University of New York" as your institution (you will need to type it in to trigger the drop-down options).*

2. Click on "Add a course or update your learner groups".
3. Select the curriculum which you would like to complete.
4. Select the learner group that best fits your position at CUNY and your role in research.
5. Complete the required modules.
6. Complete any optional modules that may be of interest to you.
7. Submit a copy of your completion certificate as follows:
   - Responsible Conduct of Research – submit training certificate to the Research Integrity Officer (RIO) of your College, and attach it to any grant proposal (internal or external) for which your are a PI or co-PI.
   - Human Subjects Protection Basic Course – upload training certificate to your user profile in Ideate.
   - Human Subjects Research Refresher Course – upload training certificate to your user profile in Ideate.
   - Conflict of Interest – submit training certificate to the Conflict of Interest Officer of your College, and attach it to any PHS-funded grant proposal.
   - Animal Care and Use – submit training certificate to the IACUC Administrator at your College.

The CITI training does not need to be completed all at once. You will have the option to save the work you have completed then resume your work at another time.

Additional information can be found at [http://www.cuny.edu/research/compliance/training-education/citi-training.html](http://www.cuny.edu/research/compliance/training-education/citi-training.html).

If you are having problems with the CITI site or course, contact the CITI Office at citisupport@med.miami.edu or at 305.243.7970.

### Assistance

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<tr>
<th>Human Research Protection Program (and IRB)</th>
<th>Faith Forgione, CUNY HRPP Coordinator <a href="mailto:faith.forgione@cuny.edu">faith.forgione@cuny.edu</a>, 646.664.8919</th>
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<tr>
<td>General Research Compliance Questions</td>
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<td>Research Integrity Officer</td>
<td>Abigail Morrison, Academic Operations Director <a href="mailto:abigail.morrison@cuny.edu">abigail.morrison@cuny.edu</a>, 646.344.7244</td>
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<td>Conflict of Interest Officer</td>
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<td>CITI Training</td>
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