

# Responsible Conduct of Research

Pocket Guide for Researchers



THE UNIVERSITY  
*of* NORTH CAROLINA  
*at* CHAPEL HILL



# Responsible Conduct of Research

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The University of North Carolina at Chapel Hill (UNC-CH)'s commitment to researchers at all stages of their careers and sponsors includes providing opportunities for educating research personnel and promoting Responsible Conduct of Research (RCR). This guide is introductory in nature and intended to provide foundational information. Based on a framework of governing laws, regulations, and policy, including NIH and NSF policies, UNC-CH has outlined RCR guidelines in 17 areas for education, training, certification, and compliance:

- Investigator Responsibilities
- Mentor/Trainee Responsibilities
- Misconduct in Research
- Conflict of Interest and Commitment
- Financial Compliance
- Collaborative Research
- Data Sharing and Ownership
- Publication and Notification Requirements
- Peer Review
- Intellectual Property
- Human Subjects in Research
- Requirements for Data Security and Privacy, Including HIPAA Guidelines
- Use of Vertebrate Animals in Research
- Safe Use of Hazardous Materials in Research
- Recombinant DNA and Human Gene Transfer Experiments
- Export Control/Shipping
- Stem Cells

For more information on NSF or NIH RCR training requirements, please go to:  
<http://www.unc.edu/depts/legal/rcp/RCRPlan.pdf>

## Principal Investigator Responsibilities

According to the National Institutes of Health (NIH), the major source of federal funds for biomedical research, the Principal Investigator (PI) is “a qualified person designated by the applicant institution to direct the project or program.” Therefore, PIs, which include faculty—funded or not—are responsible for the proper scientific conduct and scholarly outcomes of the project, as well as for ensuring compliance with the financial, ethical, and administrative aspects of the project. The PI rarely conducts scientific projects alone, but rather, forms a team of researchers who work together to accomplish the project’s objectives. The PI takes on the responsibility of ensuring that his/her research personnel are appropriately trained, and are doing good work. Research personnel can include other investigators, postdoctoral fellows, graduate students, undergraduate students, and other research support staff. PIs should supervise the design of experiments and the process of acquiring, recording, examining, interpreting, and sorting data, along with preparing scholarly manuscripts. PIs should hold regular meetings—both formal and informal—with research personnel to discuss interpretation of raw data and to correct errors in perception or presentation of results. These interactions help both the PI and research personnel build confidence in their work long before producing the final products of the research.

## Mentor/Trainee Responsibilities

A good mentor helps and serves as a strong advocate to the trainee to excel as a new investigator. Trainees can include junior faculty, graduate students, postdoctoral scholars, and undergraduate research assistants or interns. The mentor-trainee relationship evolves with time, taking on different characteristics as the trainee develops into an independent investigator. Trainees must learn the basic methods of inquiry and investigation, such as exploring and evaluating the literature in their field; maintaining good records; and examining, analyzing, and accurately interpreting data frequently. Thus, the mentor should be accessible to the trainee, making time to discuss expectations, answer questions, review papers and grant proposals, and evaluate progress. Regular meetings and ongoing conversations—even for a few minutes—are crucial to help trainees feel support and encouragement. It is rare that trainees can receive all the support they need from one person, so good mentors introduce trainees to other researchers and discipline experts to help them expand their professional networks. Mentors are expected to give trainees constructive and realistic feedback on their performance, as well as advice about career development and professional opportunities. As the trainee matures, he/she should take on an increasingly independent role in selecting, conceptualizing, and executing research projects. Note that trainees may be subject to specific training requirements if they are supported, even minimally, by a federal sponsor, such as the NIH or NSF. It is critical that the trainee take care in selecting the appropriate and approved training to receive credit (See [RCR plan](#)). For example, the NSF RCR training is NOT satisfied by taking CITI-hosted “Human Subjects Protection” training.

## Misconduct in Research

Misconduct in research violates the trust society places in scientists, scholars, and the University. Misconduct also wastes time and resources in misdirected efforts based on erroneous information. The effects of reliance upon fraudulent information can have a devastating impact on human and animal research subjects for years. Values essential in research conform to those that ideally govern behavior and activities in society. These include honesty, performing your craft with skill and thoroughness, respect and fairness in dealing with others, and responsibility to people and institutions. The University considers research misconduct to include:

**Fabrication**, defined as making up data or results, and subsequently, recording or reporting them;

**Falsification**, defined as 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; or

**Plagiarism**, defined as appropriating another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion. The University [\*Policy and Procedures on Ethics in Research\*](#) requires anyone having reason to believe that a member of the faculty or staff has engaged in research misconduct to consult with his or her department chair to determine whether the chair should report the allegation to the dean. Federal policy requires the University to investigate scientific misconduct allegations brought forward in good faith whether they are reported internally or received from a federal agency. While scientific misconduct is often assumed to be a deliberate act, it can happen unintentionally through the failure to conduct research pursuant to the requirement of federal and state laws and regulations.

## Conflict of Interest and Commitment

Conflict of interest and commitment may arise when an employee, including researchers, become engaged in activities or relationships that can, or may be perceived to, introduce bias into their primary obligations. Conflict of interest generally refers to competing financial interests, whereas conflict of commitment generally addresses situations that detract from the time and attention an employee devotes to his or her primary obligation. For example, consider a researcher having an investment in a company that is paying for research to be conducted. The researcher/investigator may be unable to overcome a real or perceived bias that could lead him or her to influence the research results. Federally sponsored research, the FDA, and the University require that PIs and those involved in the design, conduct, and reporting of research and its results disclose possible conflicts for appropriate administrative review. As of August 2012, [conflict of interest training](#) is a requirement for researchers. Through its various conflict of interest review committees and the Conflict of Interest Officer, many conflicts may be managed so that research is not affected. The disclosure and electronic submission process provides required training and “prompts” to elicit required information. In addition to the University’s conflict of interest policy, the General Administration of the greater University of North Carolina system requires that faculty and employees “exempt from the Personnel Act” (EPA) receive advance permission from department heads or deans in order to engage in “external professional activities for pay” (EPAP), the most common being consulting. The policy and required electronic disclosure form may be accessed by going to <https://apps.research.unc.edu/epap/>.

## Financial Compliance

While faculty, postdoctoral scholars, and graduate students write the grant proposals and perform the research, in most cases, the grant award goes to the University, not the individual designated as the PI on the award. Thus, the University is the financial steward of funds received to conduct research, and the [Office of Sponsored Research](#) is the 'go-to' resource for University faculty and staff involved in sponsored research projects. The sponsor expects to be kept informed of the status of each project through technical and financial reporting. The PI accepts ultimate accountability for financial compliance to UNC-Chapel Hill policy and sponsor requirements, even while day-to-day financial operations may be delegated to staff members under his/her direction. These obligations include, but are not limited to, the management of the project within funding limitations, adherence to reporting requirements, assuring that proposed budget items and award expenditures are allowable, and ensuring that the sponsor is notified regarding a change in project status or significant conditions that may affect the sponsored project. To ensure accountability, the researcher is responsible for authorizing all direct charges and reviewing project expenditures on a periodic basis. Departmental business managers or grant administrators can help PIs with this function. Researchers **do not** have the authority to accept or indicate acceptance of a grant, contract, and/or cooperative agreement on behalf of the University. These types of research agreements must be signed by an institutional signing official within designated offices of the Vice Chancellor for Research who have been delegated signature authority.

For more information related to financial compliance policies and procedures, contact OSR at 919-966-3411 or [resadminosr@unc.edu](mailto:resadminosr@unc.edu). You may also refer to the Pocket Guide for Financial Compliance of Sponsored Research/Projects.

## Collaborative Research

In today's complex funding world, researchers are exploring problems and questions not confined to a single discipline, thus setting an environment that supports the development of collaborative research. The complexities of collaborative research grow with the size of the team, the number of disciplines involved, and the number of different types and levels of research personnel. It is important to have a clear understanding of the issues that need to be addressed to assure collaborative efforts are successful. The following guidelines are provided to help facilitate effective collaborations:

- Well organized leaders need to be knowledgeable about the policies for hiring, supervising, and firing project staff, and need to be responsive to team members' concerns throughout the process.
- Knowing the terms of rights for use of the data should be established early on in the collaboration, with the possibility that the terms may change over time given the efforts of the researchers involved.
- Communication among team leadership and members should be often to prevent disputes from occurring regarding the sharing of data and project results, publication policies, and resource allocation.
- Initial meetings should be held early on regarding: goals and expected project outcomes; timelines and expected duration of a project; responsibilities and contributions of each researcher; legal obligations and if appropriate, financial rewards and royalties associated with intellectual property issues; regulatory compliance and publication negotiations; and possibilities for developing new collaborations and spin-off projects.
- Public relations and knowing who is responsible of handling media inquiries must be clearly understood to avoid confusion among the project team.

The issues identified in the above bullets may change over time, depending upon the trajectory of the research, and therefore, should be revisited periodically.

## Data Sharing and Ownership

Generally, decisions regarding data sharing among researchers should be addressed at the initiation of the research effort. Additional considerations would include whether the data is intended to stay within the University or will be shared with researchers at other institutions. Assistance is available through the [Office of University Council](#) to help draft agreements that describe and govern the use of research data. If human subjects are involved, the informed consent and HIPAA authorization forms will provide additional structure to how data may be shared and owned. If the product of the research effort will include intellectual property licensed to or from other parties, the researcher should contact the [Office of Technology Development](#) for guidance, including, possibly, the drafting of a material transfer agreement. Generally, the University owns the data that is the product of an employee's research effort, unless ownership has been transferred to, for instance, a commercial sponsor. In the event that the researcher transfers to another institution, he or she may usually take copies of the data as long as the researcher has received written permission in advance of the move from the department chair.

## Peer Review

Decisions about publishing research results can not be made without fair and objective evaluations by recognized experts. Though the peer-review process can be difficult and time-consuming, researchers are encouraged to participate in it. Those conducting peer reviews are making an important contribution to science and scholarly activity. To be qualified to review, an individual should be an expert in the subject under review. A researcher should not review if he/she feels unqualified to evaluate a particular manuscript, or has a personal or professional relationship with author(s) (including being in direct competition or collaboration with that person) that may be considered conflicts of interest. If unqualified, a reviewer should decline reviewing it. If there are potential conflicts of interest, a reviewer should disclose them to editors so that the editors can decide whether the reviewer is appropriate. The job of reviewers is to objectively judge the quality of the manuscript, and should explain and support their judgments adequately. All material under review is privileged, confidential information. Reviews should be submitted in a timely manner.

## Intellectual Property

Management of intellectual property arising from research conducted at UNC-CH is an element of most externally funded research grants and contracts with the Federal Government, non-profit institutions and charities, and industry sponsors. Researchers need to be mindful of these obligations and follow the University's policies and procedures regarding intellectual property to ensure the University can fulfill its contractual obligations to sponsors, protect researchers' interests, and preserve its rights to disseminate research results for public use and benefit.

Many research agreements address ownership and licensing rights in patentable inventions. For more information on what is an invention and a patent, see [United States Patent Law](#). Under University Policy, the University owns inventions—e.g., new processes, machines, research tools, compounds, or important scientific advancements—made by employees and others using University resources, facilities, or through University-administered funds for research. University personnel who have potentially patentable inventions must report them to the [Office of Technology Development](#) (OTD). OTD is responsible for assessing patentability of the invention, working with the investigators to protect their interests, meeting obligations to sponsors of research, and determining options for commercial deployment of the idea outside the University.

For more information on the University's Patent and Invention Policy, Copyright Policy, and commercializing innovations, contact OTD at 919-966-3929 or [otd@unc.edu](mailto:otd@unc.edu).

## Human Subjects in Research

All human subjects research requires Institutional Review Board (IRB) review and approval. There are multiple IRBs at UNC-CH that review research; all are administered by the [Office of Human Research Ethics](#) (OHRE), and which IRB reviews depends on the area of research. The PI is responsible for ensuring that:

- The materials submitted to the IRB are accurate and complete.
- IRB approval is obtained before initiating research or before making any changes to the research.
- Progress reports are submitted to the IRB as required.
- All unanticipated problems or serious adverse events involving risk to human subjects are reported to the IRB.
- All members of the research team comply with the findings, determinations, and requirements of the IRB, including their conduct of the informed consent process.

All researchers conducting human subjects research must complete human subjects protection training as required by the University's [Policy on Education and Certification of Investigators Involved in Human Subjects Research](#). The [Collaborative Institutional Training Initiative](#) (CITI) is a web-based training package that includes courses on human subjects protection, Good Clinical Practice (GCP), and the Responsible Conduct of Research (RCR). CITI Human Subjects Protection training is required of all faculty, staff, and students who are engaged in the planning, conduct, or analysis of human subjects research at UNC-CH. Completion of CITI GCP or CITI RCR training does not satisfy the UNC-CH IRB-required Human Subjects Protection training.

UNC-CH's specific policies, procedures, access to on-line training, access to the on-line submission process, and other resources for human subjects researchers are available at the OHRE website: <http://research.unc.edu/ohre/>, or contact OHRE by phone at 919-966-3113.

## Requirements for Data Security and Privacy, Including HIPAA Guidelines

The University is committed to protection of both data that would be considered sensitive (personally identifiable information) and/or that may concern proprietary business information. Data security and privacy includes physical protection and safeguarding of systems and devices that are used to collect, retain, and manage data. Increasingly, federal and state regulations direct how data should be protected. For instance, researchers working with human subjects may need access to medical information that would be governed by the Health Insurance Portability and Accountability Act (HIPAA). The University has processes in place to enable utilization of such information. Guidance and forms are available through the [Office of Human Research Ethics](#). The University has purchased site licenses to ensure that resources are available to accommodate, for instance, encryption of electronic devices and surveys. Utilization of University sanctioned tools will help ensure that the researcher's information is safe.

Data security and privacy guidance, including applicable policies, may be found at: [help.unc.edu](http://help.unc.edu) and [its.unc.edu](http://its.unc.edu).

## Guidelines for the Use of Vertebrate Animals in Research

The laws and regulations that govern the use of animals for research reflect society's increased concerns for humane care. Federal oversight and requirements for animal research are:

- [Animal Welfare Act](#) - enforced by the United States Department of Agriculture (USDA)
- [Public Health Service \(PHS\) Policy](#) - administered by the Office of Laboratory Animal Welfare
- [Oversight by an Institutional Animal Care and Use Committee](#) (IACUC)

Every investigator is obligated to understand these regulations and incorporate them into their research efforts. IACUC is responsible for reviewing all proposed activities related to the care and use of animals and for conducting semi-annual reviews of the institution's program for animal care as well as all animal facilities and animal research areas. IACUC research proposals should: ensure appropriate number of experimental animals; consider non-animal alternatives; minimize pain or distress; justify animal use; emphasize that research activities do not unnecessarily duplicate previous efforts; ensure that personnel are appropriately qualified; and ensure animal activities are in accordance with the [USDA regulations](#) and [PHS policy](#). All proposed activities, as well as proposed changes to approved activities, must be approved by the IACUC prior to implementation.

Questions about the use of vertebrate animals should be directed to the Office of Animal Care and Use at 919-966-5569. Additional information is available online at: <http://research.unc.edu/iacuc/>.



## Safe Use of Hazardous Materials in Research

The UNC-CH [Department of Environment, Health, and Safety](#) (EHS) oversees health and safety issues related to laboratory research. All laboratories must have a Laboratory Safety Plan. The Laboratory Safety Plan is a required document that outlines specific conditions, hazards, and controls in your laboratory spaces. The process for creating and submitting a Laboratory Safety Plan begins here: <http://ehs.unc.edu/ih/lab/lsp.shtml>. Each person working in the laboratory also must complete a Laboratory/Radiation Worker Registration form: <https://itsapps.unc.edu/LabRadWorker/>.

EHS offers expertise and assistance in a wide range of health and safety areas:

- Environmental Compliance
- Ergonomics
- Employee health (non-emergency)
- Fire safety
- Hazardous materials management
- Hazardous waste management
- Injury (not life threatening)
- Indoor air quality
- Laboratory set-up/close out
- Medical Surveillance
- Material Safety Data Sheets
- Radiation safety
- Recombinant DNA
- Safety Plans
- Select agents
- Shipping hazardous materials
- Training

## Recombinant DNA and Human Gene Transfer Experiments

Researchers conducting work involving recombinant DNA are responsible for complying with the [NIH Guidelines for Research Involving Recombinant DNA Molecules](#) no matter the source of funding. For information on these Guidelines, including exempt experiments and experiments requiring registration, visit the EHS Recombinant DNA web page: <http://ehs.unc.edu/training/self-study/recombinant/>.

Research proposals involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human subjects (human gene transfer) will be considered through a review process involving both NIH's Office of Recombinant DNA Activities (ORDA) and Recombinant DNA Advisory Committee (RAC). In addition, Institutional Biosafety Committee (IBC), IRB, and RAC approval is required before any research participants are enrolled.

If you work on a grant that requires a Certificate of Environmental Compliance, contact the Director of EHS for assistance. For more information, go to: <http://ehs.unc.edu/>.

For more information on these Guidelines, visit the EHS Human Gene Transfer Experiments page: <http://www.ehs.unc.edu/ih/biological/gene.shtml>.

## Export Control/Shipping

Export control and shipping regulations affect University activities at home and abroad. These regulations apply to physical exports of research materials and samples, travel to certain countries subject to U.S. sanctions, and research projects that are conducted outside of the public domain.

The federal government exercises control over the export/shipment of certain kinds of dangerous or strategically important items and technology through Export Administration Regulations enforced by the Department of Commerce (DOC). Items and technology that are controlled by the DOC are usually dual use in nature. Dual use means that they have a commercial and military use. Typically they are either hazardous per se (toxic chemicals), may have military capabilities (encryption codes), or may contribute to certain end uses, such as weapons of mass destruction (certain bacteria and viruses). Export of controlled items is not necessarily prohibited, but is regulated. Reasonable requests for exports of controlled items and technology will be granted a license.

There are severe institutional and personal penalties, including potential imprisonment, for the export of controlled items and technology without appropriate licenses. While we understand that the vast majority of our faculty are not involved in using or exporting/shipping covered materials, faculty should still be aware of these requirements.

If you believe that you are involved in either shipping any covered materials, carrying them yourself to foreign countries, or if you have foreign nationals in your lab who may be using restricted materials or technology, [Environment, Health, & Safety \(EHS\)](#) would like to hear from you. There are no penalties for past behavior, but it is our goal to protect the University and our faculty from future problems.

For information on these regulations and the resources available at the University to assist with export control and shipping matters, visit the export control web page:  
[http://www.unc.edu/campus/Export\\_Control/](http://www.unc.edu/campus/Export_Control/).

## Stem Cells

UNC-CH recognizes the potential value of Human Embryonic Stem Cells in research, including clinical research. The University encourages responsible use of stem cells as a means of advancing knowledge, with the eventual goal of using these cells in therapeutic practice to possibly cure diseases and ameliorate other disabling or debilitating health conditions. The University, however, also recognizes that some potential uses of Human Embryonic Stem Cells are not currently allowed under federal directive, and that other potential uses are ethically and socially controversial. The University has developed a policy that lays out the potential uses of Human Embryonic Stem Cells and differentiates among uses approved and disapproved by the University. This policy is consistent with the Guidelines for Human Embryonic Stem Cell Research (2005) published by the National Research Council and the Institute of Medicine. One University faculty member was a member of both groups and helped the University committee place its ideas in the larger context of an emerging national scientific consensus.

You can view the University's policy, including the IRB process, on the use of Human Embryonic Stem Cells in Research here:

[www.unc.edu/campus/policies/StemCellPolicy.pdf](http://www.unc.edu/campus/policies/StemCellPolicy.pdf).

For an electronic version of this pocket guide, go to:  
[cfe.unc.edu/pdfs/research\\_conduct\\_pocket\\_guide.pdf](http://cfe.unc.edu/pdfs/research_conduct_pocket_guide.pdf)

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