



# **HUNTER COLLEGE**

# **INSTITUTIONAL REVIEW BOARD (IRB)**

# **POLICIES & PROCEDURES**

# **MANUAL**

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1	IRB Organization.....	1-1
2	The IRB's Regulatory Authority.....	2-3
2.1	CHARTER.....	2-3
2.2	ACTIVITIES THAT MUST BE REVIEWED BY THE IRB.....	2-3
2.3	ASSURANCES AND IRB REGISTRATION.....	2-4
2.4	THE IRB'S RESPONSIBILITY.....	2-4
2.5	IRB CHAIR.....	2-5
2.6	IRB MEMBERSHIP.....	2-5
2.7	RESIGNATION AND REMOVAL IRB MEMBERS.....	2-5
2.8	LIABILITY COVERAGE.....	2-5
2.9	THE IRB OFFICE.....	2-6
2.10	ATTENDANCE EXPECTATIONS.....	2-6
2.11	CONFLICTS OF INTEREST.....	2-6
2.12	IRB MEMBER EDUCATION PROGRAMS.....	2-6
2.13	PARTICIPATION IN THE EXPEDITED REVIEW PROCESS.....	2-7
2.14	IRB MEETINGS.....	2-7
2.15	EMERGENCY MEETINGS.....	2-7
2.16	RESEARCH: A SHARED RESPONSIBILITY.....	2-8
2.17	POLICIES AND PROCEDURES.....	2-8
2.18	DOCUMENT RETENTION.....	2-8
2.19	DESTRUCTION OF COPIES.....	2-9
3	Principles that Govern the IRB.....	3-10
3.1	THE BELMONT REPORT.....	3-10
3.2	HUMAN SUBJECTS RESEARCH DEFINED.....	3-11
4	Information for Researchers.....	4-12
4.1	INTRODUCTION.....	4-12
4.2	RESEARCHER RESPONSIBILITIES.....	4-12
4.3	SCOPE OF IRB REVIEW.....	4-14
4.4	RESEARCH RISKS.....	4-14
4.5	RESEARCH CONDUCTED BY ADJUNCT FACULTY.....	4-14
4.6	RESEARCH CONDUCTED BY AN UNAFFILIATED RESEARCHER.....	4-14
4.7	RESEARCH CONDUCTED BY STUDENTS.....	4-15
4.8	RESPONSIBILITY OF STUDENT ADVISORS FOR ALL STUDENT RESEARCH PROJECTS.....	4-15
4.9	RESEARCH CONDUCTED IN COLLABORATION WITH ANOTHER INSTITUTION.....	4-15
4.10	RESEARCH CONDUCTED IN A FOREIGN COUNTRY.....	4-16
4.11	PILOT RESEARCH.....	4-16
4.12	RESEARCH USING "SECONDARY DATA".....	4-17
4.13	REQUIREMENT FOR EDUCATION ON THE PROTECTION OF HUMAN SUBJECTS.....	4-17
5	The Review Process.....	5-18
5.1	FULL IRB REVIEW.....	5-18
5.2	EXPEDITED REVIEW.....	5-18
5.3	EXEMPT RESEARCH.....	5-21
5.4	IRB DECISIONS.....	5-22
5.5	AMENDMENTS AND MODIFICATIONS TO CURRENTLY APPROVED RESEARCH.....	5-23
5.6	CONTINUING REVIEWS.....	5-23
5.7	APPROVAL PERIOD.....	5-24
5.8	THE INFORMED CONSENT PROCESS.....	5-24
5.9	QUALIFICATIONS OF RESEARCH PERSONNEL.....	5-24
5.10	QUALIFICATIONS OF IRB MEMBERS.....	5-25
5.11	TERMINATION OF IRB APPROVAL.....	5-25
5.12	SUBMISSION REQUIREMENTS.....	5-25
5.13	WHAT TO EXPECT AFTER SUBMISSION OF YOUR PROTOCOL.....	5-25
5.14	RIGHT TO APPEAL.....	5-26
6	Information Regarding Potential Research Subjects.....	6-27
6.1	JUSTIFICATION OF SAMPLE SIZE.....	6-27
6.2	WOMEN AND MINORITY POPULATIONS.....	6-27
6.3	VULNERABLE POPULATIONS.....	6-27
6.4	CHILDREN IN RESEARCH.....	6-27
6.5	PRISONERS.....	6-29
6.6	PREGNANT WOMEN, FETUSES AND NEONATES.....	6-30
6.7	COGNITIVELY AND MENTALLY IMPAIRED INDIVIDUALS.....	6-30
6.8	STUDENTS OR EMPLOYEES AS RESEARCH SUBJECTS.....	6-31
6.9	RESEARCH IN GROUPS.....	6-32
6.10	ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED INDIVIDUALS.....	6-32

6.11	STUDIES INVOLVING HUMAN EMBRYONIC STEM CELLS, GERM CELLS, AND CELL-DERIVED TEST ARTICLES 6-32	
6.12	SUBJECT POOLS .....	6-33
6.13	PAYMENTS TO SUBJECTS .....	6-33
6.14	RECRUITMENT AND ADVERTISEMENTS .....	6-33
6.15	DECEPTION IN RESEARCH .....	6-34
6.16	GATHERING INFORMATION ABOUT INDIVIDUALS OR RESEARCH ON "SECONDARY SUBJECTS" .....	6-34
6.17	PROCEDURES AND GUIDELINES WHEN SUBJECT POOL IS THE SAME AND SUBJECTS MAY BE PARTICIPANTS IN MULTIPLE STUDIES OF THE SAME RESEARCHER .....	6-34
6.18	HIPAA .....	6-35
6.19	EXISTING DATA STUDIES WHERE THE RESEARCHER IS ALSO AN EMPLOYEE .....	6-36
6.20	REFERRALS .....	6-36
7	The Consent Process .....	7-37
7.1	WHAT SUBJECTS NEED TO BE TOLD ABOUT THE RESEARCH .....	7-37
7.2	INFORMATION SHEET VS. CONSENT FORM: DOCUMENTING THE CONSENT PROCESS .....	7-37
7.3	CONSENT FORM .....	7-37
7.4	INFORMATION SHEET .....	7-38
7.5	OTHER CONSIDERATIONS .....	7-38
7.6	LANGUAGE LEVEL .....	7-38
7.7	VIDEO AND AUDIO TAPING .....	7-38
7.8	RECORDKEEPING .....	7-38
7.9	ANONYMOUS AND CONFIDENTIAL DATA .....	7-38
7.10	HOW TO ASSESS SUBJECTS' UNDERSTANDING OF THE RESEARCH .....	7-39
7.11	ASSENT .....	7-40
7.12	PASSIVE CONSENT .....	7-40
7.13	WHEN THE CONSENT REQUIREMENT CAN BE WAIVED (ORAL CONSENT VS. NO CONSENT) .....	7-40
7.14	BARRIERS TO CONSENT (LANGUAGE AND PHYSICAL) .....	7-41
7.15	CONSENT IN FOREIGN COUNTRIES .....	7-41
7.16	RE-CONSENT PROCESS IN LONGITUDINAL OR MULTI-STAGE STUDIES .....	7-42
7.17	CERTIFICATE OF CONFIDENTIALITY .....	7-42
7.18	SAMPLES AND TEMPLATES .....	7-44
7.18.1	TEMPLATE WITH BASIC ELEMENTS OF THE CONSENT FORM .....	7-44
7.19	GENERAL INFORMATION .....	7-49
8	The Basic Application Packet .....	8-51
8.1	IRB PROTOCOL COVERSHEET .....	8-51
8.2	IRB APPLICATION FORM .....	8-51
8.3	REQUIREMENT FOR EDUCATION ON THE PROTECTION OF HUMAN SUBJECTS .....	8-52
8.4	KEY PERSONNEL FORM .....	8-52
8.5	CONSENT FORM .....	8-52
8.6	OTHER IRB APPROVAL/LETTER OF SUPPORT .....	8-53
8.7	GUIDELINES FOR DEVELOPING A BASIC PROTOCOL .....	8-53
8.8	DETAILED DESCRIPTION OF THE PROTOCOL .....	8-54
8.8.1.1	State the purpose of the research. Include major hypothesis and research design.	8-54
8.8.1.2	Describe the source of subjects and the selection criteria .....	8-54
8.8.2	Provide a description of the procedures to be followed .....	8-56
8.8.3	Describe any potential harms and benefits to be derived by subjects with a discussion of the risk/benefit ratio .....	8-56
8.8.4	Describe the specific methods by which confidentiality and anonymity will be protected .....	8-57
8.8.4.1	Guidelines for protecting confidentiality .....	8-58
8.8.5	You Must Attach Any Other Information That May be Pertinent to the IRB Decision .....	8-59
8.8.6	Financial Considerations for Subjects .....	8-59
8.8.7	Deception in Research .....	8-59
8.8.8	Obtaining Informed Consent .....	8-60
9	Ongoing Responsibilities after Initial Protocol Approval .....	9-61
9.1	REPORTING ADVERSE EVENTS .....	9-61
9.2	INJURIES, ILLNESSES, OR OTHER UNANTICIPATED COMPLICATIONS POSSIBLY RESULTING FROM THE RESEARCH .....	9-61
9.3	UNANTICIPATED PROBLEMS OR NONCOMPLIANCE WITH THE REQUIREMENTS OF THE PROTOCOL .....	9-61
9.4	MAKING MODIFICATIONS TO CURRENTLY APPROVED RESEARCH .....	9-61
9.5	MINOR MODIFICATIONS TO CURRENTLY APPROVED RESEARCH .....	9-61
9.6	MAJOR MODIFICATIONS TO CURRENTLY APPROVED RESEARCH .....	9-62
9.7	APPROVAL PERIOD FOR MODIFICATIONS .....	9-62
9.8	CONTINUING REVIEW AFTER INITIAL APPLICATION APPROVAL .....	9-62
9.9	TERMINATION FOR FAILURE TO OBTAIN CONTINUING APPROVAL .....	9-64
9.10	MAINTENANCE AND RETENTION OF RECORDS AND CONSENT FORMS .....	9-64

9.11	COMPLETION/TERMINATION OF STUDY .....	9-64
10	Classroom Practica .....	10-65
10.1	RESPONSIBILITY OF STUDENT ADVISORS FOR ALL STUDENT RESEARCH PROJECTS.....	10-66
11	Forms.....	11-68
11.1	IRB APPLICATION FORM .....	11-68
11.2	IRB PROTOCOL COVERSHEET.....	11-68
11.3	IRB KEY PERSONNEL FORM.....	11-68
11.4	IRB AUDIO AND VIDEO RELEASE CONSENT FORM .....	11-68
11.5	IRB CLASSROOM PRACTICA FORM .....	11-68
11.6	IRB REQUEST FOR ADDENDUM/MODIFICATION FOR APPROVED PROTOCOL.....	11-69
11.7	UNAFFILIATED INVESTIGATOR AGREEMENT .....	11-69
11.8	HIPAA DATA USE AGREEMENT .....	11-69
11.9	IRB MANUAL .....	11-69
11.10	HIPAA FORMS.....	11-69
11.11	HIPAA RESEARCH AUTHORIZATION FORM (HIV).....	11-69
11.12	HIPAA RESEARCH AUTHORIZATION FORM (PSYCHOTHERAPY NOTES).....	11-70
11.13	HIPAA IRB WAIVER APPLICATION.....	11-70
11.14	CUNY SUBJECT INFORMATION CONFIDENTIALITY AGREEMENT .....	11-70
12	Other Policies.....	12-71
12.1	ORAL HISTORY .....	12-71
12.2	MARKETING RESEARCH IN CLASSROOM.....	12-71
12.3	PROCESS RECORDING .....	12-71
12.4	JOURNALISM .....	12-71
12.5	WHISTLE BLOWER POLICY .....	12-71
12.6	RESEARCHER NON-COMPLIANCE.....	12-72
12.6.1	WHAT CAN HAPPEN IF YOU DON'T GET IRB APPROVAL? .....	12-72
13	Appendices.....	13-74
14	GLOSSARY OF TERMS.....	14-75

# 1 IRB Organization

The use of human subjects in research activities falls under the jurisdiction of federal regulations. Researchers are granted the privilege of involving human subjects in their research under the terms of a formal assurance with the Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS). All employees, students or contractors who conduct, support, or review research involving human subjects must comply with the regulations identified in this assurance, as well as applicable state and institutional policies and standards of professional conduct and practice. Failure to comply with the terms of the assurance can result in loss of funding for human subjects research, not only for the individual researcher but for the entire institution. Noncompliance by one researcher can affect the ability of all researchers at CUNY to conduct research with human subjects.

CUNY's Federalwide Assurance FWA00003623, maintained with the OHRP at DHHS, requires that all human subjects research conducted by Hunter College employees, students or contractors, or otherwise under the auspices of Hunter, be performed in accordance with [Title 45 Code of Federal Regulations, Part 46 \(45 CFR 46\)](#) [**Note:** 45 CFR 46 consists of Sub-parts A, B, C and D. Sub-part A is also known as the "Common Rule." The text of this rule was agreed upon by seventeen government agencies and published in the [Federal Register](#) on June 18, 1991. The agencies all agreed to promulgate the same regulations based on this Common Rule so that human subjects research would be regulated consistently across the government. The Federal Register made it clear that each agency would implement the Common Rule through its particular regulations; the Department of Energy (DOE) does so through 10 CFR 745. CUNY's Federalwide Assurance with DHHS commits it to implementing all sub-parts of 45

CFR 46, not just the Common Rule. In addition, the actions of Hunter must also conform to all other applicable federal, state, and local laws and regulations.

It is also CUNY's policy that researchers respect and protect the rights and welfare of individuals recruited for or participating in research conducted by or under the auspices of the College. In the review and conduct of research involving human subjects, Hunter is guided by the ethical principles set forth in the **Belmont Report** (i.e., respect for persons, beneficence, and justice).

Hunter's Institutional Review Board (IRB) has the primary responsibility for the oversight of the protection of human subjects who have been recruited to participate or are actively participating in research projects conducted by or with the assistance of Hunter's employees, students or contractors.

This document provides information about the ethical conduct and review of human subjects research at Hunter. It explains the various federal and state regulations and institutional requirements, and provides guidance for researchers and IRB members regarding the development, review, and conduct of human subjects research.

The information presented here is the most current available. However, the field of human subject protection continues to evolve. Researchers and IRB members are encouraged to check this document for revisions or updates.

The staff of the IRB Office is also available to answer any questions researchers may have regarding the participation of human subjects in research. To contact the IRB Office, please use the following telephone number and address:

Hunter College IRB Office  
695 Park Avenue, Room E1426  
New York, NY 10021  
Phone: 212 650-3053  
Fax: 212 650-3055  
Email: [irb@hunter.cuny.edu](mailto:irb@hunter.cuny.edu)

## 2 The IRB's Regulatory Authority

The IRB is governed by federal regulations (Title 45, Part 46, Protection of Human Subjects, <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>) that dictate the scope and purpose of IRB activities. The Office of Human Research Protections (OHRP) is the federal administrative agency that monitors the IRB and its activities. OHRP monitors human research subjects protections through educational efforts, site visits, and reporting requirements. OHRP has the authority to suspend research for failure to adhere to the regulations.

The IRB also follows the ethical principles found in the Belmont Report (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>).

### 2.1 CHARTER

The Institutional Review Board (IRB) is responsible for the review and approval of all research involving human subjects conducted under the auspices of Hunter College. The IRB is charged with protecting the rights and welfare of human research subjects recruited to participate in research activities and to ensure compliance with applicable federal regulations and College and University policy. The IRB is also charged with promoting a culture of respect for human subjects through education.

### 2.2 ACTIVITIES THAT MUST BE REVIEWED BY THE IRB

IRB approval is required for all research involving human subjects. The IRB has oversight of all research involving human subjects conducted at Hunter. This oversight applies regardless of the funding source or where the research takes place. In accordance with federal regulations, all research involving human subjects must be reviewed (or determined to be exempt) by the IRB. The regulatory requirements are applicable to all College authorized activities that in whole or in part involve research with human subjects, including:

- ? Research supported by the College;
- ? Research conducted by or under the direction of any employee or agent of the College in connection with his or her institutional responsibilities;
- ? Research conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution;
- ? Research involving the use of the College's non-public information (i.e., alumni, students, staff, etc.) to identify or contact human research subjects or prospective subjects.

The requirement for IRB review applies to all human subjects research, regardless of the funding source.

## 2.3 ASSURANCES AND IRB REGISTRATION

The University has a contract with the federal government (called an "assurance" or "assurance of compliance") that allows researchers to conduct research using human subjects. This assurance specifies the University's responsibilities and must be approved by the federal Office of Human Research Protections (OHRP). All CUNY colleges are covered by this assurance. Improper research activities at any one of the CUNY schools can shut down research for the entire university.

- ? CUNY's Federalwide Assurance (FWA) is identified as FWA00003623.
- ? Hunter College has 2 IRBs registered with OHRP. They are identified as:

Amethyst Committee: IRB Organization Number (**IORG #**): **IRB00004471**  
Gold Committee: IRB Organization Number (**IORG #**): **IRB00000136**.

The Amethyst Committee is designated as a medical IRB.

Multi-site projects that are federally funded (i.e., NIH, DHHS, etc.) must have an appropriate assurance for each research site. Researchers should be aware of the type of assurance held at outside research sites. This includes research both in and outside the United States. Researchers should also be aware that federal funding agencies will not make research funds available unless all research sites have an assurance approved by OHRP. The IRB Office can assist researchers and ensure that the appropriate assurances have been obtained for all research sites.

## 2.4 THE IRB'S RESPONSIBILITY

The responsibility of Hunter's IRB is to:

- ? Ensure that human subjects engaged in research are treated with dignity;
- ? Ensure that human subjects are adequately protected from risk of harm;  
and,
- ? Ensure that all human subjects give informed consent to participate in research.

The IRB reviews and approves research protocols **before** any work is started and reviews ongoing research periodically to ensure the continued protection of subjects. In addition, the IRB reviews all changes to research protocols **before** implementation. In accordance with federal regulations, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions, and requirements, or that has been associated with unexpected serious harm to subjects.

## **2.5 IRB CHAIR**

The Chair is appointed by the President. The Chair is a voting member on all IRB issues unless s/he has a conflict of interest with a protocol under IRB review. The duties of the IRB Chair include moderating meetings, performing expedited reviews, consulting with researchers as needed, providing training to the research community at Hunter, coordinating other efforts with the IRB Office as needed and making decisions on policy. As Hunter has two IRBs there are two Chairs who work cooperatively to maintain a similar level of scrutiny by the respective Committees.

## **2.6 IRB MEMBERSHIP**

The IRB is composed of College faculty, staff and community members. Each of the two committees must have at least 10 members, both men and women. This included scientific and non-scientific members and non-affiliated members. The individual members contribute the professional competency necessary to review specific research activities. They represent a broad range of disciplines and apply their experience and expertise. In addition, the IRB seeks diversity in race, gender and cultural backgrounds to promote sensitivity to community attitudes and respect for the rights and welfare of human subjects. IRB members are selected by the IRB Coordinator and Chairs. Appointment to the IRB is by the College President. Appointments are typically for a three-year term. IRB members are all voting members on all IRB issues unless s/he has a conflict of interest with a protocol under IRB review. The duties of IRB members include attending meetings, performing expedited reviews, providing training to the research community at Hunter, consulting with researchers as needed, and collaborating with fellow members on policy decisions.

## **2.7 RESIGNATION AND REMOVAL IRB MEMBERS**

A member may resign with notice and the vacancy will be filled as quickly as possible. When a committee member consistently fails to attend meetings or fails to meet expectations, the IRB chair(s) and IRB Coordinator meet with the committee member to determine the cause. If the IRB indicates an inability to continue to function effectively as an IRB member, the Chair or Coordinator may ask the member to step down from the IRB. Members may be removed before the end of their term if their participation in IRB activities is deemed to be inadequate, inappropriate, or damaging to the reputation of the College and its research activities.

## **2.8 LIABILITY COVERAGE**

IRB members have liability insurance coverage as part of their membership in their capacity as agents of Hunter College.

## **2.9 THE IRB OFFICE**

The IRB Office provides central administration to the IRB and serves as the primary point of contact for all IRB-related issues. The Office reports to the Chairs and the Provost. The IRB Office communicates with researchers regarding IRB decisions, maintains IRB records and facilitates on-going auditing of approved protocols. The Office serves as liaison between IRB Chairs, College officials, Committee members, the Research Foundation of CUNY, CUNY Office of Research Conduct and researchers. The Office also offers consultation on protocol preparation and general compliance issues, as well as the following services:

- ? Pre-review of protocols and consent forms to identify potential problems and suggest ways to address identified problems before full IRB review (includes a discussion of risks and benefits, informed consent, recruiting subjects, advertising, privacy and confidentiality);
- ? Individual and departmental education/training on the protection of human research subjects;
- ? Assistance with the use of IRB guidelines and forms;
- ? Preparation of needed documents (Certification or Assurances); and,
- ? Resolution of research-related problems with external funding agencies.

## **2.10 ATTENDANCE EXPECTATIONS**

IRB members are responsible for attending all scheduled IRB meetings, reviewing all assigned materials, and participating in IRB discussions. Members are asked to notify the IRB Office of their impending absence prior to the scheduled IRB meeting.

## **2.11 CONFLICTS OF INTEREST**

In the event that an IRB member has a conflict of interest with any protocol submitted for review, that member must disclose this conflict to the IRB Chair or Coordinator prior to the meeting or before discussion of the protocol begins. The member in the conflict situation may respond to questions from IRB members. However, that member must remove her/himself from the room prior to the IRB's deliberation and vote on the protocol. The official minutes will reflect that the member removed him/herself from the IRB meeting during the final discussion and vote on the protocol. Investigators are not allowed to choose reviewers or a specific Committee to review their protocol.

## **2.12 IRB MEMBER EDUCATION PROGRAMS**

All new IRB members receive an orientation from the IRB Office before starting their active service. This orientation includes an overview of the Federal

regulations (45 CFR 46) established to protect human research subjects, the Belmont Report, and other documents/materials pertaining to the protection of human research subjects at Hunter. Copies of these materials will be made available to new IRB members at their orientation.

The IRB Office and the CUNY Research Conduct Office will provide continuing education and support to all IRB members. Members receive a copy of the Human Research Report on a monthly basis from the IRB Office. Human subjects research-related news articles will be provided to IRB members as deemed appropriate by the IRB Office. Other pertinent reference materials relating to human subjects research issues are available for review in the IRB Office.

### **2.13 PARTICIPATION IN THE EXPEDITED REVIEW PROCESS**

All IRB members are asked to participate in the expedited review process. The IRB Office will select two IRB members to review a protocol qualifying for expedited review. Upon completion of the review, IRB members are asked to contact the IRB Office with comments. The review should be completed in 2-3 weeks.

### **2.14 IRB MEETINGS**

Convened meetings of each of the 2 IRB Committees generally occur each month during the academic year (September through June). Meetings during the summer are announced in May. The summer review of protocols is typically done by convened meetings. The IRB generally meets only once a month during the summer months (July and August). Deadline dates for inclusion on the agenda of the meetings can be found on the IRB website, or by calling the IRB Office at (212) 650-3053. Materials for meeting are distributed to IRB members prior to commencement of the meeting and with adequate time to complete the review before the meeting.

Full-IRB discussions require a majority of IRB members (51%) to be present during protocol discussions. One of the attendees must be a nonscientific member. A majority of members present (51%) must vote to approve or disapprove a protocol. Proxy votes are not permitted. In the event that an IRB member has a conflict of interest with any protocol submitted for review, that member must disclose this conflict. The member will not be allowed to participate in the study's deliberation/discussion, vote on the study's approval/disapproval, or be counted towards quorum requirements for that particular protocol.

IRB members receive copies of protocol packets, including supporting documentation, and any other documents relating to items on the agenda prior to the meeting.

### **2.15 EMERGENCY MEETINGS**

The IRB will hold an emergency meeting, when necessary. These meetings are usually needed to deal with adverse events.

## **2.16 RESEARCH: A SHARED RESPONSIBILITY**

Hunter's researchers and research staff, the IRB and the IRB Office share collective responsibility for the ethical conduct of human subjects research. To be effective, this collaborative responsibility requires a culture of trust, openness, and honesty. Hunter must uphold the highest ethical principles in the conduct of research. By upholding the highest standards in a safe research environment, Hunter can build public support for the pursuit of greater knowledge.

The dignity and welfare of individuals who participate in research is a central concern in the protection of human subjects. Our primary goal must be to assure the development of a fair and explicit process in which subjects voluntarily decide to participate in a study based on an intelligent and knowledgeable assessment of the risks and benefits of the research.

The IRB is charged with a twofold mission:

(1) determine and certify that all projects approved by the IRB conform to the regulations and policies set forth by the DHHS regarding the health, welfare, safety, rights, and privileges of human subjects.

(2) to assist researchers in conducting ethical research that complies with the DHHS regulations in a way that permits accomplishment of the research activity.

The mission is accomplished through IRB review of protocols, discussion between researchers and the IRB during the review process, and IRB/IRB Office outreach to the research community. The process serves to ensure the safe and ethical conduct of human research and the protection of the rights and welfare of human subjects.

## **2.17 POLICIES AND PROCEDURES**

These policies and procedures are written to enable the IRB to maintain a system of compliance. These policies and procedures reflect not only the laws and regulations, but also the underlying ethical principles that are the basis of the IRB's mandate. Finally, these policies also reflect the overarching commitment of Hunter College to provide protection for all human subjects involved in research conducted under the direction of its employees, students or contractors. These policies and procedures apply to all research and classroom practica. This policy and procedures manual will be reviewed and updated as needed. The IRB meets two times a year to review and implement any new policies. The current policy and procedures manual will be available on line and in the IRB Office.

## **2.18 DOCUMENT RETENTION**

The IRB Office must retain all records regarding an application for at least three (3) years after final activity of the IRB, e.g., completion, termination, withdrawal, disapproval, etc. Documents that are maintained are:

- ? Study-related documents:
  - ? Adequate documentation of the IRB's activities will be prepared, maintained and retained in the IRB Office. Retained documents include:
    - ? Copies of all original research protocols reviewed, amendments or modifications, grant proposal (if any), approved consent documents, and reports of adverse events.
    - ? Minutes of all IRB meetings.
    - ? Copies of all submitted monitoring reports, site visit reports and other continuing review activities.
    - ? Copies of all correspondence between the IRB and the Researcher.
    - ? Reports of any complaints received from subjects.
    - ? Publications
- ? IRB Administrative Documents:
  - ? Rosters of regular and alternate IRB members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB's deliberations.
  - ? Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular member for whom the alternate may substitute.
  - ? Current membership rosters will remain in the IRB Office.
  - ? The roster of IRB members must be submitted to OHRP. Any changes in IRB membership must be reported to OHRP as they occur.
  - ? Reports of any investigative matter.

## **2.19 DESTRUCTION OF COPIES**

All material received by the IRB is considered confidential. Material will be collected at the end of the meeting and shredded. Materials that are sent to Committee members outside of meetings should be shredded or returned to the IRB for shredding.

# 3 Principles that Govern the IRB

## 3.1 THE BELMONT REPORT

The passage of the National Research Act in 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1976, the Commission published the Belmont Report, which articulates the basic ethical principles that guide the conduct of research with human subjects and form the foundation for federal regulations governing the protection of human research subjects. In the report, three principles were defined as basic to the protection of human subjects: respect, beneficence, and justice. The Hunter IRB accepts these ethical principles.

- ? **Respect**—In consideration of respect for persons, researchers are required to seek voluntary, written informed consent from potential subjects. Voluntary informed consent means that subjects are (1) given explicit assurances of the voluntary nature of their participation in terms that are easy to understand and (2) not under duress at the time they are asked to participate in the research. The consent form also includes adequate information about the study to assist subjects in intelligently deciding whether to participate in research. In addition, respect means honoring the privacy of individuals and maintaining the confidentiality of their data. Respect for minors and decision-impaired persons requires extra precautions to protect those individuals who are immature or incapacitated, perhaps even to the extent of excluding them from participation in certain research. The extent of protection depends on the risks and benefits of the research to the participants.
  
- ? **Beneficence**—This principle requires that researchers maximize the potential benefits to the subjects and minimize the potential for harm. The probability of benefit to the subjects, or in the form of generalized knowledge gained from the research, should always outweigh the probability of harm. Finally, if there is any harm resulting from participation in the research, then there must be an offsetting and compelling benefit, either to the subject or society in general.
  
- ? **Justice**—The principle of justice requires that subjects be selected fairly and that the risks and benefits of research are distributed equitably. Researchers should take precautions not to select subjects simply because of:
  - ☒ the subjects' easy availability (e.g., coworkers);
  - ☒ their compromised position (e.g., prisoners);
  - ☒ or because of social, racial, sexual, economic, or cultural biases institutionalized in society.

Researchers should base inclusion criteria on those factors that most effectively and soundly address the research problem, not on the easy availability of certain populations.

### 3.2 HUMAN SUBJECTS RESEARCH DEFINED

Federal regulations dictate what research must be reviewed by the IRB. The regulatory definition of "human subject research" requires researchers to be familiar with the individual definitions of both "Research" and "Human Subject."

? **Research**

"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

? **Human Subject**

"A human subject" is a living individual about whom a researcher (professional or student) conducting research obtains 1) data through intervention or interaction with the individual or (2) identifiable private information.

The following activities are included, but not limited, in the scope of the above definitions:

- ? Interviews, surveys, and other forms of communication;
- ? Gathering information about individuals that was collected for purposes other than this specific research (e.g., medical, school or correction records);
- ? Obtaining bodily materials such as cells, blood or urine, tissue, organs, hair, and nail clippings even if the researcher did not collect these materials;
- ? Access to medical records and data through the medical information systems;
- ? Oral histories
- ? Physical procedures (like blood drawing);
- ? Manipulation of the subject's environment.

**Note:** When a researcher is unsure whether or not an activity involves human subjects or should be considered research, s/he should contact the IRB Office.

# 4 Information for Researchers

## 4.1 INTRODUCTION

Although Hunter's researchers and research staff, the IRB, and the IRB Office share collective responsibility for the ethical conduct of human subjects research, the complex responsibilities of doing so can make the researcher's role particularly difficult and challenging. However, once the researcher understands the responsibilities involved, research can be rewarding for both the researcher and the subjects who participate. This chapter discusses the researchers' responsibilities and provides additional information regarding the development of a human subjects research protocol.

## 4.2 RESEARCHER RESPONSIBILITIES

Any researcher who conducts research involving human subjects must comply with Federal regulations governing human subjects research, as well as applicable state and institutional policies and standards of professional conduct and practice. Failure to comply with Federal regulations can result in loss of funding to conduct human subjects research by the individual, the program, the College or the entire University. Noncompliance by one researcher can affect the ability of all others at CUNY to do human subjects research. A researcher must:

1. Understand the ethical standards and regulatory requirements governing the research activities,
2. Recognize that IRB review and approval **must precede initiation** of any work involving human subjects,
3. Notify the IRB of his/her intention to use human subjects in research and submit required materials to the IRB to facilitate review of research,
4. Protect the rights and welfare of the human subjects who participate in the research through proper informed consent, etc., and
5. Notify the IRB of any adverse or unexpected events regarding subjects or changes to the research protocol.

**Note:** *When a researcher is unsure whether or not an activity involves human subjects or should be considered research, s/he should contact the IRB Office.*

All researchers and all key personnel who are engaged or plan to be engaged in research involving human subjects must successfully complete the CITI Training Program, which is a web-based training. The training can be completed at [www.citiprogram.org](http://www.citiprogram.org). It is the researcher's responsibility to keep a copy of the certificate.

The IRB Web site, [www.hunter.cuny.edu/research](http://www.hunter.cuny.edu/research), should be consulted for new and revised institutional and federal guidelines, policies and procedures, forms, etc., relating to human subjects research.

### **4.3 SCOPE OF IRB REVIEW**

The IRB reviews research to ensure that the rights and welfare of human subjects are protected. It does this by carefully assessing the following criteria:

- ? Does the study reasonably balance the benefits of the research against the risks to the subjects?
- ? Is the design of the study consistent with sound ethical guidelines and legal requirements?
- ? Are risks to subjects minimized by using procedures that are consistent with the study design and that do not unnecessarily expose subjects to risk?
- ? Is subject selection equitable?
- ? Are the informed consent procedures appropriate for all study populations and is the consent form comprehensible to all subjects?
- ? Are additional safeguards provided if potentially vulnerable subjects are to be studied (e.g., children, the cognitively impaired or mentally ill and prisoners)?

### **4.4 RESEARCH RISKS**

Human research involves risks that may be social, psychological, economic, financial, physical or legal. Individuals other than the research subject may also be at risk, including people discussed in the study (See section on Secondary Subjects), the researcher, society at large and the College. The IRB does not expect research to be free from risk, but does expect the researcher to be aware of the risks, to minimize risks when possible and inform the subject about risks accurately and honestly. Before a study is approved, the IRB will weigh the research risks in relation to:

- ? The anticipated benefits to the subjects and others,
- ? The importance of the knowledge that may reasonably be expected to result, and
- ? The informed consent process to be employed.

### **4.5 RESEARCH CONDUCTED BY ADJUNCT FACULTY**

Research conducted by adjunct faculty must be reviewed by the IRB, regardless of where the research is taking place. Researchers who are also affiliated with another institution must obtain IRB approval from that institution in addition to the Hunter IRB (if the institution has an IRB).

### **4.6 RESEARCH CONDUCTED BY AN UNAFFILIATED RESEARCHER**

Researchers who are not employed by or affiliated with Hunter or CUNY may not conduct research or recruit subjects at Hunter unless a Hunter faculty member agrees to be a named co-researcher for the protocol and the study receives IRB

approval. The unaffiliated researcher is also required to complete an Unaffiliated Investigator Form.

#### **4.7 RESEARCH CONDUCTED BY STUDENTS**

A student may only conduct research under the supervision of a faculty advisor. The faculty advisor will be held ultimately responsible for the conduct of the research and actions of the student. Student research is given the same level of IRB review as faculty-initiated research and must be approved by the IRB before being initiated.

The Faculty Advisor should mentor the student researcher through the research process. This responsibility includes teaching ethical conduct of research and appropriate scientific design. It is critical for all faculty research advisors to bear in mind that, as a teaching institution, we have an obligation to prepare our students for research opportunities here as well as in their future endeavors.

#### **4.8 RESPONSIBILITY OF STUDENT ADVISORS FOR ALL STUDENT RESEARCH PROJECTS**

- ? A Faculty Advisor of either an undergraduate or graduate student must be certified to conduct research with human subjects, even if the advisor is not currently conducting research with human subjects. Faculty Advisors can receive certification by completing the CITI program available on the CITI website as follows: [www.citiprogram.org](http://www.citiprogram.org).
- ? It is the responsibility of a Faculty Advisor to determine when an undergraduate or graduate student project does not meet the definition of a practicum and must be reviewed by the IRB. However, the advisor must be certified as noted in the previous bullet to be authorized to make this decision.
- ? It is the responsibility of the Faculty Advisor to ensure that research practica and exempt research activities are conducted according to the ethical standards of the relevant discipline.
- ? When student research activities are not practica, it is the responsibility of the Faculty Advisor to assist a student in preparing a protocol for review for the IRB and to ensure that the research is conducted in accordance with CUNY's assurance with the federal government and with applicable CUNY policy.

#### **4.9 RESEARCH CONDUCTED IN COLLABORATION WITH ANOTHER INSTITUTION**

Collaborative research must receive IRB approval from all collaborating institutions. Researchers should identify all collaborating sites in the protocol and indicate which aspects of the research will take place at each site.

It may be possible, in certain circumstances, to designate one IRB as the Primary IRB with responsibility for reviewing the entire study. Researchers who are interested in designating one IRB as the Primary IRB must contact the IRB Office and ask that the College enter into a Cooperative Agreement with another institution(s).

#### **4.10 RESEARCH CONDUCTED IN A FOREIGN COUNTRY**

When research takes place outside the United States, additional IRB approval is required.

If the study is supported by federal funds (i.e., NIH, DHHS, etc.) the researcher must obtain IRB approval from an institution that holds an assurance with the U.S. Government in the country where the research is taking place. This process is facilitated through the collaborating institution and the federal Office of Human Research Protections (OHRP). Researchers should note that federal granting agencies will not release funds to a grantee institution unless an appropriate assurance is in place.

If the study is supported by non-federal funds (i.e., private foundations, state funding, industry, etc.) approval from a local IRB or ethical review IRB in the country where the research is taking place will suffice. Usually any collaborating institution may be able to provide this service. Research in remote locations or research that is not conducted in affiliation with a large institution may present the researcher with unique challenges in identifying a local review IRB. In such cases the researcher should try to identify a local institution or governing body that can review the research and assess it in light of the local culture and customs (i.e., hospital, municipal governmental agency, school, tribal committee, etc.).

The researcher must submit evidence of local IRB review and approval once it is obtained.

#### **4.11 PILOT RESEARCH**

Research at the pilot or testing phase is subject to the same level of IRB review as any other research protocol, regardless of the number of subjects enrolled or the duration of the study. At the end of the pilot/testing phase, the researcher may either:

- 1) Close the pilot study and initiate a new protocol for the second phase of the study or
- 2) Amend the approved protocol to expand its scope and duration.

#### 4.12 RESEARCH USING "SECONDARY DATA"

Research using secondary data involves materials (data, documents, records, or specimens) that have been collected. In some cases prior IRB approval from Hunter or another institution should have been granted for the initial study. Such data must be in existence before the study is initiated. Research using secondary data is subject to the same level of review as any other research protocol.

#### 4.13 REQUIREMENT FOR EDUCATION ON THE PROTECTION OF HUMAN SUBJECTS

The National Institutes of Health (NIH) instituted a policy that requires that all proposals for contracts and grants for research involving human subjects submitted after October 1, 2000 certify that all key personnel have received education on the protection of human research subjects. This requirement applies to all applications for grants or proposals for contracts submitted to NIH after October 1st and to all new and all non-competing grants for which an award is issued after October 1st. However, researchers need to be aware that in order for CUNY to be in compliance with its legal assurance to DHHS, *CUNY is requiring that all researchers and key personnel, regardless of the research project sponsor and whether it is funded or unfunded, satisfy this new requirement.*

There are two options available to CUNY key personnel in research involving human subjects which will enable them to meet this mandated requirement for education:

- ? Successful completion of a computer-based training (CBT) course. The CBT may be accessed on the CITI web site at [www.citiprogram.org](http://www.citiprogram.org)

OR

- ? Completion of an on-campus course conducted by IRB administrative staff or faculty. (The course must be approved by RFCUNY's Office of Research Conduct.)

Researchers need to have the education requirement fulfilled at the time of submission of their application to the IRB. However, other key personnel working on the research project should have completed an education program with documentation before the beginning of the research project.

Key personnel are defined as any individual who will be involved in the design and conduct of human subjects research project.

# 5 The Review Process

## 5.1 FULL IRB REVIEW

Research that exposes subjects to risks that are greater than the kind of risks normally experienced in daily life or research which involves vulnerable subjects must be reviewed by the full IRB at a convened meeting. At such a meeting, the IRB will review the protocol and consent documents for compliance with federal regulations. The IRB will also assess whether the study's purpose and procedures are ethically appropriate. Hunter has 2 IRBs which each meet once monthly during the academic year. Researchers should consult the IRB website for submission deadlines. Researchers will be notified of the IRB decision in writing approximately 7-10 days after the IRB meeting.

Protocols that were originally approved by the full IRB must also be submitted to the IRB for continuing review. As a courtesy, researchers will be notified by the IRB Office six to eight (6–8) weeks prior to expiration of their IRB approval. An application for continuing review must be received by the IRB Office in time for review and approval in advance of the expiration date (4–5 weeks recommended). Please be advised that approved protocols are given one approval and two continuing reviews. After that time, a new protocol must be submitted. Each approval is for a period of no more than one year, under federal guidelines.

## 5.2 EXPEDITED REVIEW

Federal regulations allow for expedited review of some research if it involves no more than minimal risk and it falls within one of the specific expedited research categories. "Minimal risk" research is generally considered to be activity that has the same risk level as activities experienced in daily life or routine medical, dental or psychological examinations. The IRB however, has the discretion to require full IRB review of any study. Protocols that involve minors, the cognitively and mentally ill, or prisoners cannot be reviewed by the expedited review process.

The expedited review is done by two Committee members, who are designated by the IRB Office. There is no submission deadline for studies that qualify for expedited review. Researchers will be notified of the IRB decision within two to three weeks after the protocol has been received.

### Expedited Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical

devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

### 5.3 EXEMPT RESEARCH

Federal regulations allow six specific categories of human subjects research that are classified as exempt. Only the IRB may decide if the research is exempt. Exempt research is reviewed by the expedited review process or by the full Committee. There is no submission deadline for studies that qualify for exemption. Researchers will be notified of the IRB decision in writing approximately two to three weeks after it was received by the IRB. Exempt research will still receive annual reviews to ensure that there are no changes in the research.

The exempt research categories are (45 CFR 46.101b):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - ✍ information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - ✍ any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
  - ✍ the human subjects are elected or appointed public officials or candidates for public office; or
  - ✍ Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
  - ✍ Public benefit or service programs;
  - ✍ procedures for obtaining benefits or services under those programs;
  - ✍ possible changes in or alternatives to those programs or procedures;
  - ✍ or possible changes in methods or levels of payment for benefits or services under those programs
6. Taste and food quality evaluation and consumer acceptance studies,
  - ✍ if wholesome foods without additives are consumed or
  - ✍ if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## 5.4 IRB DECISIONS

There are three possible courses of action that the IRB may take.

- ? **Approved**  
Research that is approved outright requires no further revisions and may be initiated as soon as the researcher receives the IRB's decision and returns the signed approval letter. The IRB will approve and validate the consent form with an approval stamp. Subjects must be given only consent forms/information sheets with the IRB's validation stamp.
  
- ? **Not Approved**  
Often the IRB will require specific revisions to the protocol and/or consent form before the research will be approved. When the IRB asks for specific revisions, the researcher must submit the revised protocol to the IRB for the changes to be reviewed. The revised protocol will be reviewed by the IRB. This classification specifies that the research cannot be approved in its present format. It does not mean that it can never be approved. The IRB

will work with the researcher to make a study approvable. In very rare instances a project will not be able to be approved at all.

? Tabled or Deferred

Sometimes the IRB will require additional information about the research before the protocol can be reviewed. This usually happens because the protocol does not contain enough information to allow the IRB to fully review and understand the nature of the research. In these cases the IRB will ask the researcher to revise the protocol and submit it for re-review.

? Approval in Principle

The research concept has been reviewed and approved, though the research team has not formalized all aspects of the study. As the research is formalized it must be reviewed by the IRB. The researcher cannot contact subjects until they have received full approval.

## **5.5 AMENDMENTS AND MODIFICATIONS TO CURRENTLY APPROVED RESEARCH**

Substantive changes in research during the period for which IRB approval has already been given shall not be initiated by researchers without IRB review and approval. The only exception to this policy is if it becomes necessary to revise a protocol to eliminate apparent immediate hazards to the subject. These changes must be reported immediately to the IRB.

Amendments or modifications to previously approved research, submitted between scheduled continuing reviews, that involve only minor changes in previously approved protocols or minor changes in Consent Forms may qualify for expedited review. Only changes that do not increase the risk to research subjects may receive an expedited review. Modifications to approved protocols that may affect the risk to subjects are forwarded to the full Committee for review. Researchers should submit an IRB Request for Addendum/Modification for Approved Protocol to the IRB prior to implementing these changes. The modifications cannot be implemented unless approval has been granted.

## **5.6 CONTINUING REVIEWS**

The IRB must conduct continuing review of protocols at intervals appropriate to the degree of risk, but not less than once per year. It is the researcher's responsibility to ensure that the research is reviewed on or before expiration of the current approval period, even if the research activity did not begin until some time after the IRB gave its initial approval. As a courtesy, researchers will be notified by the IRB Office six to eight (6–8) weeks prior to expiration of their IRB approval. An application for continuing review must be received by the IRB Office in time for review and approval in advance of the expiration date (4–5 weeks recommended). Please be advised that approved protocols are given

one approval and two continuing reviews. After that time, a new protocol must be submitted.

Continuing review and approval is also necessary if recruitment of subjects stops but previously enrolled subjects continue to participate in the research or the study is in the data analysis phase at Hunter.

If there is a lapse in the protocol, you will receive a certified letter indicating that the protocol has been closed. If you wish to reopen the file, you must contact the IRB Office.

## **5.7 APPROVAL PERIOD**

Typically protocols receive a one-year approval. Some projects may receive shorter approval periods based on the risks/benefits ratio or some other determination. The IRB will determine the approval period when the project is approved.

## **5.8 THE INFORMED CONSENT PROCESS**

The IRB will carefully evaluate the informed consent process: when, where, and how consent is obtained and any provisions for the ongoing consent of subjects. Federal regulations on informed consent stipulate required elements of consent. The IRB will verify that these elements have been incorporated into the consent document. The consent document must present all necessary information to the prospective subject in as clear and easily readable a manner as possible. Please refer to the coversheet in developing a Consent Form.

The IRB will determine that informed consent (1) is obtained from the subject or the subject's legally authorized representative, (2) is written in language understandable to the subject or the representative, (3) is obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate, and (4) does not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to relieve the researcher, the sponsor, or the institution or its agents from liability for negligence.

## **5.9 QUALIFICATIONS OF RESEARCH PERSONNEL**

Procedures requiring special skills on the part of the researchers, licensure, accreditation, and/or experience in qualifying the researcher for the performance of the proposed procedures are reviewed by the IRB. In addition, the IRB will consider the facilities and equipment used to conduct the research and maintain the rights and welfare of the subjects.

## 5.10 QUALIFICATIONS OF IRB MEMBERS

IRB members cover a broad range of disciplines. If however, a protocol that is being reviewed requires expertise that is not present on the Committee, it will seek the counsel of consultants with expertise in the subject area.

## 5.11 TERMINATION OF IRB APPROVAL

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to the researcher, appropriate institutional officials, OHRP, any other sponsoring federal agencies, and/or private sponsors, if appropriate.

## 5.12 SUBMISSION REQUIREMENTS

Protocols for review must include all materials specified in Chapter 7. Please provide the IRB Office with 3 copies of all materials for exempt and expedited studies and 12 copies for studies that will be reviewed by the full IRB.

## 5.13 WHAT TO EXPECT AFTER SUBMISSION OF YOUR PROTOCOL

*After a protocol is submitted to the IRB Office, it will be reviewed for completeness. If your protocol is missing items, the IRB Office will contact you. If your protocol meets the preliminary criteria, the review process will be initiated. The IRB Office will assign a protocol number and makes the final determination as to the type of review. After the review, you will be notified by e-mail and/or mail if there are changes to your project that are needed. You should receive correspondence within 7-10 days. You will be sent a reminder every month for two months. After the second month, you will receive a certified letter from the IRB Office indicating that the protocol has been closed. If you wish to reopen the file, you must contact the IRB.*

*When your protocol is approved you will receive a copy of approved documents which may include the following:*

- ✍ Approval letter (2 copies)*
- ✍ Adverse event reporting form*
- ✍ Flyers or other recruitment material*
- ✍ Consent forms*

If the project is a student research project, materials will be mailed to the faculty advisor.

*You must read, sign and return one copy of the approval letter to the IRB Office. If this is not received, your project is not approved.*

#### **5.14 RIGHT TO APPEAL**

Researchers have the right to appeal the IRB's decision in writing to the IRB Office. The item will be placed on the next available agenda for full review discussion and vote. If the decision is not satisfactory the researcher can appeal to the CUNY Office of Research Conduct.

# 6 Information Regarding Potential Research Subjects

## 6.1 JUSTIFICATION OF SAMPLE SIZE

Research should seek to engage a number of subjects sufficient to answer the research question posed. Researchers should identify in the protocol and the consent form the number of anticipated subjects in the study. Sample size can be a risk to subjects.

## 6.2 WOMEN AND MINORITY POPULATIONS

The benefits and burdens of research should be distributed fairly within society and researchers should always seek racial and gender equity in the recruitment of subjects. The deliberate exclusion of women or any group of minorities must be justified in the protocol. Researchers are expected to seek subjects appropriate for the study, and not merely convenience samples.

## 6.3 VULNERABLE POPULATIONS

Certain populations are considered more vulnerable than others because of their particular conditions or situations in life. Research involving vulnerable populations requires additional protections that must be described in the protocol. *Research involving these populations must be reviewed by the full IRB board.*

## 6.4 CHILDREN IN RESEARCH

Children (anyone under 18 years of age) can participate as research subjects only if the research meets certain standards, defined in the federal regulations (Subpart D of 45 CFR 46). Specifically, the research may not be greater than minimal risk unless it provides a direct benefit to the child.

Written parental permission is required for studies involving children and, depending on the nature of the research and the availability of both parents, the IRB may require that one or both parents provide written consent. Once parental permission has been obtained, the agreement or assent of the child is required. The child's assent is documented with an assent form, a child-friendly document that outlines the essential information about the research. While the parents/guardians must provide legal consent for the child to participate in research, the child must always assent to his/her own participation; assent being an active affirmation of a desire to participate. Children who are able to read and write (usually age 6 and older) should participate in the consent process by using an assent form written in language especially for the child. (see also the

section on Assent in Chapter 6).

Federal regulations allow the IRB to approve research involving children only if special provisions are met and the research falls into one of four categories, based on the degree of risk and benefit to individual subjects. Those categories are discussed in the following sections.

Research involving no more than minimal risk.

When the IRB finds that no greater than minimal risk to children is presented, it may approve the proposal **only if** adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

If the IRB finds that more than minimal risk to children is presented by an intervention or procedure but that the intervention or procedure has the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, the IRB may approve the research only if (1) the risk is justified by the anticipated benefit to the subjects, (2) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and (3) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not have the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, the IRB may approve the research **only if** (1) the risk represents a minor increase over minimal risk, (2) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations, (3) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, **and** (4) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

If the IRB does not believe the research proposal meets any of the requirements set forth above, it may still approve the application but **only if** (1) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, **and** (2) the Secretary of the DHHS, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, or law) and following an opportunity for public review and comment, has determined either:

1. The research, in fact, satisfies one of the conditions set forth above, or
2. The research satisfies the following conditions: (a) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (b) the research will be conducted in accordance with sound ethical principles; and (c) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

The IRB must also determine how permission is to be obtained from the child's parent or legal guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient. In other types of research, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

## 6.5 PRISONERS

A prisoner is defined by federal regulations as any individual involuntarily confined or detained in a penal institution. This definition includes individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, as well as individuals being held prior to arraignment, trial or sentencing. Hunter has broadened the definition to include those on probation or parole as they also require special considerations. Research involving prisoners must have as its goal either a direct benefit to the individual subject or seek an understanding of issues and conditions specific to prisoners.

Because their autonomy is limited, prisoners may participate only in certain categories of research, and special precautions are needed to ensure that their consent to participate in the research is both knowing and voluntary (45 CFR 46.302). Prisoners may participate in the following kinds of research:

- ? Studies of the possible causes, effects, and process of incarceration and criminal behavior, if those studies present no more than minimal risk or inconvenience to the subjects.
- ? Studies of prisons as institutions, or of prisoners as incarcerated persons, if those studies present no more than minimal risk or inconvenience to the subjects.

- 2 Research on conditions affecting prisoners as a class (e.g., research on hepatitis, drug addiction, sexual assaults, and other conditions more prevalent in a prison population than elsewhere), but only after the Secretary of DHHS, has consulted with experts in medicine, ethics, and penology and published a notice approving the proposed research in the Federal Register.

Research on practices that are intended, and reasonably likely, to enhance the well-being of the subjects; however, if some of the prisoners will be assigned to control groups which will not benefit from the research, then the study must first be approved by the Secretary of DHHS, after consultation with appropriate experts, as described above.

## **6.6 PREGNANT WOMEN, FETUSES AND NEONATES**

Research on pregnant women, fetuses and neonates may not include invasive procedures unless it provides a direct benefit to the mother and only exposes the fetus to minimal risk.

If it is possible that pregnant women and their fetuses may be involved in a study, the protocol should include an assessment of the advantages and consequences of their inclusion in the study. This type of research poses special concerns for the IRB.

## **6.7 COGNITIVELY AND MENTALLY IMPAIRED INDIVIDUALS**

Cognitively or mentally impaired individuals are those who have a diminished capacity for decision-making and who may be unable to understand fully the risks of research. Research may only involve cognitively or mentally impaired individuals if it offers a direct benefit to the individual subject or to the subject's class or condition. If the subjects are not capable of giving consent for themselves, it must be obtained from their legal guardians. In that case assent from the subject must be obtained. (See also section on Assent in Chapter 6)

Federal regulations specify that cognitively or mentally impaired adults deserve special care and protection as human subjects. The category of cognitively or mentally impaired includes, but is not limited to, people suffering from mental retardation, neurological diseases and disabilities affecting judgment, mental disorders producing delusion or confusion, and/or dementia.

Researchers must take special care when assessing informed consent and voluntary participation when participants may suffer from cognitive impairments. In general, the informed consent process must address the need to preserve participant decision-making autonomy. Researchers must show that they have made every possible attempt to seek the informed consent of the participant as well as the informed consent of the participant's proxy. As a general rule, all adults regardless of their diagnosis or condition, should be presumed competent

to consent unless there is evidence of serious mental disability that would impair reasoning or judgment.

You must assure that potential participants are fully informed about the voluntary nature of their participation, and that they remain free to withdraw at any time, even when proxy consent has been obtained. It is also essential that both participants and their proxies are fully informed about the risk/benefit ratio of the study.

You must include a description of appropriate psychological or medical screening criteria.

## **6.8 STUDENTS OR EMPLOYEES AS RESEARCH SUBJECTS**

Students recruited as subjects in faculty-initiated research, clients recruited for practitioner-initiated research and employees recruited for employer-initiated have special considerations that apply for engaging them in research. Researchers should pay particular attention to the circumstances surrounding the research and whether the students/employees may feel pressured to participate in the research because of their relationship with the researcher.

Researchers recruiting students or employees in research should:

- ? Make sure that subjects know that they may choose not to participate in the research and that the decision will not affect their grade/class standing or employment.
- ? Provide students with an equal alternative to participation, which should be comparable in terms of effort, time commitment and credit given.
- ? Clients, students or staff may feel they HAVE TO or MUST participate in a study if their practitioner, teacher or supervisor asks them. It is recommended that teachers not use class time to complete interviews or questionnaires. It is also preferable, if possible, to avoid having teachers, staff or practitioners recruit their own workers, students or clients directly for their study. If asking staff/teachers to recruit subjects on the principal researcher's behalf, it is preferable for the staff/teacher not to know if their workers/students have actually participated. Here are ways to handle that:
  - ? They could provide information to the clients/students asking them to contact the researcher directly;
  - ? They could get permission from the clients/students to give client names to the principal researcher. The principal researcher, would then contact them directly;
  - ? If staff must or cannot help but know who participates, it must be stated in the recruitment script and consent form that the subject's participation is voluntary, and there will be no withdrawal of services or other penalties if they choose not to participate.

## **6.9 RESEARCH IN GROUPS**

It is important to convey to the participants in focus groups, that they should not discuss what is said in the group outside of the group.

It may be helpful to include this statement in consent forms, "To protect the privacy of the group members, please refrain from speaking to others about what is said within the group."

Be sensitive to the impact of group pressure when recruiting subjects in a group session, public meeting or class setting. To minimize, the researcher (or someone else) could distribute cards to the subject pool, asking people interested in participating to write down their contact information, and then the researcher can contact them. Collect the cards from everyone so no one in the group will be overtly aware of who volunteered. Alternatively, the researcher can distribute a recruitment flyer, which asks the subject pool, in writing, to contact the researcher.

## **6.10 ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED INDIVIDUALS**

Economically or educationally disadvantaged individuals may be particularly vulnerable to the risks of research. Economically disadvantaged subjects may be easily persuaded to participate in research if the economic compensation is so great that it would result in the subject ignoring or disregarding the research risks because of the income generated by the study. In such cases researchers should be careful to set economic compensation at a meaningful level that compensates the subject for her/his time, but not so great that it becomes coercive. It is also important in such cases that the risks to the subjects be made clear to the subjects.

Educationally disadvantaged subjects may not be able to fully understand the concepts presented by the research and the researcher should take extra precautions to ensure that the subjects fully understand what is being asked of them.

## **6.11 STUDIES INVOLVING HUMAN EMBRYONIC STEM CELLS, GERM CELLS, AND CELL-DERIVED TEST ARTICLES**

There are typically 2 types of research involving these types of cells.

- In vitro research using cell lines that are already derived and established, from which the identity of the donor cannot readily be ascertained by the researcher, requires review by the IRB.
- Research using cell lines that allow identification of a donor, including cells that retain links to coded information that would allow identification of donors, is generally considered human

subjects research and requires IRB review. Researchers may sometimes obtain a written agreement from the holder of the identifiable private information (e.g., the driver of the cell line) such that information will not be released to the researcher under any circumstances, and that the research will be conducted within the terms of the applicable Assurance by all parties engaged in the research.

All human subjects research involving the use of cells derived from human embryos or fetal tissue (1) is governed by 45 CFR 46, (2) may be subject to FDA regulations, and (3) must have IRB review and approval.

## **6.12 SUBJECT POOLS**

The only subject pool at Hunter is the pool in the Department of Psychology. The Department of Psychology requires that all students taking Psych 100 participate in ongoing psychological research. This participation involves obtaining three hours of research participant credit. A study lasting up to one hour earns one hour of credit. A study lasting more than one hour (in a single session, or in two separate sessions) earns two credits. All of the studies in which the students participate have IRB approval. All Hunter College faculty members can use the subject pool as a source of subjects, but first preference is given to Psychology faculty.

## **6.13 PAYMENTS TO SUBJECTS**

It is appropriate to offer payment to subjects as compensation for their time and involvement and to cover expenses incurred by their participation. It is not appropriate however, to offer payment that is so high that it would encourage an individual to ignore or disregard the research risks. Excessive compensation is considered to be coercive.

## **6.14 RECRUITMENT AND ADVERTISEMENTS**

The IRB must review and approve all advertisements and recruitment materials before they can be used. If they are not submitted at the time of initial IRB review and approval, they must be submitted as an amendment/ modification before recruitment is initiated.

Advertisements/flyers should contain the following information:

- ? Names of the researchers and contact information
- ? Hunter's name and researcher's affiliation
- ? Purpose of the research
- ? General eligibility criteria
- ? Accurate and honest description of benefits and/or compensation (free treatment, payment)

? A statement that it is a research study.

Advertisements should not make extravagant claims, use attention-getting techniques, nor pressure readers to participate.

### **6.15 DECEPTION IN RESEARCH**

The use of deception in research raises special problems that the IRB will review closely. One consideration is whether the deception is necessary. A researcher proposing to use deception should justify its use. Federal regulations prohibit the use of deceptive techniques that place subjects at greater than minimal risk. The IRB may modify the normal informed consent process for research involving deception when subjects are not placed at risk. However, potential participants should be advised in the consent form that the information they are given is not complete and they should also be debriefed after the research procedures are completed.

The debriefing should include a detailed description of the ways in which deception was used. The researcher is responsible for ensuring that the subject leaves the research setting with an accurate understanding of the deception. The debriefing process, including any written materials, should be explained to the IRB as a part of submitted protocols. It is also important to give the subjects information or a place to get information if they wish to explore the area being researched further.

### **6.16 GATHERING INFORMATION ABOUT INDIVIDUALS OR RESEARCH ON "SECONDARY SUBJECTS"**

Occasionally researchers will seek information about individuals who are not principals to the research. These individuals could be members of the principal subject's family, sexual partners, friends, co-workers, etc. Such individuals may be subjects in their own right, even if the researcher never has any contact with the individual. The federal regulations define a human subject, not only as someone with whom the researcher interacts, but also as someone **about whom** the researcher seeks information. Therefore, the IRB must evaluate the consent process for each group of subjects and will expect the protocol to describe an appropriate consent process for each such group. It may be possible for the researcher to ask the IRB to waive the requirement for consent, but only in rare circumstances. Only the IRB can waive or modify the consent process. Researchers are not authorized to make this decision.

### **6.17 PROCEDURES AND GUIDELINES WHEN SUBJECT POOL IS THE SAME AND SUBJECTS MAY BE PARTICIPANTS IN MULTIPLE STUDIES OF THE SAME RESEARCHER**

The Committee is concerned with the burden being placed on subjects in these types of studies. When reviewing these types of projects, the IRB will review whether there is overlapping of the same subjects and what is the rationale for the overlap. Researchers will be required to report at the one-year period, the number of subjects common to each study.

## 6.18 HIPAA

Federal regulations issued under the Health Insurance Portability and Accountability Act ("HIPAA") that deal with the privacy of health information, including mental health information went into effect on April 14, 2003.

Under the HIPAA privacy regulations, a CUNY researcher must obtain a written authorization (a "HIPAA Research Authorization" from his or her research subjects in order to use and/or disclose any individually identifiable protected health information ("PHI") of these subjects that is created or maintained by, or obtained from, a person or entity covered under HIPAA.\* Examples of entities covered under HIPAA are hospitals; physicians, and practices in psychology, psychotherapy, or social work; health insurers, HMOs, and health plans; and certain community clinics and social service and mental health agencies.

CUNY is not an entity directly covered by HIPAA. CUNY researchers, are therefore not covered under the HIPAA privacy regulations unless, in order to conduct research, they are using or disclosing patient or client information that they (a) create or receive when acting as HIPAA--covered health care providers, (b) create or receive as members of the workforce of a HIPAA-covered entity, or (c) obtain from a HIPAA-covered entity. For example, CUNY faculty or students who conduct or assist with research may also be employees or trainees in hospital or social service settings that are covered by HIPAA and may be using data obtained from those settings in research. CUNY researchers may also be collaborating with co-researchers who are covered by HIPAA.

When a study requires use or disclosure of health information from or by a covered entity or its employees or trainees, the CUNY Principal Researcher should complete this authorization form and submit it to the appropriate CUNY IRB for review prior to presenting the form to research subjects. The CUNY Principal Researcher should take care to ensure that all necessary uses and disclosures of health information are described accurately and completely in the authorization form.

This HIPAA Research Authorization form is a separate form, and does not replace, the informed consent form that CUNY researchers may be required to have participants in their human subjects research sign. Consult the CUNY Principal Investigator's Manual for an explanation of the informed consent requirements.

Questions about this form should be directed to the IRB Office or the Privacy Officer of the covered entity (e.g., hospital, physician practice, social service

agency, or managed care organization) whose protected health information will be used or disclosed for the research.

#### **6.19 EXISTING DATA STUDIES WHERE THE RESEARCHER IS ALSO AN EMPLOYEE**

Studies where the researcher is also an employee of the organization, require added safeguards as many times the employee/researcher is the individuals de-identifying the data. Researchers will need to include a Data Use Agreement. A copy is available on our website. When available, it is preferable that someone else at or in the agency de-identify the data. If that is not possible, we must also have a letter from the agency that states that there is no one else in the agency to de-identify the data.

#### **6.20 REFERRALS**

In almost all studies referrals are needed if subjects should experience any unanticipated effects (emotional distress or discomfort) as a result of participation in the research study. Referrals should be given to all subjects, even in anonymous studies. Referrals should be given at the time of consent. Referrals should be local and should incur no costs to the subjects, if possible. Where possible, referrals should include a specific contact person, not a general phone number of an agency.

# 7 The Consent Process

## 7.1 WHAT SUBJECTS NEED TO BE TOLD ABOUT THE RESEARCH

Consent is a process, not a form. All research subjects must give their consent to participate in a research study. Consent is a necessary part for all research studies. Consent is only considered valid if the subjects are given enough information to allow them to weigh the study's risks and benefits and if the information is told to them in terms that they can understand. Subjects always have the right to decline or even withdraw from any study.

The consent process is made up of two parts: 1) the discussion that takes place between the researcher and the subject and 2) a written document (either a consent form or information sheet) that captures the nature of the consent discussion. The consent process should be specific to each subject population as well as the individual subject. There may be some subjects with special considerations, such as children, prisoners, cognitively impaired individuals, economically/educationally disadvantaged individuals and others. The IRB will always look to see that the study and consent process provide additional protections for these vulnerable populations. (See the section on vulnerable subjects in Chapter 5)

## 7.2 INFORMATION SHEET VS. CONSENT FORM: DOCUMENTING THE CONSENT PROCESS

The consent discussion that takes place between a researcher and subject must be captured in a document called an informed consent form or consent form. Unless the IRB gives a researcher permission to alter the consent process, all research subjects must indicate in writing their willingness to participate by signing the consent form. However, written consent may not be necessary or appropriate in certain studies, such as surveys or in research where the subjects are to remain anonymous. In these cases, the researcher should prepare an information sheet appropriate for the study. Federal regulations identify certain specific elements required for informed consent, and, depending on the nature of the research, the IRB may require additional elements. This assures that the criteria for obtaining informed consent are met and understood by all parties involved in the study. Researchers should consult the coversheet.

## 7.3 CONSENT FORM

Researchers are encouraged to review the consent form and coversheet; however, deviations from this format are allowed in order to best suit the

individual research study. Regardless of the layout, all consent forms must adhere to the regulations and formatting detailed in the coversheet.

#### **7.4 INFORMATION SHEET**

An information sheet is similar to a consent form in every way except it is not signed by the subject. An information sheet should be used when the study seeks anonymous data and/or when the IRB has granted the study a waiver of signed consent.

#### **7.5 OTHER CONSIDERATIONS**

The following elements must be considered and applied as needed to each study:

#### **7.6 LANGUAGE LEVEL**

The consent form/information sheet must be written in language "understandable to the subject". The IRB reviews consent forms very carefully to ensure that they would be understandable to a wide audience. Key elements to consider when writing a consent form are:

- ? It should be written at no higher than an 8th grade level (similar to a popular magazine or newspaper -- language copied from a grant proposal or protocol is not appropriate).
- ? It should be written in the second person ("you are invited to participate, you will be asked to give a blood sample...")
- ? It should be written as if the author and the reader are engaged in conversation.
- ? It should not be written as dense blocks of text.

#### **7.7 VIDEO AND AUDIO TAPING**

The consent form should clearly state if the research involves the use of video or audio taping of subjects. In addition, there is a separate form for permission to audio or video tape. A sample is provided on our website. Subjects may be given an opportunity to view (or listen to) the recording after it is completed.

#### **7.8 RECORDKEEPING**

Each subject must be given a complete copy of the consent form. The researcher should also keep one copy of the consent form. Researchers are required to keep consent forms on file for 3 years following the completion of the research.

#### **7.9 ANONYMOUS AND CONFIDENTIAL DATA**

*Confidentiality* means only a limited number of people will know who participated and what the content and results of their participation were; usually, it is only the researcher and research associates, or the faculty advisor in the case of student research. *Anonymity* means that even the researcher will not know who participated. This is usually limited to self-administered questionnaires or other instruments that are completed and returned without names or other identifying characteristics.

Subjects should not be promised anonymity unless the research data is truly anonymous. Anonymity cannot be guaranteed unless there is no method by which the researcher can connect the research results with individual subjects providing the data. If there are codes or a master list that would enable the researcher to identify subjects, the research is not anonymous even though the subject names do not appear in the research data. In this case the IRB would consider the data to be confidential.

## **7.10 HOW TO ASSESS SUBJECTS' UNDERSTANDING OF THE RESEARCH**

The subjects must genuinely understand what is being asked of them if there is to be informed consent. Therefore, researchers should strive to convey information to subjects and not merely disclose it to them. Subjects should be able to say what they are consenting to. It is the researcher's responsibility, not the subject's, to ensure that he/she understands the research. Therefore, it is critical that the researcher not only answer questions, but ask them so as to further the discussion and prompt the subject to think more carefully about her/his participation in the research.

Useful questions will be open-ended; rather than asking for yes or no answers, they ask for explanations. Such answers are, therefore, more indicative of what the subject truly understands. Some examples of open-ended questions:

- ? Just so that I'm sure you understand what is expected of you here, would you please explain to me what you think we're going to ask you to do?
- ? Describe in your own words the purpose of the study.
- ? What more would you like to know?
- ? What is the possible benefit to you of being in the study? What are the possible risks?

In contrast, examples of closed-end and less useful questions are:

- ? Do you understand?
- ? Do you have any questions?
- ? Do you see that there are some risks to being in this study?

## 7.11 ASSENT

In the State of New York only individuals who are 18 years or older may legally consent to participate in research. This legal authority may be withheld from some classes of individuals with limited decision-making or cognitive ability.

Individuals who do not have the authority to consent to participate in research must still provide their assent. "Assent" is an active affirmation of a desire to participate and differs from "consent" which is recognized as being granted from an individual with the legal authority to do so. Even very young children or those with limited cognitive ability can assent and they can certainly indicate a desire not to participate, which must be honored. If the individual giving assent is able to read and write (usually age 6) then assent should be documented using an assent form; otherwise assent should be obtained through a conversation with the subject. Both the assent discussion with the subject and the assent form should be in language especially tailored for the subject class and should describe the following:

- ? Tell why the study is being conducted;
- ? Describe what will happen and for how long or how often;
- ? Say its up to the child/individual to participate and that its okay to say no;
- ? Explain if it will hurt and for how long and how often;
- ? Say what the child's/individual's other choices are;
- ? Describe any good things that might happen;
- ? Say whether there is any compensation for participating; and,
- ? Ask for questions.

The assent form should be limited to one page. Illustrations might be helpful and larger type makes it easier for some individuals to read. In studies involving older children or adolescents it may be possible for the child to read and indicate assent on the assent form. Typically their assent form would contain all elements of informed consent but would be in language appropriate for them.

## 7.12 PASSIVE CONSENT

The concept of "passive consent" is not acceptable. Passive consent is a recruitment method which is used in obtaining parental consent in studies involving children. Typically, researchers provide parents with information regarding the study, and ask that they return the letter only if they **do not** want their child participate. If the form is not returned the child **will** participate in the research. This process will not be allowed. You must obtain parental consent.

## 7.13 WHEN THE CONSENT REQUIREMENT CAN BE WAIVED (ORAL CONSENT VS. NO CONSENT)

Federal regulations allow the conditions for informed consent to be altered to either 1) waive the requirement for written consent and allow the study to

proceed on the subject's oral consent or 2) waive the requirement for consent entirely. Only the IRB can waive or modify the consent process. Researchers are not authorized to make this decision.

In order for **written consent to be waived**, the researcher must rely on oral consent from the subject. Oral consent is only allowed under conditions that would normally only require oral consent or where subject confidentiality is paramount and the subjects written record of participation would place him/her in jeopardy. Written consent can only be waived under the following conditions (45 CFR 46.117(c):

"[T]he only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

"That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context."

In studies where the subject will not sign a consent form, the researcher must give the subject an information sheet containing all the same information as a consent form would, except that it is not signed by the subject.

The IRB can **waive the requirement for consent altogether**, but only under the following specific circumstances:

- ? The research involves no greater than minimal risk to subjects;
- ? The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- ? The research would be impracticable without the waiver or alteration; and,
- ? The subjects will be informed of the study when it is over (if possible).

#### **7.14 BARRIERS TO CONSENT (LANGUAGE AND PHYSICAL)**

Researchers should prepare both English-language and translated consent forms for protocols involving non-English speaking subjects. The IRB has a team of consultants who will verify the translations after the study and the English version of the consent have been approved.

In the event that a subject has a physical limitation that could affect the consent process the researcher should provide alternate means to obtain consent and should consider asking the IRB to waive or alter some of the elements of consent.

#### **7.15 CONSENT IN FOREIGN COUNTRIES**

Field research done outside of the United States, especially in non-western societies or places where the subjects do not speak English poses some problems in obtaining written documentation of informed consent. In these situations, it is sometimes impossible, for a variety of reasons, to obtain written consent. If that is the case, the researcher must provide the IRB with a statement of the reasons why it should waive written consent, and also provide an acceptable alternative method of obtaining oral consent, which is appropriate to both the subjects and their culture.

If the subjects may be economically or educationally disadvantaged the researcher should pay particular attention to these issues and ensure that appropriate safeguards have been implemented.

### **7.16 RE-CONSENT PROCESS IN LONGITUDINAL OR MULTI-STAGE STUDIES.**

The researcher must review the subject's decision to continue participation in the research when:

- a) significant time has elapsed between obtaining initial consent
- b) new potentially relevant information has become available
- c) there has been changes in the research or the subject's condition.

Re-consent:

- a) Must be documented by the subject's signature at each stage or the researcher can review the initial consent with the subject at each stage.
- b) May be a briefer form or the original consent form.
- c) Researcher must propose a mechanism and instrument to re-consent subjects.
- d) For research studies with weekly contact no mechanism will be needed. For studies with yearly contact a mechanism is needed.
- e) Cognitive ability has to be accounted for and you must provide rationale to justify decision.

### **7.17 CERTIFICATE OF CONFIDENTIALITY**

A certificate of confidentiality protects the subject's confidentiality by protecting research records from subpoena. The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects).

Applications for federally funded research must be made to the agencies responsible for the funding. However, certificates of confidentiality are not limited to use in federally funded studies. An application must be made for

particular research projects. Once obtained a certificate of confidentiality is not transferable from one study to another. In addition, if there are major changes in the protocol, the personnel responsible for the study, the issuing agency must be notified by the submission of an amended application.

Researchers should obtain certificates of confidentiality if a study is of a sensitive nature and protection is necessary to reach the objectives of the research. OHRP finds research to be sensitive if it involves collecting any of the following types of information:

1. Information relating to sexual attitudes, preferences or practices
2. Information relating to the use of alcohol, drugs or other addictive products
3. Information pertaining to illegal conduct
4. Information that, if released, could reasonably be damaging to an individual's financial standing, employability, or reputation in the community
5. Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination
6. Information pertaining to an individual's psychological well-being or mental health
7. Genetic Information.

The following language is typical of Certificate of Confidentiality requirements. Either this, or other similar language must be present in the consent form.

*"To help protect your privacy, the researchers have obtained a Certificate of Confidentiality from the National Institutes of Health. With this certificate, the researchers cannot be forced to disclose the information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA).*

*You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself and your involvement in the research. If an insurer, employer or other person obtains your written consent to receive research information, then the researcher may not use the Certificate to withhold that information.*

*The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant of the research project under the following circumstances, the present danger of child abuse, suicide, and/or homicide."*

## 7.18 SAMPLES AND TEMPLATES

The researcher must provide copies of all consent and assent forms. If the researcher believes that written consent is not appropriate, he or she should provide the IRB with a statement of the reasons why written consent should be waived. An oral consent that includes all the elements of consent is sometimes used in obtaining oral consent from the subject. If this is the case, a copy of the script should also be provided to the IRB.

We have provided a sample on the website and a template follow. Please use and adapt as necessary.

### 7.18.1 TEMPLATE WITH BASIC ELEMENTS OF THE CONSENT FORM

Consent forms should be in the second person. Listed below are elements that should be included. The model that appears uses a block format to make it easier to read, though this format is not mandatory.

#### ***Purpose And Background***

This section should present the introduction to the study, indicating who is conducting the research, stating the aim of the study, giving a brief summary of the background or reason for the project, and explaining why the individual has been asked to participate.

This section should **not** begin with phrases similar to "You agree to participate" because the prospective subject has not yet had a chance to read the form, and could not yet make an informed decision about whether or not to participate. Rather, this section should indicate that the individual is being "asked", rather than "chosen" or "invited" to participate, because words like "chosen" or "invited" have connotations that are not necessarily those associated with being a participant in a research study.

- ? Who is the researcher? (" Sarah Brown is a faculty member at Hunter College (department or school) and is conducting a study about...")
- ? What the study is about? ("The study is about the challenges immigrant families face in the United States...".)
- ? Criterion for Participation ("You have been identified as a possible participant because...)
- ? Number of Participants  
The number of anticipated participants should be stated. This is an additional 'risk' consideration. Therefore, the total number of subjects is important to consider before beginning the study. For example, if there are only five subjects in a study, and the study is interviewing an agency where only 5 people are employed, the possibility of being identified may pose a risk to the subjects.

- ? Voluntary Participation  
Subjects must know that their participation is voluntary and that if they refuse to participate, it will not affect them in any way. This information must read as follows, "Participation in this study is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you are entitled."

### ***Procedures***

Each procedure should be discussed preferably in the sequence in which it occurs. If the study involves screening procedures, these should be mentioned first and identified as tests that will determine eligibility to participate in the study. This section should clearly state what will be done to the individual as a result of participation in the study, and, where appropriate, how this differs from standard treatment or what would happen to the individual if he/she did not participate in the study.

- ? What will the subjects be asked to do? Will it be interviews, focus groups, etc.? ("You will participate in a focus group about...")
- ? Where will it take place? ("The interview will take place in a private space at...")
- ? Expected duration of the subject's participation. How long will it take? ("The study will take 30 minutes to complete." Or "You will be asked to come for 2 sessions; each session will take one hour.")

### ***Risks and/or Discomforts***

The risks and/or possible discomforts of all study procedures should be listed and explained in this section. It is best to describe the risks of each procedure in a separate point and arrange them according to severity and the likelihood of occurrence. Where appropriate, the precautions that will be taken to avoid certain outcomes from occurring should be indicated and what will be done should they occur.

- ? It is important to consider the emotional impact of the research on the people who are your research subjects, even if the study is of a seemingly impersonal subject matter. PLEASE NOTE: There is always the possibility of harm to the subjects, even if remote and minor. Examples of types of risks to subjects are: Physical – risk of heart attack if project involves subjects working out on a treadmill; Psychological – survey questions remind subjects of traumatic or emotional events; Social – disclosure of individual responses could lead to a loss of community standing; Legal – survey questions may be self-incriminating; Economic – disclosure of individual responses

could result in loss of employment.

- ? If you are asking about a more sensitive subject area or the clients are potentially vulnerable, you must identify the possible impacts of such sensitive subject matters. Include phrases such as "The study may raise painful or difficult issues. In the event that the study raises some difficult/painful feelings (insert appropriate words) for you... You can stop or not answer a particular question. You may also stop the interview/process at any time."
- ? Indicate what the subject should do if he/she is bothered or upset as a result of participation (e.g., "In the event that the study raises some concerns during your participation or afterwards, you can consult... [Name, title of person at agency, at (phone number)]" or "The researcher will provide you with a list of resources to assist you, should you need them." You must attach a referral list.

### ***Benefits***

Any potential direct benefits to the subject should be described. In behavioral research there typically are no direct benefits. An example of a benefits statement would be, "There are no direct benefits. However, participating in the study may increase your knowledge of...)

### ***Alternatives***

This section should discuss any alternatives to participation in the study. If the study involves only normal, healthy volunteers, and thus the only alternative is to decline participation in the study, this need not be mentioned in a separate section because the individual's right to choose not to participate will be made clear in the last section of the form.

### ***Financial Considerations***

When referring to money that subjects will receive in return for participation in a study, the words, "reimbursement" or "payment" may be used. However, the term "compensation" should not be used because it is used on consent forms to designate compensation for injury. Researchers should avoid connotations of undue influence to participate or that the subject is being employed by the researcher. Rather, the sense should be that subjects will be reimbursed for their time, travel expenses, and the inconvenience of being a research subject.

This section should state the total dollar amount that the subject will be paid for participation in the study, and should give any other relevant information such as

pro-rating if a subject does not complete the study. If appropriate, a payment schedule should be included in this section. Subjects should not be required to complete the entire study in order to be reimbursed.

Subjects should be informed how payment will be made (e.g., in cash, by check) and when they will be paid (e.g., immediately after the interview, approximately six weeks after individual completion of the study or one-third upon completion of the first of three phases of the study). It is important that this information be clear and complete. If there will be no payment or reimbursement to subjects for study participation, this information should be stated in this section.

### ***Privacy and Confidentiality***

Indicate how much confidentiality there will be and how it will be maintained. Indicate:

- ? What the results will be used for? ("The study is part of a research project for...")
- ? Tell subjects how the data will be collected – e.g., "The researcher will tape record the interview with your permission. No one but the researcher (and her/his research professor) will listen to the tape. The tapes/the interviews will use identifying codes. Your name will not appear on the transcripts. Tapes will be destroyed after interviews are transcribed."
- ? Explain how the data will be handled and stored. - This information must read as follows, "No personal identifiers will/can be linked to the data. All materials will be kept in a locked file cabinet in the researcher's locked office to which only the researcher (and [list any others who have access]) has access. "The data will be stored for three years. After that, all materials may be destroyed. As long as the data exists it will be kept secured."
- ? Tell subjects what will happen to the data that is collected - "The information will be used to produce a paper for a graduate research project," or "The researcher will be providing some general information about the results of this study to the agency. Indicate if anyone will know if they have participated in this study, and if so, who will know.
- ? You should briefly describe how the confidentiality of private information will be protected, i.e., coding of records, limiting access to the study records, not using any individual identifiers in publications or reports resulting from the study. " All identifying information about you and others who participated will be omitted or disguised," or alternatively, "Only aggregate data will be reported in any reports or publications derived

from this research."

- ? Limits to confidentiality - The following language is necessary in almost all instances regardless of subject matter. "The researcher is mandated to report to the proper authorities suspected child abuse, and any indications that you are in imminent danger of harming yourself or others." In some situations you may want to explain how you will handle this issue. "If the researcher becomes concerned that you are a danger to yourself or others, s/he will alert (counselor, agency director/police, etc.)"

Note: The one way to protect research records from subpoena is through a Federal Certificate of Confidentiality. See Chapter 7 for more information.

### ***Withdrawal***

These two statements must appear in the consent form:

- ? "You may discontinue participation at any time without penalty or loss of benefits or services to which you are entitled."
- ? "You do not have to answer any question that makes you uncomfortable."

### ***Contact Information***

The contact information should read as follows:

"If you have questions about the study, you can contact the researcher, (name of researcher at (xxx) xxx-xxxx or his/her faculty advisor (name of faculty advisor) at (xxx)xxx-xxxx. You should contact the Hunter College IRB Office at (212) 650-3053, if you have questions regarding your rights as a subject or if you feel you have experienced a research-related injury."

Or alternately

"If you have questions about the study, you can contact the researcher, (name of researcher at (xxx) xxx-xxxx or his/her faculty advisor (name of faculty advisor) at (xxx)xxx-xxxx. "You should contact the Hunter College IRB Office at (212) 650-3053, if you have questions regarding your rights as a subject or if you feel you have been harmed as a result of your participation in this research."

### ***Signatures***

- ? For a waiver of signed consent  
(i.e., use of an Information Sheet rather than a consent form)

The last paragraph should read:

*"The information you provide is anonymous. No one will know how you responded to these questions. Please do not put your name or other identifying information on the questionnaire to assure anonymity. By completing and returning the instrument you are*

giving consent "

? For a signed consent form

1. The last paragraph should read:  
*"I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form for my records and future reference."* (Note: this statement should be in the first person.)
2. This should be followed lines for the subject's printed name, his or her signature and the date of signature.
3. This should be followed with the signature of person obtaining consent. This provides subjects with a record of who explained the study to them. This should include the printed name of the specific individual obtaining consent, his or her signature and the date of signature.

## 7.19 GENERAL INFORMATION

Delays in IRB approval commonly result from the submission of an inadequate consent form. The following guidelines are meant to assist you with the basic format of your consent form.

- ? **Eighth-grade reading level**—The primary goal of a consent form is to provide all required information about a study in language and format that is easily comprehensible, and presented at the most likely level of understanding of the subject population. For most studies, the consent form should be written at an eighth-grade reading level. Everyday vocabulary and simple sentence structure should be used throughout the form.
- ? **Lay language**—Unless the subjects are themselves medical professionals, scientific or technical terms should either be replaced with or defined in lay language. For example, "Retrospective Study" to " study looking back over past experience" and "Assess" to "to learn about"
- ? **Non-legalistic language**—Legalistic sounding language such as "You hereby agree," "You certify that," "You, the undersigned, do acknowledge that," should not be used. Also, any phrases similar to the following should not be used: "You understand that," "You realize that," "You have been told that," "It has been explained to me that." Not only do these phrases not ensure a subject's comprehension but they lend the appearance of a legal document to the consent form.

- ? **Consistent use of person**—The person in which the form is written should be used consistently throughout. The IRB recommends that the form be written in the second person of the subject, that is, "You have been asked to participate in a research study."
- ? **Correct spelling and grammar**—The entire form should be carefully proofread for correct spelling and grammar before it is submitted to the IRB for review.

# 8 The Basic Application Packet

Most IRB applications for human subjects consist of six core documents: (1) IRB Protocol Application Coversheet, (2) IRB Application Form, (3) Consent/Assent forms, in some instances, (4) Key Personnel Form, (5) Evidence of completing of the requirement for education on the protection of human subjects and (6) a letter of support from the cooperating agency. These forms are available at <http://www.hunter.cuny.edu/research/IRB.htm> or from the IRB Office. Other documents may be required as part of the submission depending on the type of research. Please consult the IRB Office if you are unsure.

All researchers should carefully review the following requirements for submission of applications to the IRB. Submission of incomplete application packets will result in the delay of the review and approval process. The review process will not be initiated if the proposal is incomplete and/or does not fulfill the IRB's requirements.

The IRB Office is available to answer any questions researchers may have regarding the participation of human subjects in research or the review of applications by the IRB. To contact the IRB Office please use the following information:

Hunter College of CUNY  
IRB Office  
695 Park Avenue, Room E1426  
New York, NY 10021  
Phone: 212 650-3053  
Fax: 212 650-3055  
Email: [irb@hunter.cuny.edu](mailto:irb@hunter.cuny.edu)

## 8.1 IRB PROTOCOL COVERSHEET

The IRB Protocol Coversheet is a form that provides the IRB with basic information about the principal researcher and the proposal. The information provided on this form will facilitate an effective review by the IRB. This form is also a tool that is useful to researchers as it provides clarification and helpful tips on completing an IRB application.

## 8.2 IRB APPLICATION FORM

The IRB Application form is an official account of the intended research methods and procedures, with special attention paid to how benefit is maximized and risk minimized and autonomy respected. This protocol application clarifies what is to be done, how, and why. This application must reflect what is actually done in

the research. Once the IRB has approved a protocol for a particular project, the researcher is bound to follow these procedures. The protocol is a control document—an official statement that specifies how the study is being conducted. It is a document that all researchers associated with the project are expected to read and follow. The protocol becomes a vital part of an official "paper trail" showing that the research is acceptable to a legally constituted IRB of reviewers. Should anyone raise questions about the research, the approved protocol is powerful evidence that the project is of sufficient value to justify any risks or inconveniences involved. If the researcher decides to change the protocol, they must submit an IRB Request for Addendum/Modification for Approved Protocol form. This must be approved by the IRB prior to initiating the change.

### **8.3 REQUIREMENT FOR EDUCATION ON THE PROTECTION OF HUMAN SUBJECTS**

There are two options available to CUNY key personnel in research involving human subjects which will enable them to meet this mandated requirement for education:

- ? successful completion of the CITI training . The CITI training may be accessed at [www.citiprogram.org](http://www.citiprogram.org) .

*OR*

- ? completion of an on-campus course conducted by IRB administrative staff or faculty. (The course must be approved by RFCUNY's Office of Research Conduct.)

Researchers need to have the education requirement fulfilled at the time of submission of their application to the IRB. However, other key personnel working on the research project should have completed an education program with documentation before the beginning of the research project.

### **8.4 KEY PERSONNEL FORM**

The key personnel form is a form that should list all key personnel. Key personnel are defined as any individual who will be involved in the design and conduct of human subjects research project. For further information on how to satisfy the training requirement, please review the section on Requirement for Education on the Protection of Human Subjects in Chapter 4. As personnel are added or changed a new form must be completed and submitted to the IRB Office.

### **8.5 CONSENT FORM**

Consent forms are used to obtain participants' consent to participate in a research study. A sample Consent Form is available <http://www.hunter.cuny.edu/research/irb.htm>. Once approved, the Consent Form will be stamped with the protocol number, the approval effective date and expiration date. All subjects participating in the research must read, sign, and be given a signed copy of the approved and stamped consent form prior to participating in the research activity.

If the protocol involves a collaboration with another institution and subject contact occurs at that institution, the Hunter IRB may accept the collaborating institution's Consent Form in lieu of a Hunter Consent Form.

## **8.6 OTHER IRB APPROVAL/LETTER OF SUPPORT**

The Committee must have a letter from the cooperating institution. This letter is needed if this is a collaborative research effort, or if recruitment will take place at another institution. There are two types of letters:

### *If the other site has an IRB:*

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 research sites for Hunter investigators, and rarely have their own 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 Department of Education has an established IRB and all approval letters must come from that IRB.

## **8.7 GUIDELINES FOR DEVELOPING A BASIC PROTOCOL**

A research protocol is essential to planning ethically responsible research and to working with the Hunter IRB. In developing a human subjects research protocol, researchers should contemplate systematically (in writing) the research rationale, methods, and procedures, and the steps that will be taken in response to ethical considerations. The Hunter IRB encourages researchers to view the protocol as a planning tool, not simply a bureaucratic hurdle. Researchers are encouraged to think through the ethical considerations along with the methodological ones. Treating ethical considerations as an afterthought in the protocol development process can unfortunately lead to a research plan that is not workable or approvable from the IRB's perspective. Keeping that in mind, researchers are encouraged to consider the following guidelines when developing a protocol.

## **8.8 DETAILED DESCRIPTION OF THE PROTOCOL**

A detailed description of the protocol will include a discussion of the following points.

### **8.8.1.1 State the purpose of the research. Include major hypothesis and research design.**

- ? The title and sponsor of the study, if any
- ? The purpose of the research and the hypotheses to be tested. What is the focus of your study? What is the study about?
- ? The historical background of the research, referencing scientific literature.
- ? How do you intend to use the results of the study?
- ? Why are you conducting this study?
- ? Who are you and what is your affiliation to the agency?
- ? The duration of the project and how this window of time coincides with other time constraints, such as the duration of funding, etc.

### **8.8.1.2 Describe the source of subjects and the selection criteria.**

- ? Who are the subjects for the study? Explain why a particular population is being used.
- ? Why has the person been asked to participate in the study?
- ? How many people do you anticipate will be study subjects?
- ? How are you selecting them?
- ? How will you recruit them?
- ? What will they be told?
- ? The location of the research—specify the exact community, institution, etc., where various components of the research are to be performed, the reason why that setting was chosen, and how the researcher happens to have access to it.
- ? If you are in a teacher-student, practitioner-patient, supervisor-staff member or any similar type of relationship, please be sure to address how you will address the possibility that these relationships may make someone feel they must participate.

- ? If your research is in a group setting, please be sure to address the dynamics of the group.

In addition to the above information, researchers will also need to give careful thought and attention to their recruitment procedures. That information must also be presented to the IRB and detailed in the research protocol.

Further information and guidelines regarding recruitment and selection of subjects is discussed below.

#### **8.8.1.2.1 Recruitment of subjects**

Respect for potential subjects begins with recruitment procedures that ensure the voluntary participation of the subject. Recruitment is the dialogue that takes place between a researcher and a potential subject prior to the initiation of the consent process. In many cases, it is the introduction to the consent process.

Various recruitment tools can be used to inform potential subjects of a research activity and provide them with an opportunity to contact the researcher. Recruitment tools may include recruitment scripts, postcards, flyers, advertisements, press releases, brochures, verbal exchanges, and postings on the Internet. The IRB must review and approve any recruitment tool. Copies of all recruitment materials should be included with the initial application. If the material is not ready at the time of initial application, researchers may submit the material as an amendment to an already approved project. In all cases, recruitment tools must be approved prior to their use. The content of advertisements should be limited to the following information:

- ? The name of the researcher and contact information.
- ? A simple and concise description of the purpose of the research.
- ? General eligibility criteria for participation.
- ? A truthful description of the possible benefits which may result from participation in the research. If there are no benefits, please indicate whether subjects are paid for their participation or receive free treatment.
- ? A statement that it is a research study.

A recruitment script is a briefing and introduction to the study. A recruitment script is needed for in-person contact, telephone contact or written contact. A recruitment script contains much of the same information that is included in a consent form.

- ? For written contact (e-mail, letters, etc.) the recruitment script should be in the form of a letter. Researchers may choose to combine the consent form and recruitment letter, especially if it is an anonymous study.

- ? For in-person contact, a recruitment script should be a conversation which the researcher will use with potential subjects to introduce the study.
- ? For telephone contact, a recruitment script should be a conversation that the researcher will use with potential subjects to introduce the study. Researcher should establish that the subject fits the group or class of subjects you are seeking, i.e., "*Are you/I assume you are....*"

#### **8.8.1.2.2 Selection of subjects**

The IRB will closely examine research that selects subjects solely due to their easy availability, subordinate position, or those from vulnerable groups (e.g., children, prisoners, cognitively or mentally ill, etc.).

The IRB will seek assurance that potential subjects are not coerced into participating in the research, nor must they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate. A person in authority, such as a supervisor recruiting coworkers, must take special precautions to ensure that a potential subject's decision to participate in research is not based on subtle pressures such as fear of a poor appraisal or loss of job. Researchers proposing to recruit and select subordinates, students, or other coworkers as research subjects must justify the necessity for the inclusion of these individuals in the protocol.

#### **8.8.2 Provide a description of the procedures to be followed**

- ? Provide a detailed description of what the subjects will experience.
- ? Describe the setting where the research will take place.
- ? Is this standard practice? Is this part of your everyday activities?
- ? If this is a study of existing data, explain how you have rights to access the data.

#### **8.8.3 Describe any potential harms and benefits to be derived by subjects with a discussion of the risk/benefit ratio.**

Generally, there are no direct benefits for subjects in behavioral research. There is always the possibility of harm to subjects, even if remote and minor. Risks may include discomfort, embarrassment about revealing person information, etc. The research protocol must include a discussion of both the possible benefits and risks of the research. Payment for participation in research is not considered a benefit.

Some research proposals involve the handling of sensitive information that may result in injury to subjects through a breach of confidentiality. These breaches may result in embarrassment within a subject's business or social group, loss of

employment, or criminal prosecution. The IRB is especially concerned about information regarding drug and alcohol use, mental illness, sexual behavior, and illegal activities. For these situations, researchers must clearly detail strong safety precautions to ensure that the research does not cause social or economic risks to the subjects. Researchers might consider using Certificates of Confidentiality if the research would result in injury to subjects through a breach of confidentiality.

#### **8.8.4 Describe the specific methods by which confidentiality and anonymity will be protected.**

- ? Who has access to the data?
- ? What will happen to the data once the study has been completed?
- ? Make sure you are using the terms anonymity and confidentiality properly.
- ? Explain how you intend to keep information confidential. Identify if you can link a subject to the data.
- ? How will the data be stored? You must state that data will be kept in a locked cabinet in locked offices (specify the location) for a specified period of time. It must be stored for at least three years.
- ? It may be necessary to say that all individuals will be disguised in any written reports, particularly if the subject pool is very small.
- ? You must address the limits to confidentiality: In face-to-face interviews, you must state that if you become "concerned that you are a danger to yourself or others, s/he will alert the proper authorities." In research that involves parents and children, you are mandated to report any concerns about child abuse or neglect to the proper authorities.

Privacy refers to a person's interest in controlling another's access to data about him/herself. Confidentiality is an extension of the concept of privacy; it refers to data (some record about the person, such as notes or a videotape of the person) and to how data are to be handled in keeping with the subject's interest in controlling the access of others to information about him/herself. Ideally, confidentiality is handled in an informed consent agreement between researcher and subject; the agreement states what may be done with private information that the subject conveys to the researcher. The terms of the confidentiality agreement need to be tailored to the particular situation.

Researchers are required to maintain and protect the privacy and the confidentiality of all personally identifiable information of all human subjects participating in research, except as may be required by law or released with the written permission of the subject. Subjects have the right to be protected against invasion of their privacy, and to expect that their personal dignity will be maintained and the confidentiality of their private information will be preserved. The more sensitive the research material, the greater the care required in obtaining, handling, and storing data.

Information through which subjects may be identified include their names, employee numbers, hospital ID numbers, social security numbers, driver's license numbers, home addresses, photographs, videotapes, and the like. Individuals also may be identified by description, for example, as the personnel manager in a particular company, the sixth grade teacher in a certain school, or the pediatric nurse at a local hospital. If information or data to be collected may be traced back to individual subjects, safeguards should be provided to ensure confidentiality.

**Confidentiality vs. Anonymity:** Confidentiality means only a limited number of people will know who participated and what the content and results of their participation were; usually, it is only the researcher and research associates, or the faculty advisor in the case of student research. Anonymity means that even the researcher will not know who participated. This is usually limited to self-administered questionnaires or other instruments that are completed and returned without names or other identifying characteristics.

If a questionnaire is anonymous, state, "The information you provide is anonymous. No one will know how you responded to these questions. Please do not put your name or other identifying information on the questionnaire to assure anonymity. By completing and returning the instrument you are giving consent."

Researchers will be asked by the IRB to describe how the data and links to subjects will be stored and maintained. They should also consider whether or not they will (1) provide information about subjects to others not involved in the research and (2) provide information they have learned about the subjects to the subject. Finally, researchers should consider to what extent a breach of confidentiality or invasion of privacy would constitute harm. If harm is a possibility, researchers must provide adequate provisions to protect participants from those harms and inform subjects of the possible harm.

#### **8.8.4.1 Guidelines for protecting confidentiality**

- Limit recording of personal information to that which is essential to the research.
- Store personally identifiable data securely and limit access to the principal researcher and authorized staff.
- Code data as early in the research as possible, and when appropriate, develop a plan for the ultimate disposition or destruction of the code linking the data to individual subjects.
- Apply for federal Certificates of Confidentiality in all situations for which certificates are reasonable and available. (Contact the IRB Office for further information.)

- Do not disclose personally identifiable data to anyone other than the research team without the written consent of the subjects or their legal representative. (Exceptions may be made in case of emergency need for intervention or as required by regulatory agencies).

### **8.8.5 You Must Attach Any Other Information That May be Pertinent to the IRB Decision**

- ? If you are conducting or recruiting subjects from an agency, you must obtain permission to do so. Some agencies have their own IRB which you must obtain approval. (See section on Other IRB Approval/Letter of Support.)
- ? You must attach all tools and instruments that you will use.
- ? If you are studying existing data, provide the Committee with a sample of what the data will look like and a copy of the tool that you will use to extract the data.
- ? In studies involving existing data you must provide the Committee with details about the data. Is the data de-identified? Who does the de-identification? Do HIPAA rules apply? Refer the Hunter IRB coversheet for guidance on HIPAA matters. (See section on HIPAA in Chapter 5.)

### **8.8.6 Financial Considerations for Subjects**

If subjects are to be paid for their participation in the research activity, the researcher should provide information regarding the total dollar amount that subjects will be paid for participation in the study, and should give any other relevant information such as prorating the payment if a subject does not complete the study, or a bonus payment at the end of the study. Subjects should not be required to complete the entire study before receiving any reimbursement. Bonus payments for study completion should be modest. If it is a complex payment schedule, please provide a chart.

### **8.8.7 Deception in Research**

The use of deception in research raises special problems that the IRB will review closely. One consideration is whether the deception is necessary. A researcher proposing to use deception should justify its use. Federal regulations prohibit the use of deceptive techniques that place subjects at greater than minimal risk. The IRB may modify the normal informed consent process for research involving deception when subjects are not placed at risk. However, potential participants should be advised in the consent form that the information they are given is not complete and they should also be debriefed after the research procedures are completed.

The debriefing should include a detailed description of the ways in which deception was used. The researcher is responsible for ensuring that the subject leaves the research setting with an accurate understanding of the deception. The debriefing process, including any written materials, should be explained to

the IRB as a part of submitted protocol. It is also important to give the subjects information or a place to get information if they wish to explore the area being researched further.

#### **8.8.8 Obtaining Informed Consent**

Informed consent is an ongoing process that starts with the initial presentation of a research activity to a prospective subject by the researcher and continues through the research activity until the subject ends his/her participation or the study closes.

Prospective subjects are rarely aware of research activities prior to an initial presentation by the principal researcher, or a member of the study team, and many subjects make their decision regarding whether to participate in the research at this point. As a result, it is critical that the initial presentation provide subjects with a clear understanding of the research, its procedures, and risks and benefits. Researchers are encouraged to provide sufficient time for a potential subject to reflect on the nature of participation during this important initial presentation of the research activity. Providing a potential subject with understandable information in the initial session will improve comprehension and enhance the potential for a more informed consent by the subject when agreeing to participate in the research.

The consent process does not end with the signing of a consent form. Research is an ongoing process that involves the constant reevaluation of current information and procedures. It is important that researchers apprise subjects of new research information that may have an impact on the subject's willingness to continue participation in the study. Researchers should note, however, that the IRB must review and approve communications with subjects relating to their participation in the study prior to communicating that information to the subject. Please refer to Chapter 6 on consent.

# 9 Ongoing Responsibilities after Initial Protocol Approval

After a protocol has been approved by the IRB, the researcher has several ongoing reporting responsibilities to the IRB. Those responsibilities are listed below.

## 9.1 REPORTING ADVERSE EVENTS

Anticipated adverse events (serious or not) should be reported to the IRB within 48 hours. Researchers should complete the Adverse Event Report Form, which was sent with your approval letter. All adverse events will be brought to the full IRB for review and possible intervention. Even events that occurred at another institution must be reported to the IRB using the Adverse Event Report Form.

## 9.2 INJURIES, ILLNESSES, OR OTHER UNANTICIPATED COMPLICATIONS POSSIBLY RESULTING FROM THE RESEARCH

Any potentially serious, unanticipated complications affecting a subject require immediate reaction by the researcher to help mitigate the harm suffered and prevent further harm. In addition, researchers are responsible for reporting to the IRB Office any injuries, illnesses, or other unanticipated complications possibly related to the research. This reporting must take place within 48 hours of the occurrence.

## 9.3 UNANTICIPATED PROBLEMS OR NONCOMPLIANCE WITH THE REQUIREMENTS OF THE PROTOCOL

Researchers are responsible for reporting to the IRB Office any unanticipated problems or noncompliance with the requirements of the approved protocol within 48 hours. The IRB will discuss these matters at a meeting of the full IRB.

## 9.4 MAKING MODIFICATIONS TO CURRENTLY APPROVED RESEARCH

All modifications to currently approved research must have IRB review and approval prior to implementation. Researchers should submit an "IRB Request for Addendum/Modification for Approved Protocol" form. Researchers should highlight or use bold font to indicate where changes or additions have occurred on the revised documents.

## 9.5 MINOR MODIFICATIONS TO CURRENTLY APPROVED RESEARCH

A minor modification is defined as a change that (1) would not materially affect an assessment of the risks and benefits of the study or (2) does not substantially change the specific aims or design of the study. Minor changes that do not increase the risk to research subjects may receive an expedited review.

Examples of minor modifications include:

- ? An increase or decrease in proposed human research subject enrollment,
- ? Changes to improve the clarity of statements or to correct typographical errors, provided that such changes do not alter the content or intent of the statement,
- ? A change in principal researcher or the addition or deletion of qualified researchers.

## **9.6 MAJOR MODIFICATIONS TO CURRENTLY APPROVED RESEARCH**

A major modification is defined as a change that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Major modifications to approved protocols that may increase the risk to subjects require a full IRB review.

## **9.7 APPROVAL PERIOD FOR MODIFICATIONS**

The IRB may only approve modifications submitted during a current approval year to the end of that period. For example, if the new or annual review takes place on December 31, 2005, the protocol will have an expiration date of December 30, 2006. If a modification is approved during this time, the expiration date still remains December 30, 2006. All modifications, amendments, and, when applicable, informed consent forms should be incorporated into the renewal application for IRB consideration during the annual review.

## **9.8 CONTINUING REVIEW AFTER INITIAL APPLICATION APPROVAL**

The IRB must conduct continuing review of protocols at intervals appropriate to the degree of risk, but not less than once per year. It is the researcher's responsibility to ensure that the protocol is reviewed on or before expiration of the current approval period, even if the research activity did not begin until some time after the IRB gave its initial approval. As a courtesy, researchers will be notified by the IRB Office six to eight (6–8) weeks prior to expiration of their IRB approval. An application for continuing review must be received by the IRB Office in time for review and approval in advance of the expiration date (4–5 weeks recommended). Please be advised that approved protocols are given one approval and two continuing reviews. After that time, a new protocol must be submitted.

Continuing review and approval is also necessary if recruitment of subjects stops but previously enrolled subjects continue to participate in the research or the study is in data analysis at Hunter.

Researchers are to append to this document the IRB application which incorporates all of the addenda and modifications submitted to and approved by the IRB during the previous approval period, letter(s) of support from cooperating institution and consent documents. To the extent they are relevant to research risks only, the researcher is asked to summarize their research findings thus far, any recent literature in the field, any amendments or modifications to the research since the last review and/or any other relevant information, including findings at collaborating institutions

Questions that are asked in the renewal application are:

- ? How many subjects have you enrolled in the study since your last review?
- ? What is the total number of subjects enrolled in the study since its inception?
- ? How many subjects have signed consent forms?
- ? How many amendments/modifications were approved in the past year?
- ? Have there been any adverse events or unanticipated problems involving risks to subjects or others since the last review?
- ? Have there been any voluntary or involuntary withdrawals of subjects from research or any complaints about the research?
- ? Do you advertise the study? If yes, please provide flyers or other recruitment materials
- ? Is a change in researchers or procedures anticipated?
- ? Have you had problems meeting your target number of subjects?
- ? Has your opinion of the study's risks and benefits changed since this study was last reviewed?
- ? Has anything occurred in the last year to change your opinion of the risk/benefit ratio? (i.e., literature, your results to date, summary of pertinent findings, etc.)
- ? Has anything occurred in the last year to revise the protocol or consent form in any way?

Consent forms and other supporting documentation must also be reviewed by the IRB each time the protocol is updated. If the research activity involves a collaborating institution, a copy of the other institution's current IRB approval letter is also required.

**Note:** *There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted. If the IRB does not re-approve the research by the specified expiration date,*

*subject accrual and research activities must be suspended pending re-approval of the research by the IRB.*

Enrollment of new subjects cannot occur after the expiration of IRB approval. If the researcher is actively pursuing renewal with the IRB and the IRB finds that it may be in the best interests of already-enrolled subjects' safety to continue with study treatments and procedures, the IRB may allow continuation of treatment for already-enrolled subjects during the time required to complete the review process.

## **9.9 TERMINATION FOR FAILURE TO OBTAIN CONTINUING APPROVAL**

The IRB has the authority to terminate or suspend approval of research that is not being conducted in accordance with regulatory and Hunter requirements regarding continuing review. When study approval is terminated by the IRB due to lack of compliance with continuing review requirements, in addition to stopping all research activities, any subjects currently participating should be notified that the study has been terminated.

## **9.10 MAINTENANCE AND RETENTION OF RECORDS AND CONSENT FORMS**

During the study, all documents, electronic files, videotapes, etc., which contain the subject's personal identifiers, must be kept in locked storage with access restricted to the researcher and/or designee(s). Access restrictions must continue even after the study is completed.

At a minimum, researchers must maintain research records for at least three (3) years after completion of the research. All records must be accessible for inspection by authorized representatives of the IRB, OHRP, the federal department or agency supporting the research, and sponsor, if any. Beyond three (3) years, requirements for record retention vary with the type of research conducted, the provisions of the researcher's funding source, and Hunter requirements. It is the researcher's responsibility to understand clearly the retention requirements of Hunter and/or their sponsor.

## **9.11 COMPLETION/TERMINATION OF STUDY**

To formally complete a study file, the IRB requests that researchers officially notify the IRB Office when a study is terminated or completed or after data analysis is complete. As part of the close-out process when the study is up for renewal, researchers are asked to complete a section of the IRB request for renewal form.

# 10 Classroom Practica

Research as defined in the 45 CFR 46 and conducted by graduate and undergraduate students at Hunter is subject to federal regulations which require that all research protocols involving human subjects be reviewed by an Institutional Review IRB for the protection of Human Subjects in Research (IRB). However, these regulations allow certain types of course-related studies to be exempted from IRB review.

Research practica (usually in the form of course-related research projects and/or directed studies) are designed to provide to students an opportunity to practice various research methods such as interview, observation and survey techniques, measurement of behavior (e.g., reaction time, speech, problem solving) as well as data analysis. Typically such projects are quite limited in scope, do not lead to generalizable knowledge and are not undertaken with that goal in mind. For example, a student may interview a peer when the interview does not involve any sensitive, personal information.

Such projects should not put the subjects at more than minimal risk, and the data must be recorded anonymously by the students (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names). These projects are considered "classroom exercises" and are not subject to review by the IRB. They do not require review unless the student researcher anticipates publishing the results or presenting at a professional meeting, or unless the faculty expects to compile all students' results with the intention of publishing or presenting.

Students engaged in the process of learning research techniques understandably want to focus on compelling or real-life issues. In the process of reviewing student research, however, the IRB has found topics and subjects that raise concerns for the well-being of the subjects and students themselves. Projects involving collection of data about illegal activities, or which could cause emotional distress in the subjects, or which would place the students at risk if confidentiality were breached, and those with children as subjects need to be constructed with special care.

*Projects that meet these criteria must complete an IRB Classroom Practica form*

The IRB is available for consultation with students and for class presentation regarding issues of the protection of the rights and welfare of human subjects. It is important to note that data collected as practica cannot at a later date be used for presentation at conferences, publications, or doctoral dissertations.

Any research conducted by students, graduate or undergraduate, that does not fall under the definition of a research practicum, which uses human beings as subjects, and which is intended to contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes, but is not limited to, all independent undergraduate research projects and honors theses, master's theses and dissertations.

Recognizing the time constraints imposed on projects that must be begun and completed within a single semester, the IRB will make every effort to work with instructors to process proposals promptly. However, instructors must plan for and allow adequate time for the review process to occur (approximately a week to a month, depending on the particular human subjects issues raised by the proposed research). The later in the term a protocol is received, the more difficult it will be to accomplish the review in time for the projects to be completed during the current semester. It is very strongly urged that instructors submit proposals within the first three weeks of the semester for projects that must be completed during the current semester. For larger more sophisticated projects, especially for graduate students in year-long research thesis courses, it is recommended that protocols be submitted in time for review before the end of the first semester. In some cases, when students in a course are all using similar methods of recruitment and data collection, instructors may submit an aggregate proposal.

## **10.1 RESPONSIBILITY OF STUDENT ADVISORS FOR ALL STUDENT RESEARCH PROJECTS**

- ? Faculty advisors of both undergraduate and graduate students and faculty members teaching courses involving a research thesis or other project that will require their students to have an IRB review must be certified to conduct research with human subjects, even if they are not currently conducting research with human subjects. Please refer to the section on Requirement for Education on the Protection of Human Subjects.
- ? It is the responsibility of faculty advisors to determine when an undergraduate or graduate student project does not meet the definition of a practicum and must be reviewed by the IRB. However, the advisor must be certified as noted in the previous bullet to be authorized to make this decision.
- ? It is the responsibility of faculty advisors to ensure that research practica and exempt research activities are conducted according to the ethical standards of the relevant discipline.
- ? When student research activities are not practica, it is the responsibility of faculty advisors to assist students in preparing review materials for the IRB

and to ensure that the research is conducted in accordance with CUNY's agreement with the federal government (the FWA) and with applicable CUNY policy.

- ? Maintain adequate records for renewal or close out of processes.

# 11 Forms

## 11.1 IRB APPLICATION FORM

This form is required. The IRB Application form is an official account of the intended research methods and procedures, with special attention paid to how benefit is maximized and risk minimized and autonomy respected. This protocol application clarifies what is to be done, how, and why. This application must reflect what is actually done in the research. Please refer to chapter 8 for more details.

## 11.2 IRB PROTOCOL COVERSHEET

This form is required. The IRB Protocol Coversheet is a form that provides the IRB with basic information about the principal researcher and the proposal. The information provided on this form will facilitate an effective review by the IRB. This form is also a tool that is useful to researchers as it provides clarification and helpful tips on completing an IRB application.

## 11.3 IRB KEY PERSONNEL FORM

This form is a required. The key personnel form is a form that should list all key personnel. Key personnel are defined as any individual who will be involved in the design and conduct of human subjects research project. For further information on how to satisfy the training requirement, please review the section on Requirement for Education on the Protection of Human Subjects in Chapter 4. As personnel are added or changed a new form must be completed and submitted to the IRB Office.

## 11.4 IRB AUDIO AND VIDEO RELEASE CONSENT FORM

This form is to be used to obtain participant consent to be audio or video taped in conjunction with a research study. This form should be used with a consent form.

## 11.5 IRB CLASSROOM PRACTICA FORM

This form should be used by a faculty member to engage in research practica. This is usually in the form of course-related research projects and/or directed

studies and are designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques, measurement of behavior (e.g., reaction time, speech, problem solving) as well as data analysis.

#### **11.6 IRB CLASSROOM PRACTICA STUDENT CERTIFICATION FORM**

This form should be used by each student involved in research practica. This form accompanies the IRB Classroom Practica form and the CBT certificate.

#### **11.7 IRB REQUEST FOR ADDENDUM/MODIFICATION FOR APPROVED PROTOCOL**

This form is used to make any modification to an approved protocol.

#### **11.8 UNAFFILIATED INVESTIGATOR AGREEMENT**

This form is used for non-CUNY investigators. If a researcher who is not affiliated with Hunter or CUNY, they must find a faculty member willing to sponsor their research project and complete this form. This form certifies that unaffiliated researcher will abide by Hunter's policies and procedures.

#### **11.9 HIPAA DATA USE AGREEMENT**

For studies using existing data, this form specifies how the institution granting permission to use the data wishes it to be used.

#### **11.10 IRB MANUAL**

This document provides overall guidance on CUNY policy.

#### **11.11 HIPAA FORMS**

HIPAA Research Authorization Form (General)  
General consent form for participants to authorize use of HIPAA classified data.

#### **11.12 HIPAA RESEARCH AUTHORIZATION FORM (HIV)**

Consent form for participants to authorize use of HIV HIPAA classified data.

### **11.13 HIPAA RESEARCH AUTHORIZATION FORM (PSYCHOTHERAPY NOTES)**

Consent form for participants to authorize use of HIPAA classified psychotherapy notes.

### **11.14 HIPAA IRB WAIVER APPLICATION**

This form is used to waiver obtaining consent from subjects using HIPAA classified data.

### **11.15 CUNY SUBJECT INFORMATION CONFIDENTIALITY AGREEMENT**

This form is used as a confidentiality agreement for HIPAA related data.

# 12 Other Policies

## 12.1 ORAL HISTORY

CUNY has determined that IRB review is still necessary for projects involving oral history interviews. Please review the details of the memo from University Associate Dean for Research, Gillian Small.

## 12.2 MARKETING RESEARCH IN CLASSROOM

Faculty members are often asked to conduct marketing research in the classroom. The Committee has determined that this type of research is subject to IRB review. When there is monetary compensation involved, the compensation will be reviewed on a case by case basis.

## 12.3 PROCESS RECORDING

Many Social Work students use their process recordings as a research project. The IRB has determined that clients must give permission before these recordings are used for their own learning and in classrooms.

## 12.4 JOURNALISM

Journalistic investigations are outside the purview of the IRB and do not require review. When journalism, communications, oral history or similar projects incorporate research protocols, are designed to test hypotheses and anticipate that results will be published in scholarly venues, as is the case with many graduate programs, the research must receive IRB review and approval before it begins. Some projects fall in gray areas. If you are not sure about your own project, please contact the IRB Office.

There is no difference in the review of funded and non-funded research. Researchers with studies that involve human subjects are instructed to submit their IRB protocol as soon as they submit their grant proposal.

## 12.5 WHISTLE BLOWER POLICY

The IRB is required to review allegations of misconduct and to take action to protect human subjects. Call the IRB Office at (212)-650-3053 to report a concern.

Reviewing complaints and allegations of non-compliance are critical to the IRB's ability to protect human subjects. A climate free of fear of sanction is required to foster appropriate reports and ensure a fair review of allegations. Retaliation against good faith "whistle blowers" is illegal and will not be tolerated at this institution.

## 12.6 RESEARCHER NON-COMPLIANCE

The IRB is required to review allegations of researcher noncompliance with IRB-approved protocols as well as Federal regulations and College policy pertaining to human subject research. The IRB will also review allegations of misconduct that violate the rights of research subjects. Incidents of noncompliance will be reviewed by the IRB for corrective action appropriate to the incident. In all cases the IRB's primary concern will be to protect the welfare of the research subjects.

The IRB will report to the CUNY Office of Research Conduct which will report to the federal Office for Human Research Protections (OHRP), and any other sponsoring Federal department or agency head:

- ? any serious or continuing noncompliance with the regulations or requirements of the IRB
- ? any injuries to human subjects or other unanticipated problems involving risks to subjects or others

### 12.6.1 WHAT CAN HAPPEN IF YOU 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: Doctoral and Graduate students **must** present to the CUNY Graduate School and Graduate Center 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 no sponsor will release funds to the College for the researcher's use without IRB approval. The Research Foundation will not set up accounts for projects lacking necessary IRB approval.

Articles and books may not be published: Most professional publishers and 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.

# 13 Appendices

Appendix 1 The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Appendix 2 45 CFR 46: Protection of Human Subjects

Appendix 3 Federalwide Assurance of Compliance with DHHS Regulations for the Protection of Human Research Subjects

Appendix 4 Oral History Memo from Gillian Small, CUNY University Dean of Research

# 14 GLOSSARY OF TERMS

**ADVERSE EVENT** Any problematic physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event.

**APPROVED** The IRB has reviewed the study and made a determination that the study has met all requirements. Subjects may be enrolled in the study.

**ASSENT** Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research.

**ASSURANCE** A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

**AUTONOMY** Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

**BELMONT REPORT** A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

**BENEFICENCE** An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

**BENEFIT** A valued or desired outcome; an advantage.

**CHILDREN** Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)].

**CDC** Centers for Disease Control and Prevention; an agency within the Public Health Service, Department of Health and Human Services.

**Code of Federal Regulations (CFR)** is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis.

**COGNITIVELY IMPAIRED** Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

**COMPENSATION** Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research.

**COMPETENCE** Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: *Incompetence, Incapacity*.)

**CONFIDENTIALITY** Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

**CONSENT** See: *Informed Consent*.

**CUNY** City University of New York

**DEBRIEFING** Giving subjects previously undisclosed information about the research project following completion of their participation in research.

**DHHS** A federal agency: U.S. Department of Health and Human Services.

**EQUITABLE** Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

**ETHNOGRAPHIC RESEARCH** Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time.

**EXPEDITED REVIEW** Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

**FDA** Food and Drug Administration; an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

**FEDERAL POLICY (THE)** The federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Currently, sixteen federal agencies have adopted the Federal Policy. (Also known as the "Common Rule.")

**FULL BOARD REVIEW** Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting. Also known as convened meeting.

**GUARDIAN** An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)].

**HIPAA** Health Insurance Portability and Accountability Act of 1996.

**HUMAN SUBJECTS** Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

**INCOMPETENCE** Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity.

**INFORMED CONSENT** A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

**INSTITUTION** Any public or private entity or agency (including federal, state, and local agencies).

**INSTITUTIONAL REVIEW BOARD (IRB)** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

**INSTITUTIONALIZED** Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).

**INSTITUTIONALIZED COGNITIVELY IMPAIRED** Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled (e.g., a psychiatric hospital, home, or school for the retarded).

**JUSTICE** An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

**LEGALLY AUTHORIZED REPRESENTATIVE** A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

**LONGITUDINAL STUDY** A study designed to follow subjects forward through time.

**MENTALLY DISABLED** See: *Cognitively Impaired*.

**MINIMAL RISK** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**NIH** National Institutes of Health: a federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research.

**NUREMBERG CODE** A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

**PERMISSION** The agreement of parent(s) or guardian to the participation of their child or ward in research [45 CFR 46.402(c)].

**PREGNANCY** The period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (*i.e.*, has been delivered). Implantation is confirmed through a presumptive sign of pregnancy such as missed menses or a positive pregnancy test [45 CFR 46.203(b)]. This "confirmation" may be in error, but, for research purposes, investigators would presume that a living fetus was present until evidence to the contrary was clear. Although fertilization occurs a week or more before implantation, the current inability to detect the fertilization event or the presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

**PRINCIPAL INVESTIGATOR** The scientist or scholar with primary responsibility for the design and conduct of a research project. (See also: Investigator.)

**PRISONER** An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)].

**PRIVACY** Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

**PROSPECTIVE STUDIES** Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

**PROTOCOL** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**QUORUM** A quorum is defined as a majority of the voting members appointed to the IRB membership. In the case of the IRB, a quorum must include at least one member whose primary concerns are in non-scientific areas. At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote.

**RANDOM, RANDOM ASSIGNMENT, RANDOMIZATION, RANDOMIZED** Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

**RESEARCH** A systematic investigation (*i.e.*, the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

**RESPECT FOR PERSONS** An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

**RETROSPECTIVE STUDIES** Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited

through interviews or surveys. Case control studies are an example of this type of research.

**RISK** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (*See also: Minimal Risk.*)

**SITE VISIT** A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.

**STUDY CLOSURE** Study approved by the IRB can be closed by the investigator, the sponsor or the IRB.

**STUDY COMPLETED** Study completed as approved by IRB, including data analysis, and finalized.

**SUBJECTS (HUMAN)** *See: Human Subjects.*

**SURVEYS** Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

**VOLUNTARY** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

Developed  
for the Hunter College IRB  
byCarolynn Julien, IRB Coordinator

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