An Introduction to Research Integrity & Compliance

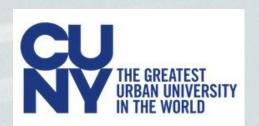
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Research Compliance at CUNY

- The mission of the Research Office is to promote and support the research, scholarly, and creative pursuits of the CUNY community in accordance with the highest ethical standards.
- The Office of Research offers oversight, administrative support, and educational training in all areas of compliance, and performs quality improvement functions.
- ☐ The CUNY University Integrated Institutional Review Board is charged with protecting the rights and welfare of human research participants.
- ☐ The IRB ensures that proposed research complies with federal guidelines, state and local regulations, sponsor and regulatory requirements, CUNY policies, and accepted ethical principles and standards.



A Guide to Research Compliance at CUNY

Principles, Regulations, Laws & Policies

Local Campus Policies

CUNY Policies

Sponsor Requirements New York State & City Laws

Federal Regulations: 45 CFR 46

Ethical Principles (The Belmont Report)

What is Research?

Research is defined as a *systematic investigation*, including research development, testing, and evaluation, designed to develop or contribute to *generalizable knowledge*.

"a systematic experiment, study, evaluation, demonstration or survey, in any academic field, designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, causes, functions or effects"

Research is a process to discover new knowledge.

Research is the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies and understandings. This could include synthesis and analysis of previous research to the extent that it leads to new and creative outcomes.

Federal definition, Office of Research Integrity: https://ori.hhs.gov/what-research

Research Components

- A Systematic Investigation follows a predetermined plan for looking at a particular issue, testing a hypothesis or research question, or developing a new theory.
 - It is methodologically driven and data or information is collected in an organized and consistent way.
 - Collection of quantitative or qualitative data
 - Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
 - Collection of data using experimental designs such as clinical trials
 - Observation of individual or group behavior
 - Conclusions are drawn from the results
- ☐ Contribute to **Generalizable Knowledge** means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied.
 - The intent of the research is to add information to your field of study.
 - The results are expected to be generalized to a larger population beyond the subject population and site of study. The knowledge contributes to an already established body of knowledge
 - Other investigators, scholars, and practitioners may benefit from this knowledge
 - Publication, presentation or other distribution of the results is intended to inform the field of study. Publication alone does equate to research.

Activities Which MAY Not be Research

Please consult with the campus RIO or HRPP Coordinator if you are not sure if your project qualifies as research.

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
 - Note: Studies using participant observation and ethnographic methods, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, where the findings apply to the larger studied community or group (and not just the individuals from whom the information was obtained), however, are considered to be research.
- Program Evaluation/Quality Improvement activities designed for local improvement efforts (i.e. Course/Program Improvement) limited to dissemination or implementation within the college.
- Activities designed for educational purposes ONLY (such as classroom projects, research practica, etc). Results will NOT contribute to generalizable knowledge; results will not be shared with the larger community; results are not designed to be published or used as data for any future activities.

Responsible Conduct of Research Includes

- Research Misconduct
- Conflict of Interest and Commitment
- Protection of Human Subjects
- Animal Welfare
- Export Control
- Biosafety
- Peer Review
- Mentor/Trainee Responsibilities
- Publication Practices and Responsible Authorship
- Data Management: Acquisition, Protection,
 Sharing and Ownership
- Collaborative Science & Research Agreements

RCR Home Page: for CUNY policies & procedures and additional information on all the topics above.



Research Misconduct Includes

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:

Appropriation of another person's ideas, processes, results or words without giving appropriate credit



CUNY's Policy Regarding the Disposition of Allegations of Research Misconduct



RCR & Undergraduate Research



CUNY Research Policy: "All CUNY faculty, staff, postdoctoral scholars, graduate and undergraduate students involved in research are required to complete training in RCR."

Section 2.3. Graduate and Undergraduate Students:

Graduate and undergraduate students who are involved in research, regardless of funding, must complete CUNY-required modules of the Collaborative Institutional Training Initiative's (CITI) on-line training in RCR within six weeks of initiating their research activities.

- Any student that is receiving monetary compensation for their work related to research, must complete the RCR CITI training.
- If the student is presenting their work as research (ex. at a conference, poster presentation, journal, etc), they must complete the RCR CITI training.
- If the student is conducting research for classroom purposes only, they should receive instruction in the responsible conduct of research. This means that at a minimum, the professor should review RCR information with them.
 - It is recommended that if a specific course focuses on research (for example, research design or methodology, data analysis, quantitative techniques, scientific method), students complete the RCR CITI training.

^{*} If the student is conducting human subject research, the HSR training is required in addition to the RCR training.

Human Research Protection Program (HRPP)



The CUNY HRPP is comprised of 3 University Integrated Institutional Review Boards (IRBs) and 19 on-site HRPP offices.

Each **CUNY HRPP Coordinator**:

- ☐ 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 RF CUNY staff.
- ☐ 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.
- □Serves as the first point of contact for human subject researchers, conducts exempt reviews, facilitates expedited reviews, and conducts initial administrative/policy reviews of convened Institutional Review Board (IRB) submissions.



CUNY HRPP



Why is IRB Approval Required?



- IRBs protect research participants and help researchers live up to their ethical obligations.
- CUNY has filed Federalwide Assurances (FWA) with the US Department of Health and Human Services Office for Human Research Protections, which documents CUNY's commitment to comply with federal regulations for the protection of human subjects in research.
- 3. The University will not support unapproved research: Liability issues arising from unapproved research become the responsibility of the investigator.
- 4. Research non-compliance can result in loss of wages and/or employment. It can result in civil and/or criminal penalties.
- 5. Funding may be withheld: IRB approval is required if you are a participant in a grant program. These programs will not release funds without IRB approval.
- 6. Articles may not be published: Most professional journals require evidence of IRB approval when considering articles for publication.
- 7. For students:
 - a) Course credit may be withheld
 - b) Dissertation or thesis work will not be accepted without IRB approval
 - c) Degrees will not be awarded for work based on non-IRB reviewed projects

Researcher Responsibilities

- ☐ Comply with all ethical principles of responsible conduct of research
 - Federal regulations, State laws, CUNY policies, the Institution's Assurance, and sponsor requirements.
- Complete the CUNY required modules of the Collaborative Institutional Training Initiative (CITI) on-line training. RCR required for all researchers. Additional HSR required for human subject research.
- Ensure that all human subjects research receive IRB approval prior to its initiation.
- Ensure the rights and welfare of each research subject:
 - Sufficient investigator time
 - Appropriate equipment and space
 - Qualified research team members
 - Prompt reporting of non-compliance, unanticipated problems and adverse events



CUNY Undergraduate Research Programs

<u>CUNY Research Scholars Program (CRSP)</u>: provides funded laboratory experiences for Associates degree students over a one-year period.

<u>Velay Women Scholars Research Fellowship:</u> is a ten-week, summer undergraduate research and professional development experience for women in STEM.

<u>CUNY Summer Undergraduate Research Program</u> (CSURP): is a ten-week program that offers a hands-on research experience and is open to students interested in five key research areas: environmental science, nanoscience, neuroscience, photonics, and structural biology.

Externally Funded Programs:

- •NYC Louis Stokes Alliance for Minority Participation
- •NIH Minority Access to Research Careers
- •NIH Bridges to the Baccalaureate Program
- •NIH Research Initiative for Scientific Enhancement
- •NSF Scholarships in Science, Technology, Engineering and Mathematics
- •NSF Research Experiences for Undergraduates

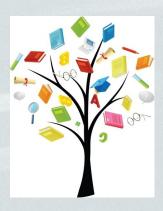
CUNY Undergraduate Research Programs



CUNY Training & Educational Requirements

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

<u>Protection of Human Subjects</u>: In addition to the RCR certificate, ALL CUNY faculty members, postdoctoral scholars, graduate and undergraduate students involved in human subjects research as key personnel must complete the Basic Course in the protection of human subjects *prior to* Institutional Review Board (IRB) approval of their protocol. 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.



CUNY Training Requirements

CUNY Policy on RCR Training

CUNY subscribes to the Collaborative Institutional Training Initiative's (CITI) fulfill all of CUNY's educational requirements.

www.citiprogram.org



LaGuardia Community College Research Compliance Staff

Sponsored Research Compliance; College Conflicts Officer: Laura Bartovics, Director, Grants Development Office

Institutional Animal Care and Use Committee (IACUC):

Dr. Tara Scales, Health Science Department

Institutional Biosafety:

Peter Jayasekara, Director, Environmental Health & Safety Operations

Human Research Protection Program Coordinator (HRPP): Xiwu Feng, Education & Language Acquisition Department

Research Integrity Officer, Human Research Protection Program Coordinator (HRPP), Export Control Administrator, Point Person for Research Agreements:

Jessica Zeichner-Saca, Executive Associate to the Provost