

## **FREQUENTLY ASKED QUESTIONS ABOUT THE USE OF HUMAN SUBJECTS IN RESEARCH**

### **WHAT IS THE PURPOSE OF THE IRB?**

The Institutional Review Board (IRB) for the Protection of Human Research Participants is an independent compliance committee mandated by the U.S. Department of Health and Human Services (DHHS). (See Title 45 Part 46 of the Code of Federal Regulations). The role of the IRB is to protect the rights and welfare of persons recruited to participate in research activities conducted under the auspices of Hunter College. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and institutional policy. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB. Research that has been reviewed and approved by the IRB is subject to continuing IRB review and must be reevaluated at least annually, or more frequently if specified by the IRB.

### **WHO MUST APPLY FOR HUMAN SUBJECTS REVIEW THROUGH THE IRB?**

Anyone who intends to conduct research that involves people must apply for and receive IRB approval before beginning any research.

### **WHAT IS RESEARCH?**

Research is a systematic investigation designed to develop or contribute to generalized knowledge, or investigation designed to test a hypothesis.

### **I'M NOT APPLYING FOR FUNDING FOR MY RESEARCH, DO I STILL HAVE TO GO THROUGH IRB?**

Yes. Any research involving human subjects must be submitted to the IRB whether or not there is funding source. Review for the protection of human subjects is made without regard for funding source.

### **WHAT'S THE WORST THAT CAN HAPPEN IF I DON'T GET IRB APPROVAL?**

Aside from potential ethical implications for the subject and for the investigator, bypassing IRB review brings other risks:

#### *Ramifications for Students*

Credit may be withheld: The College may, at its discretion, refuse to grant students course credit for research conducted without IRB approval.

Dissertation or thesis work will not be accepted: Graduate students **must** present to the Graduate School evidence of IRB approval for their projects involving human subjects. Thesis or dissertation work will not be accepted without it. Degrees will not be awarded for work based on non-IRB-reviewed projects.

Articles may not be published: Most professional journals require evidence of IRB approval when considering articles for publication.

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.

### *Ramifications for Faculty and Staff*

Funding may be withheld: Federal sponsors, and virtually all private sponsors, require IRB approval as a condition of funding. Sponsors may postpone review of proposals for which review is not complete or pending at the time of proposal submission. Virtually all sponsors will not release funds to the University for the investigator's use without IRB approval. The Research Foundation will not set up accounts for projects lacking necessary IRB approval.

Articles may not be published: Most professional journals require evidence of IRB approval when considering articles for publication.

The University will not support unapproved research: Liability issues arising from unapproved research become the responsibility of the investigator. Persons conducting unapproved research are deemed to be acting outside the scope of authority granted them by the University. The University will not, therefore, provide an investigator of an unapproved project the resources to answer a liability complaint.

Suspension of Research: The College can suspend all research activities for a specified time frame as a disciplinary measure.

### **WHERE DO I GET AN IRB APPLICATION FOR REVIEW?**

#### *☞ In Person*

Applications are available in Room E1426

#### *☞ Via the Web*

Human Subjects information and application materials are available on the IRB web site at <http://www.hunter.cuny.edu/IRB>.

#### *☞ By Phone*

You may call (212) 650-3053 to request an application form or ask questions about the IRB application process.

#### *☞ By E-mail*

You may email [irb@hunter.cuny.edu](mailto:irb@hunter.cuny.edu) to request an application.

### **WHERE DO I SEND MY COMPLETED APPLICATION, AND WHAT HAPPENS AFTER I TURN IN MY FORMS?**

Return your completed application to Carolyn Julien in the IRB Office, Room E1426. If you're mailing your application from off-campus, the mailing address is:

*Hunter College  
IRB Office  
695 Park Avenue, Room E1426  
New York, NY 10021*

Once the application is received, it is assigned a protocol number and is routed for IRB review. Investigators are notified as soon as possible, in writing, of the IRB's decision.

### **WHAT ARE THE DIFFERENT LEVELS OF IRB REVIEW?**

There are three types of IRB review:

#### *☞ Exempt Review*

"Exempt" DOES NOT mean the protocol is exempt from IRB review.

#### *☞ Expedited Review*

#### *☞ Full Review*

### **WHAT IS A VULNERABLE SUBJECT?**

Subjects that are minors, prisoners, fetuses, pregnant women or individuals that have a diminished mental capacity are considered vulnerable subjects.

## **I NEED TO PLAN DATA COLLECTION AROUND IRB APPROVAL HOW LONG DOES REVIEW TAKE?**

*Please note: You may not begin your research until the IRB has given your research protocol full unconditional approval.*

Review of Exempt or Expedited protocols takes about two to three weeks. The review process for protocols submitted for Full Review can take up to a month or longer to complete. You should include sufficient time in your research plan as allowance for any IRB-required changes to the research protocol.

## **HOW OFTEN DOES THE IRB MEET?**

The IRB generally meets each month during the academic year (September through May). Meetings during the summer are announced in May.

## **WHAT DOES THE IRB LOOK FOR IN AN APPLICATION?**

The IRB seeks:

- Research design that's sound, given the proposed use of human subjects in the project
- Equitable selection of subjects
- Balanced risks and benefits
- A thoughtful and comprehensive informed consent process

## **HOW DO I KNOW THE IRB WILL UNDERSTAND MY PROPOSED RESEARCH?**

The IRB consists of faculty, researchers and members of the community at large. Individual experiences and interests cross diverse areas. Protocols should be clearly understood by members of all disciplines.

The IRB will seek assistance from qualified persons outside its membership when it receives protocols that require expertise beyond that available on the Committee. While outside experts may inform the IRB's decisions, they do not vote on research protocols presented for review.

## **DO I HAVE TO ATTEND THE IRB MEETING WHEN MY PROTOCOL IS REVIEWED?**

No. If the IRB has questions, or believes the investigator(s) could lend valuable insight for review, the IRB may contact the researcher during the meeting. Please be sure that contact numbers on the application are correct.

## **HOW DO I KNOW WHEN MY PROTOCOL HAS BEEN APPROVED?**

You will receive a written approval letter and approved consent form (if applicable). You must sign and return a copy of the approval letter. You may not begin your research until the IRB has given your research protocol full approval.

## **I'M CONDUCTING ALL OR PART OF MY RESEARCH OFF-SITE (AT A NON-HUNTER SITE). SHOULD I APPLY FOR PROJECT APPROVAL THROUGH THE OTHER SITE'S IRB AND THE HUNTER IRB?**

*If the other site has an IRB:*

Yes. Many hospitals, universities and other institutions have their own IRBs. If the site of your research has an IRB, the site IRB and the Hunter IRB must both approve your project before you start. You may submit your protocol for review to Hunter at the same time you submit your protocol to the other institution's IRB for review, or you may submit the protocol after the other institution's review is completed. Remember that review and approval requirements may vary among institutions, so you should familiarize yourself with each IRB's policies.

*If the other site doesn't have an IRB:*

Elementary schools, nursing homes and community centers often serve as non-Hunter research sites, and rarely have IRBs. You should ask appropriate personnel (e.g., school principal, director of nursing home, community center director) at the research site to provide a letter indicating that (s)he has read your research proposal, and that you, the investigator, have permission to conduct your research at his or her facilities. The Hunter IRB requires evidence of site permission for its review and approval of your project. Please note that we cannot accept letters from principals or other officials of any New York City public school, as the New York City Public schools have an established IRB and all approval letters must come from that IRB.

### *For Other CUNY campuses*

You must submit to the Hunter IRB the approved protocol, consent documents, instruments and the approval letter from the other CUNY campus.

### **I WANT TO ADMINISTER MY STUDY IN A LANGUAGE OTHER THAN ENGLISH. WHAT DO I DO?**

All consent documents and instruments, must be translated. The IRB must certify that the translated documents translate equivalently in English.

### **DO I NEED ANY SPECIAL TRAINING TO USE HUMAN PARTICIPANTS IN RESEARCH?**

Yes. We have an assurance with the Office of Human Research Protection (OHRP), U.S. Department of Health and Human Services. This assurance includes a requirement that all key personnel working with human subjects receive training in ethical guidelines and regulations. "Key personnel" is defined as any individual responsible for the design and conduct of the study. This would include persons who have direct and substantive involvement in proposing, performing, reviewing, analyzing, or reporting research and includes students fulfilling these roles as well as their faculty advisors.

The CITI training will satisfy this training requirement. Certificates are issued at the completion of the training. If you are involved in a research protocol a copy of this certificate must be on file at the IRB Office.

### **I'M WORKING WITH OTHER RESEARCHERS ON THIS PROJECT. WHAT SHOULD I DO?**

The IRB will want to know the name of each person on the project. The IRB will also need CITI/CBT certificates for all personnel on the project and a Key Personnel form.

### **WHAT HAPPENS IF MY PROTOCOL IS NOT APPROVED?**

The Committee will send its comments to you asking for revisions to your protocol. Changes must be submitted to the Committee for its review.

### **WHAT ARE MY RESPONSIBILITIES AFTER PROTOCOL APPROVAL?**

You are responsible for...

- ☞ familiarizing yourself with ethical guidelines and regulations regarding the protection of human participants from research risks
- ☞ conducting the research according to the approved protocol
- ☞ obtaining written informed consent using the approved consent form for each and every study participant if required by the IRB
- ☞ immediately reporting to the IRB, through the IRB Office, and your immediate administrator, any unanticipated effects on participants which become apparent during the course or as a result of experimentation, and the actions taken as a result
- ☞ obtaining prior review from the IRB if you wish to amend or alter the scope of the project or implement changes in the approved consent form
- ☞ maintaining documentation of consent forms and progress reports for three years in a safe place
- ☞ cooperating with the IRB in the continuing review of and final reporting on the project as required by Federal regulations and the IRB.

### **HOW LONG IS THE APPROVAL FOR?**

A standard approval is for a period of one year. You will receive a progress report two months prior to the end-date of your approved protocol. At that time, you may elect to continue your project. You can receive two continuations on an approved protocol. After two continuations, you must complete a new protocol if your study is still continuing. The IRB may request progress reports for some protocols on a quarterly basis.

**MY PROJECT IS GOING TO TAKE LONGER THAN THE APPROVAL PERIOD TO COMPLETE. IS IT POSSIBLE TO EXTEND THE PROJECT? IF SO, HOW?**

Yes. Any project in good standing may be extended. You will be sent a notice about 2 months prior to the approval expiration. This must be completed before the project expiration. If you are proposing changes to your project along with the extension, include appropriate materials as you would for a modification. Renewals are reviewed at the same level as the original protocol - i.e., Full Review renewals are reviewed by the full IRB. You should plan accordingly to avoid disruption in data collection.

**MY PROTOCOL WAS APPROVED, BUT NOW I WANT TO MODIFY IT. HOW DO I DO THAT?**

Changes to a research protocol must be reviewed and approved by the IRB prior to their implementation. To submit proposed changes for IRB review, complete an IRB Request for Addendum/Modification for Approved Protocol. Attach new or revised instruments, measures, consent documents, etc., as appropriate. Requests for modifications are reviewed at the same level as the original protocol - i.e., Full Review modifications are reviewed by the Full IRB.

**WHAT IS AN ADVERSE EVENT AND HOW DO I REPORT IT?**

Breaches in protocol, adverse events and unanticipated problems, include, but are not limited to breakdowns in the consent process, violations of confidentiality of the data, complaints by participants, and adverse physical events. Serious problems and adverse events must be reported to the IRB within 48 hours.

**I HAVE NEW PERSONNEL THAT WANT TO WORK ON MY APPROVED PROTOCOL. WHAT DO I DO?**

All new personnel must complete the CITI training and forward the certificate(s) along with a revised key personnel form to the IRB Office.

**MY RESEARCH IS FINISHED. NOW WHAT?**

You must complete a form to inform the committee about your research. This will be sent to you one month prior to the expiration of your approved protocol.

**I STILL HAVE QUESTION. WHO CAN HELP?**

E-mail or call the IRB Office (212) 650-3053 or [irb@hunter.cuny.edu](mailto:irb@hunter.cuny.edu) for assistance.