

HUNTER COLLEGE OF THE CITY UNIVERSITY OF NEW YORK

PRINCIPAL INVESTIGATOR'S MANUAL

**FOR SUBMITTING PROPOSALS FOR REVIEW
BY THE CUNY INSTITUTIONAL REVIEW BOARDS**

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CUNY PRINCIPAL INVESTIGATOR'S MANUAL FOR RESEARCH INVOLVING HUMAN SUBJECTS

Note: Please read this manual carefully. It contains important information that will help you complete the “Application to Use Human Subjects in Research” form. Failure to follow instructions may result in a delay in the approval process.

THE PURPOSE OF THIS MANUAL

This manual is intended as a guide for faculty, students, fellows, staff, and any other members of the City University of New York (CUNY) who plan to carry out research, whether funded or unfunded, involving the participation of human subjects. It provides basic information about what materials are needed to apply for human subjects approval and how to do it.

All research that is conducted by an individual in connection with his or her institutional responsibilities and/or which involves the use of any of the University's property or facilities must conform to a standard of ethics reflected in specific regulations of the United States Department of Health and Human Services (DHHS) in order to assure that the rights and welfare of human subjects are protected. CUNY has a Multiple Project Assurance Agreement with DHHS, which describes University policies and procedures for the protection of human subjects in all research which involves them. Copies of the Multiple Project Assurance and of the Federal Regulations governing research involving human subjects may be obtained from your campus IRB Office or by accessing it online at <http://www.rfcuny.org/ResCompliance/overview.html>. At most CUNY campuses, the IRB Office is housed within the Grants Office/Office for Sponsored Research, while at a few campuses it is located in a faculty office. Your Grants Office will be able to direct you appropriately should they not have the information you require on-hand. Information on the CUNY Grants Offices can be found on-line at <http://www.rfcuny.org/R&DWeb/grants.html>.

INTRODUCTION

Research with human subjects, which is conducted by any member of the CUNY community or anyone using CUNY facilities, must be reviewed and approved by a CUNY Institutional Review Board (referred to hereafter as the IRB). The purpose of this review is to allow the IRB to evaluate the “risk to benefit ratio” of the research. The IRB's **only** interest is in protecting the safety, welfare, privacy and rights of human research subjects. It is not the IRB's objective to pass judgment on other aspects of the research except as it relates to this ratio. However, it is within the IRB's purview if it determines the need to appraise research methodology as it relates to human subjects protection. To this end, principal investigators shall prepare protocols giving complete descriptions of the proposed research.

The application for review of research involving human subjects must contain specific information. This information allows the IRB to evaluate the:

1. risks to subject(s);
2. benefits to subject(s) and/or society;
3. specific nature of subjects' participation including:
 - recruitment of subjects,
 - voluntary nature of subject participation,
 - informed consent,
 - remuneration (if any) to subject,
 - specific procedures to be followed.

In order to submit research for review, investigators must complete the **APPLICATION FOR APPROVAL TO USE HUMAN RESEARCH SUBJECTS IN RESEARCH**, which may be obtained through the IRB Office or by accessing it on-line at <http://www.rfcuny.org/FormsWeb/ResCompliance/application.pdf>.

The most important concerns of the IRB are to assure subjects' safety, preserve subjects' anonymity and confidentiality, and assure that participation is voluntary. Thus, the application should provide the IRB with information related to these areas. For example, a question of undue influence may arise when an instructor solicits students from his/her own classroom for participation in a research project in which the instructor is involved. Another concern is the desire for subjects to be fully informed of the procedures to be employed in the study and of possible adverse effects. Also, the procedures should not influence subjects to continue in a study if they desire to stop participation.

In order to facilitate approval of the application for use of human subjects in research, it is necessary for all relevant information to be included in the application. It is of equal importance that the document present a clear and concise explanation of the proposed research project. **Delays in approval by the IRB are frequently a result of:** a) insufficient information; b) relevant information being omitted from the application (or placed in appendices rather than in the text of the application); c) presenting information in a manner that is too technical and cannot be understood by IRB members whose backgrounds and areas of expertise vary greatly and d) the consent document contains grammatical and/or spelling errors or its language is inappropriate to the subject population being targeted.

IRB COMPOSITION

The IRB is composed of faculty who are engaged in research using human subjects, faculty who study human behavior, a non-scientist and at least one community member who is not affiliated with the City University of New York. A roster of current members may be obtained at your IRB Office. A list of IRB Offices and IRB Chairs for each campus may be found at <http://www.rfcuny.org/ResCompliance/cunyrbchairs.html>.

DEFINITIONS

1. Human Subject - “Human Subject is a living person about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the person, or (2) identifiable private information.
2. Intervention - “Intervention” includes both physical procedures by which data are gathered (e.g. venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
3. Interaction - includes communication or interpersonal contact between investigator and subject.
4. Minimal Risk - “Minimal Risk” means that 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.
5. Private Information - “Private Information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
6. Research - “Research” means systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to the generalizable knowledge. Activities which meet this definition constitute research for purposes of this assurance, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
7. Established and Accepted Methods - Some methods become established through the rigorous standardization procedures prescribed by law, as in the case of drugs, devices, or biologicals, by operation of law, or, as in the case of many educational tests, under the aegis of professional societies or non-profit agencies. Determination as to when a method passes from the experimental stage and becomes “established and accepted” is a matter of judgement.
8. Legally Authorized Representative - “Legally authorized representative” means an individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject’s participation in the procedure(s) involved in the research.
9. IRB - “IRB” means an Institutional Review Board established in accord with the basic DHHS policy for the protection of human research subjects (45 CFR Part 46) and for the purposes expressed in that policy.
10. IRB approval - “IRB approval” means the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other applicable institutional, statutory, and regulatory requirements.

INSTRUCTIONS FOR COMPLETING THE “APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH”

(**Note:** This instruction section is written to coincide with the IRB Application Form. In other words, the numbered section headings correspond to the page and question on the application form, e.g., "1,4" below refers to page 1, question 4 on the form).

Please Note: The application should stand on its own, without reference to any attached grant proposals or articles published, in press, or under review. (Just cutting and pasting paragraphs from a grant proposal causes confusion during the review process.) In addition, information placed in appendices may be overlooked. The application should provide all information necessary for IRB members unfamiliar with the experimenter's field of research to be able to evaluate the risks to subjects, how subjects will be recruited, the potential benefits, and how informed consent shall be obtained.

Pg. 1, Question 1: If you are seeking IRB approval as part of a grant application process, the title of the project should be the same on both the “Application for Approval” and within the grant proposal.

1, 2 & 3: PI’s & Co PI’s may list contact information other than their regular campus address in this space if they prefer to be contacted elsewhere. Co-PI’s at non-CUNY institutions should list full information about their affiliation here.

1, 4: Check “Other” if you are not affiliated with CUNY but are seeking to conduct research involving the CUNY community or the use of CUNY facilities.

1, 5: All student research **must** be approved by a faculty advisor before it is submitted to the IRB for review.

Page 2, Question 6: All research that involves fetuses, pregnant women, prisoners, or groups who may have diminished capacity to provide consent or who may be high risk, **must** be provided full review. Most research involving minors falls into this category as well.

2, 6 (cont.): RESEARCH INVOLVING CHILDREN AS SUBJECTS

Children are considered a vulnerable and therefore “protected” population in the context of serving as research subjects. In New York State, children are defined as those persons who are under 18 years old and have not obtained the legal age for consent to treatment or procedures involved in the research.

In addition to those materials normally required for review by the IRB on the Protection of Human Subjects, a parental or guardian consent form, including all traditional elements of informed consent, is required. A child assent form should be used for subjects 12 years of age

or older. Language should be understandable and include a brief description of the task(s) involved and a statement on the right to withdraw at any time without penalty. For subjects under 12 years of age, an assent procedure should be employed. Assent is defined as an affirmative agreement (as opposed to tacit consent) to participate in research.

If child subjects are being obtained from another institution(s), written permission from an official from the institution(s) authorized to do so, must accompany the protocol.

2, 6 (cont.): RESEARCH INVOLVING PRISONERS AS SUBJECTS

Federal policy dictates that the use of prisoners as human research subjects is strictly prohibited without the prior approval of the Human Subjects IRB. This restriction also applies to the compassionate use of investigational agents or devices on prisoners.

If prisoners are to be potential subjects of a project, the researcher must indicate this in the application. If a Principal Investigator plans to have prisoners as subjects in his or her research project, please contact the IRB Office before finalizing the protocol. Additional time may be necessary to process proposals involving prisoners as subjects since the IRB will need to refer the proposed project to an individual or individuals who will have been designated as prisoner advocate(s). These precautions are mandated by the Federal regulations governing research involving human subjects. Copies of these regulations are available from the IRB Office and can also be accessed on-line at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>. Written permission will need to be obtained as well from the cooperating institution from which subjects will be recruited.

2, 7: The investigator is justified in withholding information from or giving incomplete or erroneous information to research subjects only when it can be demonstrated that the research cannot be conducted in any other way and that subjects will not be placed at risk. **Research involving deception must be provided full review.** At the earliest possible moment consonant with the validity of the research, the subject should be informed of the actual purpose of the research and procedures must be developed to relieve any distress encountered. **All research involving deception must attach a full description of the debriefing procedure to be used to the application.**

2, 8: Subjects at Risk: “Subjects at risk” means any individual who may be exposed to the possibility of injury, e.g. physical, psychological, or social injury, as a consequence of participation as a subject in any research or related activity which departs from the application of those established and accepted methods necessary to meet his needs or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. When reviewing protocols with more than minimal risk to subjects, the IRB will often delay approval of a protocol and make recommendations to the investigator for alterations in the wording of informed consent documents or for changes in the protocol to further minimize potential risks to subjects. **Research may not begin until IRB approval has been granted.**

2, 9: The IRB grants approval for one year from the date of initial approval *only*, regardless of when research actually begins. If, for example, funding was sought but not received from one source, but received from another source later on, the project must be reapproved if more than a year has elapsed. Use the continuing review form available from the IRB Office to report changes in protocol for projects which are already underway. The form can also be accessed on-line at

<http://www.rfcuny.org/FormsWeb/ResCompliance/continuing.pdf>.

2, 10 & 11: Answering these questions aids the IRB support staff to ensure all required documentation is in place.

2, 12: Certain research projects will involve hospitals, schools, organizations, etc., that are not affiliated with the City University of New York. In such cases, the Principal Investigator is required to obtain a copy of the organization's agreement to participate and/or, if applicable, that institution's IRB approval before the recruitment of subjects may begin. For research that requires IRB approval by more than one institution, protocols must be identical.

Deadlines:

The IRB's practice is to circulate applications requiring full or expedited review to IRB members prior to the meeting. Any questions, comments or concerns raised by members are discussed at the next meeting and transmitted in writing after the meeting to the Principal Investigator for a written response.

It is the Principal Investigator's responsibility to see that the application is complete (i.e., all questions are answered), that required materials are attached (e.g., a copy of the informed consent form to be used), and that the **application is submitted prior to the next IRB meeting**. Most CUNY campuses require submission of applications at least 12 days before the IRB meeting, but the requirements on your campus may be different; check with your IRB Chair, IRB Administrator or Grants Officer. Failure to adhere to these requirements may lead to a delay in review and/or approval.

Special Deadline Considerations:

Investigators should be aware that for **non-competing continuation applications**, the National Institutes of Health require IRB approval coincident with the grant/contract/funding application. This means that the Human Subjects review must take place prior to submission of the grant application. For non-competing continuation grants, use the CONTINUING REVIEW FORM. This form must be submitted even if no changes have been made in the approved procedures. For **competing continuation applications** most federal agencies allow approval within 60 days of proposal submission.

It is suggested that Investigators submit an IRB application prior to or as soon as possible after submitting a grant proposal to prevent a delay in the awarding of funds. Applications for human

subjects approval for PSC-CUNY funds should be submitted no later than February in order to assure the desired start date of July 1 if the proposal is funded.

3, 13: Requirements for Training and Certification of Key Personnel in Human Subject Research:

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 investigators and key personnel, regardless of the research project sponsor and whether it is funded or unfunded, satisfy this new requirement.**

NIH has posted a web series of “frequently-asked questions” regarding these new requirements. These “FAQs” can be accessed on-line at http://grants.nih.gov/grants/policy/hs_educ_faq.htm.

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 developed by the Office of Research Conduct. The CBT may be accessed on the RFCUNY's web site at <http://www.rfcuny.org/ResConduct/CBT>.

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.)

Principal Investigators need to have the education requirement fulfilled at the time of submission of their application to the appropriate 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.

3, 14: CHOOSING THE APPROPRIATE TYPE OF REVIEW:

Principal Investigators can request the type of review they believe is appropriate to their project. However, the IRB Chair ultimately determines which type of review is appropriate. The IRB may request additional documentation if needed in order to determine if the use of a particular type of review is justified.

EXEMPT Review Procedures

Federal regulations “exempt” some types of research from regular review procedures by the IRB, though use of this term can be confusing. “Exempt” research is in fact reviewed. If found exempt, the project need not follow *continuing* review procedures unless significant changes are made to the research protocol. Federal regulations permit the Principal Investigator to request that a protocol be reviewed as possibly exempt.

Categories of Research Eligible for Exempt Review: 45CFR46.101(b)

The following information from the Office of Human Research Protections (OHRP) regarding expedited review procedures and categories can also be found at the following site:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101>

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: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of 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. (See **Note** below.)
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: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) 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 investigator 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:
 - (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs; or (iv)

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, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level for 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 United States Department of Agriculture.

Note: The exemption at (2) above, for research involving survey or interview procedures or observation of public behavior, does **not** apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

The remaining exemptions apply to research involving children.

EXPEDITED Review Procedures?

The following information from the Office of Human Research Protections (OHRP) regarding expedited review procedures and categories can also be found at the following site: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm>

Applicability for Expedited Review:

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

[?] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories for Expedited Review:

(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, nonpregnant 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

[?] Children are defined in the HHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” 45 CFR 46.402(a).

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 nonresearch 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.

FULL Review Procedures

Research that involves more than minimal risk, or is not covered by the categories listed previously, requires full review. Reports of research approved under expedited or exempt procedures are made at each regular IRB meeting.

HAVE QUESTIONS ABOUT WHICH TYPE OF REVIEW TO SELECT?

A **complete application** is necessary for all categories of research proposals. According to Federal Regulations, if the IRB member(s) assigned for expedited review have questions about the appropriateness of expedited review or concerns about the nature of human subjects participation, the proposal is reviewed by the full IRB at its next meeting.

The IRB Office can provide advice and assistance to help investigators determine if projects are exempt.

PAGES 4 & 5:

4, 1: PURPOSE AND DESIGN OF RESEARCH

The description of your research should be in language that can be understood by non-experts in your field and should be in detail sufficient for the IRB to make a judgement about the adequacy of the human subjects protections proposed. Such protections are the only concern of the IRB; judgement about a particular project's validity or feasibility lies within its jurisdiction to the extent that it relates to human subjects protection. Research methodology appraisal is within the IRB's purview if it determines the need relative to fulfillment of its mission.

4, 2: SELECTION AND RECRUITMENT OF SUBJECTS FOR PARTICIPATION IN RESEARCH

When selecting subjects for research, it is important to consider carefully the category of subjects being chosen. Federal guidelines require a scientific justification if women and/or minorities are to be excluded from a subject population. In addition, vulnerable populations,

e.g., prisoners, pregnant women, institutionalized individuals, or children, are to be studied only under certain conditions, and only if the study could not be undertaken without them.

When recruiting subjects for research, it is important to follow procedures that will ensure that subject participation is truly voluntary and that no procedures that could be construed as even minimally coercive have been employed. The preferred method of recruitment is to disseminate information about the research study to potential subjects and to instruct them to contact the investigator if they are interested in participating. In the interest of respecting individuals' rights to privacy and confidentiality, recruitment procedures should involve having interested subjects identify themselves to the investigator rather than the investigator obtaining names and addresses from a third party and soliciting participation directly from individuals. Some acceptable and non-intrusive means of recruiting subjects are listed on the following page.

4, 2 (cont.): ACCEPTABLE MEANS FOR THE SELECTION AND RECRUITMENT OF SUBJECTS FOR PARTICIPATION IN RESEARCH:

- Placing an advertisement in a newspaper, journal, or other periodical requesting that interested persons who meet relevant criteria contact the investigator;
- Posting a sign or placing flyers in a public area or, with permission from the appropriate authority, in a private area (such as a university, store, library, health club, etc.) requesting that interested persons who meet relevant criteria contact the investigator;
- Obtaining names from public records, such as telephone directories;
- Obtaining names from organization membership or client records to which the investigator has legal access and for which s/he has obtained permission from the appropriate authority.

Researchers should avoid using their own patients or students as subjects due to the nature of the existing relationship and the unavoidable potential coercion. When recruiting subjects from hospitals, private medical or psychotherapy practices, schools, religious groups or businesses, steps should be taken to ensure that potential subjects do not feel obligated to participate because they wish to please an authority figure who they believe wants or expects them to participate. Every effort should be made to use recruitment procedures that do not involve the referring doctor, teacher, therapist, cleric, etc., knowing which individuals eventually participated in the study. To fulfill this objective, subjects should be recruited in these circumstances with minimum direct involvement of the referral source. Whenever possible, the investigator should request that the referral person simply inform clients of the study and instruct them to contact the investigator if they would like to participate. Names and addresses of potential subjects should never be directly requested from referral sources unless permission has been given by these individuals to release their names.

In a hospital-based study, particularly when there may be medical or emotional contraindications to participation, it is necessary to obtain approval from patients' physicians prior to their participation. Thus, in addition to selecting patients who meet specific criteria to be eligible to participate, the referring physician or other health care professional should also select patients on the basis of who is deemed to be both competent to give informed consent and capable of carrying out the required tasks without jeopardizing his/her health and safety.

In certain cases, a subject's right to privacy may be superseded by a desire to minimize coercion. In a corporate setting, for example, a researcher who personally has access to a personnel roster may be justified in approaching subjects directly if it means that the employer is thereby disassociated from the recruitment process and will not have access even to a list of potential subjects. A discussion of the merits of direct recruitment should be included in the Application for Approval to Use Human Subjects in Research. Steps for protecting the confidentiality of the data to be obtained and the anonymity of the subjects are of paramount concern when employees are being asked to participate at their place of business.

4, 2 (cont.): SELECTION AND RECRUITMENT OF SUBJECTS FOR PARTICIPATION IN RESEARCH:

In summary, names of potential subjects are not to be obtained from hospitals or private practices unless the referral agent has obtained permission from each individual to release the name. Whenever possible, potential subjects should be informed of research indirectly and instructed to contact the investigator if they are interested in participating. To reach specific populations independent of a third party referral source, information can be disseminated in written form in periodicals, by posting a sign in a convenient place or arranging to have flyers distributed to eligible individuals. A description of a research study may also be presented verbally to groups or individuals, preferably by someone whose position or relationship to potential subjects will not create pressure, or perceived pressure, for individuals to comply.

Access to Educational and/or Student Records

Investigators who require access to educational and/or demographic records must negotiate with those institutions for access to that information. The IRB will not approve any application unless access to that information already has been granted by the appropriate institution. If the outside institution requires IRB approval, the IRB may approve the application contingent upon the outside institution's approval. Agreement to provide information by outside institutions does not obligate the IRB to approve the project.

The IRB expects the same standards of confidentiality and anonymity to be exercised with information obtained from other institutions as is required for information obtained from the City University of New York.

Use of Students Enrolled in a Course

The IRB is required to ensure that a subject's participation in research is voluntary. Thus, practices such as: i) recruiting subjects from a course in which the investigator is also instructor; and/or ii) offering extra credit and/or inducements which affect the course grade unless comparable opportunities are offered to non-participants, are usually not approved by the IRB.

4, 3: PROCEDURES TO BE FOLLOWED

If for any reason your project involves experimental or non-standard means of collecting data where standard procedures exist, a justification for the use of the non-standard procedures should be included here.

4, 4: TYPES AND LEVELS OF RISK

In general, the higher the risk involved in the project, the more detailed the explanation, precautions, and informed consent must be. The nature and type of informed consent is determined by the level of risk. Accordingly, the following broad guidelines for degrees of risk may be of assistance in making a necessary determination.

High Risk: Activities involving medical or behavioral science projects that may induce a potentially harmful altered physical or mental state or condition are forms of personal invasion and, as such, are considered to be in a “high risk” category. (Examples include biopsy procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exercise; hypnotism; and subjection to deceit, public embarrassment and humiliation.) In these cases there must be especially careful documentation to show that the benefits outweigh the risks.

Intermediate Risk: Activities involving a wide range of medical, social, and behavioral projects in which there is no immediate physical risk to the subject are considered to be in an “intermediate risk” category. (Examples include personality inventories; interviews; questionnaires; the dissemination of any data or information concerning an identified individual; information gathering activities conducted in classrooms or elsewhere; individual or group therapy sessions; or the use of photographs, taped records, and stored data.) Since some of these types of procedures may involve varying degrees of dignity through the imposition of demeaning or dehumanizing conditions, prior written informed consent is also required. However, since this type of activity does not involve physical invasion but is where voluntary consent on the part of the subject is desirable, a more simplified consent is acceptable.

Low Risk: Certain activities are classified as “low risk” and may not require a written informed consent. (An example is the use of completely anonymous questionnaires.) If a written

informed consent is deemed unnecessary or undesirable in a particular instance, there follows an additional responsibility to establish that:

- 1) the risk to the subject is minimal;
- 2) obtaining a consent would invalidate objectives of considerable immediate importance; and/or
- 3) any reasonable alternative means for attaining the objectives have been thoroughly explored and would be less advantageous to the subject.

Low risk involves situations in which there is no conceivable physical or mental discomfort, and the measurements made on subjects can be considered to be reasonably unobtrusive. In these situations written informed consent may be waived.

4, 5: CONFIDENTIALITY AND ANONYMITY

If a Federal Certificate of Confidentiality has been obtained or is being sought, this should be noted here and a copy provided if it is available.

4, 6: DEBRIEFING PROCEDURES/REVELATION OF POTENTIALLY TROUBLESOME SITUATIONS

If individuals possessing any special skills or training are to be present during procedures, this should be noted here. Where possible, investigators should provide the IRB with a list of agencies, hospitals, professionals, etc., to whom they may refer subjects who reveal a need for such assistance.

5, 7: INFORMED CONSENT

The description of the informed consent process and the informed consent form are one of the most important portions of the APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH. The form must give a clear and concise explanation of the research to be conducted and the procedures to be employed. The form must be written in language appropriate for the targeted subject population (e.g., English and Spanish versions should be written for a multi-cultural study).

An informed consent document ideally should be one or two pages in length. The form should be written in language that is age- and culture-appropriate. The statement should be written clearly enough for the potential participant to understand what involvement in the study entails, so that she or he may make a reasonable, intelligent, and informed decision. The language should be kept simple, and the sentences short. The language of the form should be

understandable at the eighth-grade reading level for studies using adult populations. The typeface should be large enough so that even subjects with impaired vision can read it.

It is possible that the research may produce psychological difficulties for a subject; therefore, it may be necessary to make arrangements for those difficulties to be dealt with by a professional. For example, in one study of people with chronic illness, the Investigator provided all subjects with a list of mutual-help organizations in the local area.

After review of the informed consent document, subjects should have a clear understanding of the procedures which will be followed with regard to their participation. The subject should be able to make an informed decision concerning participation, **free of explicit or perceived coercion**. Potential risks and procedures to minimize such risks must be stated in detail in clear, precise language. A statement should be included in which the subject declares himself/herself fully informed and agrees to participate on a purely voluntary basis. Finally, the subject should be given a copy of the consent form, and/or any information sheets that he/she is required to read.

Copies of the completed informed consent forms should be retained by the Principal Investigator for a period of at least three years following termination of the project.

Sample informed consent documents are contained in Appendix II of this Manual. Please note that these samples are meant as guidelines only and should not be used as templates into which the particulars of your project are filled.

A copy of the sample consent form(s) to be used must be included with each APPLICATION FOR APPROVAL and must be approved by the IRB. At the time of approval, the consent form will be stamped with an expiration date, after which time it may not be used. Projects must file a CONTINUING REVIEW FORM, available from the IRB Office or by accessing it online at <http://www.rfcuny.org/FormsWeb/ResCompliance/continuing.pdf>, if they will be continuing beyond this date.

Elements of the informed consent form:

The following elements must be included in the informed consent form:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental (i.e., in medical research, those procedures which deviate from standard, accepted practice). If the purpose of the research cannot be fully revealed to subjects, describe exactly what subjects will be told, the justification for any deception of subjects, and plans to debrief subjects after their participation in the research.

- The Principal Investigator(s) name(s) and affiliation(s).

- A description of any reasonably foreseeable risks or discomforts (both physical and mental) that could reasonably be anticipated. This includes any potential financial risks or burden which could ensue such as who has responsibility for any costs or expenses which might arise from the study.
- A description of any benefits to the subject or to others which may reasonably be expected from the research. In most research, expected results are tenuous, at best. If no direct benefits due to participation are foreseen, it is appropriate to state this.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If the participant has been promised financial compensation, but chooses to withdraw, state that a pro-rated portion of the fee will be paid up to the point of withdrawal.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing how anonymity and confidentiality will be maintained.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained which should include how records will be kept confidential, (e.g., locked cabinet, erasing of tapes, etc.). If audiotaping is to occur, indicate who will hear the tapes, where they will be stored, and how and when they will be disposed. If videotaping is to occur, indicate to whom the tapes are to be shown and where they will be stored.
- The informed consent form must have a line for the subject's and researcher's signatures, and the date of consent. If the participation must be anonymous and the form is to be signed with an X, then the signature of a witness must also be obtained. The Investigator should retain a copy of the signed consent form and provide a copy to the subject.
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research-related injury to the subject. The informed consent form should include a phrase such as:

If you have any questions regarding this research, you can call Professor _____ at (area) TELEPHONE. If you have any questions concerning your rights as a participant in this study, you can call the CAMPUS IRB Office at _____.

A Note on Language Style:

The language used in the consent form must be appropriate to the subject's level of education and understanding. Exculpatory language through which the subject is made to waive his/her legal rights or releases or appears to release the institution from liability for negligence may not be included. When applicable, a consent form should be translated into the subjects' first language.

The consent form, and any materials used to recruit subjects should be submitted to the IRB at the time application for human subjects approval is made. If these materials are written in a foreign language, both the forms to be used and their English translations are to be submitted.

Informed Consent With Minors As Subjects

Children under age 18 are considered legally incompetent to give informed consent. As human subjects, children are especially vulnerable. The following definitions are important for research with minors: (a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted, (b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent, (c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research, (d) "Parent" means a child's biological or adoptive parent, (e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

The IRB has decided that written assent should be obtained from children aged 12 and older; verbal assent should be obtained from children under 12 years of age. Assent from a child should be requested only after the child's parents or guardians have agreed that the child may participate. In most cases, the signature of one parent or guardian is sufficient. However, in studies involving greater than minimal risk, signatures from both parents or guardians may be required.

Information provided during the procedure to obtain consent or assent from children should be presented in a form understandable by the children selected for the study. We encourage researchers to consider alternatives to the conventional consent form used with adults. Appropriate alternatives include: a checklist, pictures, role playing and audio-visual methods

(slides, videos, cassettes). The basic information about procedures, purpose, selection, risks, benefits and willingness of the researcher to answer questions should be provided to children serving as research subjects.

Oral Consent

In certain cases, the Principal Investigator may determine that oral consent is more appropriate and more adequately safeguards the subject. The oral consent form shall consist of a written consent document presented orally to the subjects (or his/her legally authorized representative). The IRB shall approve the written text of what is said to the subject or representatives. A copy of the information that is read to the subject should be given to the subject or the representative to keep. There should be a witness to the oral presentation who can attest that the information was given as stated.

When it Might be Appropriate to Omit Use of Consent Form

As a general rule, the IRB believes informed consent should be obtained from all research subjects. However, if the Principal Investigator believes that obtaining a signed consent form would be inappropriate, such a request must be justified according to the following criteria:

1. The only record linking the subject and the research would be the consent form and the principal risk would be potential harm resulting from a breach of confidentiality.
2. The research presents no more than minimal risk and involves no procedures for which written consent is normally required outside the research context. For example, in a sample survey of volunteers, investigators would describe the nature of the interview to the subjects. Rather than seek written approval, participation here is regarded as de facto consent.
3. **Tacit Consent**. When participation entails only the completion of anonymous written questionnaires, consent may be considered to be tacit. Provided that responses can in no way be used to identify subjects, written consent is not necessary. (To ensure that participation is voluntary, the investigator should not be present when subjects are filling out the instruments and subjects must not be required to hand back their responses directly to the investigator.)

When the use of a consent form is waived, the IRB requires the Principal Investigator to provide subjects with a written statement regarding the research.

PAGE 6, EXEMPT REVIEW:

To request an exemption, simply select one of the six categories on page six of the "Application" and respond to the questions on pages 4 and 5. Be sure to provide information on the subject population, the means of subject selection, how anonymity will be assured and

what informed consent procedures, if any, will be followed. If your research involves surveys which have already been prepared, append them as well. Failure to provide the IRB with a sufficient justification of your request for an exemption will result in delays in approval. If for any reason the IRB finds it cannot grant your project an exemption, the project will undergo either expedited or full committee review as the Chair sees fit. In such cases, you may expect to be asked to provide additional information.

PAGE 7, SIGNATURE AND CERTIFICATION:

Signatures: Student researchers must obtain the signature of their faculty advisor before the IRB will consider their application.

Reporting Unanticipated Problems and Changes in Protocol. Any unanticipated problems involving risks to subjects or others participating in a research study or proposed changes to a previously approved application must be promptly reported in a written memorandum to the IRB. This includes changes in the (approved) consent form, sample composition, sample recruitment, or study procedures.

Applicants Seeking External Funding: Federal regulations require that protocols be “tracked” to grant proposals, although IRB review and grant proposal preparation are independent activities. The IRB Office will fill in the internal reference number.

More general information on the IRB Review Process and on Human Subjects Protections in general is contained in the CUNY *Protection of Human Subjects Information Folder* available at your campus IRB Office. It contains sections of the OHRP’s IRB Guidebook, sections of the Code of Federal Regulations which pertain to Human Subjects Protections, and the Belmont Report, a statement of Ethical Principles in the conduct of Human Subjects Research. Each of these can be found respectively at the following websites:
http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm,
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm> and
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>. The CUNY *Protection of Human Subjects Information Folder* contains suggestions for further reading as well. Your IRB Office also has information on periodicals, on-line and other resources in the area.

The CUNY Principal Investigator's Manual was adapted from a manual created by the Committee for the Protection of Human Subjects at the Graduate School and University Center. During the Summer and Fall of 1997, a Task Force consisting of IRB Chairs, Grants Officers and Research Foundation staff revised the manual for use throughout the University; further recommendations on content and format were made by the members of the University-wide IRB. Some additional material was adapted from the Principal Investigator's Manual in use at SUNY Albany. We gratefully acknowledge the permission of Dr. Jeffrey Cohen of the Office for Research at SUNY Albany for his permission to use this material.

FREQUENT OVERSIGHTS IN APPLICATION MATERIALS AND CONSENT FORMS

1. The language in the consent form must be understandable to the population being addressed (e.g., children). In the event that consent forms may be best understood in another language, that version must be submitted along with an English translation.
2. The name and status of the investigator, as well as the University, school and department identifiers should be incorporated into the consent form text. The address and telephone number where the researcher can be reached should questions arise also must be included; where appropriate, the name of and telephone number of a faculty advisor should be included as well.
3. When cooperating institutions are involved, a letter of cooperation from an authorized official should be included. If a letter is not available at the time of application, it must be submitted before research may begin.
4. Methods for maintaining confidentiality of the data should be described in detail (i.e., coding procedures, who has access to the files, where files are kept, and how anonymity is protected).
5. When treatment or services are involved, an affirmation should be included indicating that an individual's decision not to participate will in no way affect the availability of services to which individuals are entitled.
6. When students are involved, an affirmation should be included indicating that non-participation will in no way affect academic standing.
7. When children are involved, both parental permission and children's consent or assent are required.
8. When video or audio-taping is involved, an opportunity to review the completed tape must be given so that subjects may ask that it not be used (either in whole or in part).

9. Requests to have proposals classified as exempt must be accompanied by a supporting statement, detailing which category of exemption is being claimed, and why the researcher believes the activity falls into this category. In the case of minors (individuals under 18 who are participants in research), exemptions are limited to the following categories of research:

- studies that constitute normal educational practices in educational settings;
- educational tests, where identifiers are not recorded;
- collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available, or if the information is recorded so that subjects cannot be identified.
- observation (as opposed to participation) by the principal investigator of public behavior where identifiers are not recorded by the principal investigator and there is neither a risk of harm to subjects nor observation of sensitive aspects of the subjects' own behavior.

APPENDIX 1: CLINICAL PSYCHOLOGICAL RESEARCH AND THE USE OF HUMAN SUBJECTS

Single system designs (i.e., studies of individual cases), where the instruments and technique of interest to the researcher would have been introduced to the patient's treatment at that time anyway and the technique is not experimental, are considered standard practice and therefore not a concern of the IRB on the Protection of Human Subjects.

In all research utilizing data collected in the course of an individual's treatment, the investigator must take proper steps to ensure that subject anonymity and confidentiality are maintained. The utilization of any instrument or therapeutic technique which is not part of standard treatment requires the subject's informed consent from the outset. It is normally not possible to obtain informed consent during ongoing treatment; therefore, any intent of the therapist to use data collected in the course of treatment must be stated prior to commencing that treatment.

Where clinic intake procedures routinely include a request for the patient's permission for data from his/her records to be used in research, no additional consent need be sought by the therapist/investigator. In the event that such a request is not part of the clinic's general procedure and strict oversight at the clinical setting is not possible, the faculty sponsor should be prepared to advise students of appropriate consent procedures.

Case notes may be utilized in publications and dissertations as long as anonymity and confidentiality are maintained. This is part of normal procedures in the field of clinical psychology. There is no experimental situation involved here; thus no specific subject consent or IRB approval is required.

Consent for publication requested from patients (as opposed to the subject consent form for participation in research) is not a concern of the IRB and the IRB does not require that copies of such consent be submitted or that it be apprised of such consent.

APPENDIX II: SAMPLE INFORMED CONSENT DOCUMENTS

To help researchers draft the forms needed for their research project, the IRB has developed several sample Consent Forms. The forms are for hypothetical research protocols: with greater than minimal, psychological risk; a survey with greater than minimal social risk; an innocuous experiment on normal adults; and a simple questionnaire survey. We suggest you use the sample forms as examples, not requirements.

Sample Consent Form,#1

Background: This consent form is for a study of psychological treatment of a disorder. Thus, the study has greater than minimal psychological risk. The hypothetical research is about a non-drug treatment for high blood pressure. The study has several phases and subjects must be informed about the risks and procedures for all of the phases. It is possible, in a multi-phase study, to break up the consent procedure, but the subjects need to know what the overall study involves before they agree to participate in the first phase.

Blood Pressure Research Study

We are asking you to take part in a research study on high blood pressure .

The CUNY Biopsychology Clinic is doing this research to study the psychological treatment of high blood pressure. **The study will consist of several parts.** The first part involves several **physical and psychological tests** to find out more about your high blood pressure. The second part involves the psychological treatment of high blood pressure. In the third part, the follow-up phase, people who participated will be seen every 3 months for up to a year for some short tests. After one year, they will have a complete physical and psychological examination.

The psychological treatment being studied in this research is called “biofeedback”. With “biofeedback” people learn to control their blood pressure without drugs by controlling the temperature of their fingertips and feet. **If you do not volunteer to be in this study you could have your high blood pressure treated with drugs or with some other form of therapy.** If you volunteer for this study, you will not receive any medication for your high blood pressure, which is what most people receive as treatment for this condition. So, you could go to a doctor and receive medication or some other form of therapy for your blood pressure if you chose not to participate in this study.

If you volunteer to take part in the first part of the study, you will receive a thorough psychological and physical examination to learn more about your high blood pressure. We will **interview** you briefly about your medical history and your state of mind, give you several **psychological tests** to learn more about your personality and state of mind, and give you a physical examination to learn more about your condition. **We will draw one tube of blood three different times and ask you for two urine samples.** If you volunteer to take part, a skilled lab tech will draw one tube of blood (about two teaspoonfuls). We will draw the

blood during the examination, at one month, and in one year. To draw the blood from you, we will ask you to come back to the CUNY Clinic in 1 month and 1 year.

We will take the urine samples at the CUNY Medical Center during the physical examination and 1 year later. We use the blood tests and the urine samples to find out more about your condition. **We will also do some other tests to learn more about your high blood pressure.**

If you volunteer, we will attach you to a machine to measure your physical reactions. This machine, which is harmless and painless, is similar to the kind of “lie detectors” you see in movies or on TV, but we will not be using it for that; rather, we will be using it to see how you react to different things. While you are attached, we will ask you to do a number of activities: We will ask you to try and relax and to try and control certain responses; We will ask you to perform some arithmetic in your head and to imagine some things which may be related to your high blood pressure; and we will ask you to hold your hand in a mixture of ice and water for 1 ½ minutes.

If you volunteer, we will ask you to keep track of your blood pressure every day and to keep track of your practice of what you have learned. During the first part of the study, we will ask you to keep **daily records** of your blood pressure and return them promptly to the clinic. You will be given a blood pressure gauge to this. **If you are eligible and choose to participate in the treatment part of the study, you will receive psychological treatment for your blood pressure.** We will see you for 16 sessions over an 8 week period of time. During these sessions we will teach you how to control the temperature in your fingers and feet. You will be expected to continue to keep daily records of your blood pressure and practice what you have learned and keep records of it. At the end of the training, you will have another set of physical and psychological examinations, similar to the first part of the study.

If you continue with the follow-up part of the study, you will be tested for up to a year. You will have a **brief examination every 3 months** and a **thorough examination at the end of 1 year.**

There are no major risks in being in this study. In the physical and psychological examinations and laboratory tests **there are no risks greater than those usually associated with this sort of examination.** There are no risks in keeping the daily blood pressure and practice records. In the ice water test you will experience **temporary pain and cold.** Your blood pressure will also go up. You can stop this test at any point. **There are no major risks with the treatment part of the study.** You may feel some temporary strange sensations as you become deeply relaxed, which make you concerned or you may feel frustrated at not being able to control your bodily responses. These are normal reactions; however, you should inform the researcher if either of these occur. **There are small risks with your not being on blood pressure medication** and your blood pressure being high (above 90 mm) during the 14-16 weeks of treatment. These risks include the possibility of heart attack, stroke, or rupture of major blood vessels. The risk of one of these events happening is about 12 chances in 1,000 if

you receive no treatment for your high blood pressure. Based on our previous research, this risk is reduced with treatment to about 4 chances in 1,000. If you did not enter the study but remained on medication, your risk for one of these events is about 1 chance in 1,000.

The study may benefit those who participate. If you participate you may get some benefit from the experience. In the first part of the study you may learn more about yourself and your condition. You may also become eligible for the treatment part of the study. Although we cannot be sure, by participating in the treatment part of the study you may learn how to reduce your blood pressure and decrease your need for medication. **We will guard your confidentiality.** We protect all information about you and your taking part in this study as much as we can. We have trained all staff not to tell anyone outside the study any information about a participant.

We may end your participation for a number of reasons: 1. Your blood pressure rises to dangerous levels; 2. Other physical or psychological problems arise which would interfere with the study; 3. You do not keep accurate records of your blood pressure and practice; 4. You fail to keep appointments and fail to make up missed appointments; or 5. If we feel it is in your best interests for your health.

In case of injury or reactions, call Dr. Ida H. Service at ___ - ___ - ____. If you have an injury or reaction that may be caused by your being in this study, please call Dr. Service immediately. Although the CUNY Clinic and the University do not have a plan for paying the cost of any injury or reaction from the study, they are still fully responsible for what happens and you still have your legal rights. If you have questions about the research, call Dr. Service or write her:

Address (Street, City State, Zip)

You have rights as a research volunteer. Taking part in this study is voluntary. If you do not take part, you will have no penalty and lose no benefits. You may stop taking part in this study at any time. **You may stop taking part at any time**, with no penalty or loss of any benefits to which you are otherwise entitled. If you have any questions about **your rights as a research volunteer**, call or write:

Ed Ethics
CUNY Institutional Review Board
Office for Research
Address (Street, City State, Zip)

Consent Statement: I have read and understood the information above. The researchers have answered all the questions I had to my satisfaction. They gave me a copy of this form. I consent to take part in the Blood Pressure Research Study.

Signature: _____ **Date:** _____,

Witness: _____ **Date:** _____,

(Note: The readability of this Consent Form is 8th grade. There are 72 sentences with an average length of 20 words and only 11% are in the passive voice. The text is 1418 words.)

Sample Consent Form, #2

Background: This consent form is for a survey of sensitive and risky information. Thus, the survey has greater than minimal social risk. The hypothetical research is about domestic violence. Research about stigmatized, incurable, genetic, or sexual diseases, or illegal behavior such as substance abuse or prostitution, all have similar risks. This hypothetical research is in and by a hypothetical Family Crisis Center, serving battered women in a rural reservation community. It provides drop-in counseling services; shelter is provided by a network of Safe Homes. The research is in two phases: (1) use the existing data of the initial care interview by the counselor; and (2) do follow-up interviews at 1 and 6 months. If the data in the first phase were anonymous, the phase could be reviewed under expedited review by using existing data anonymously. However, the researchers want to reinforce the empowerment of the women. Thus, they chose to ask for consent to use even that existing data. The benefits, risks, and management of risks for participating in the research for the potential volunteer are primarily the same as those for the woman going to the Center for help, and had been covered extensively in the discussion between counselor and woman.

Volunteer Consent to a Study about Domestic Violence

The Family Crisis Center asks you to take part in a research study about violence in the homes in this community. The study will help us understand the type and severity of violence that occurs in local homes. The Crisis Center will use the study to plan better programs to prevent domestic violence, and to treat the family victims of violence including children.

We are asking to interview all women seen by the Center. **Please understand that you will always get care by the Family Crisis Center whether or not you agree to take part! If you agree to take part, your counselor will put some of your story into the research.** Neither you nor anyone will be named or identified. You told the counselor your history already. If you agree, she will use the facts of your history for the study. She may ask a few more questions, to complete your history. A doctor will also review your chart for injuries you had that may be related to problems with your partner. **She will also want to talk with you in 1 month and 6 months.** She will ask you how you are doing. You can tell her then what you thought about the Crisis Center, and what should be done to help you and other women, families, and children. She knows that your partner may be angry if he found out you talked with us. So, she will ask you what is the best way to contact you to setup a time to talk. **She will contact you only by the way you want.**

The Family Crisis Center is a safe place to come and talk. **The benefits to you taking part are seeing your counselor on a scheduled basis.** She will help you think through your situation, like she did today. You both can discuss your needs then; she may suggest programs or people that can help you then. **If you take part, however, the main benefit is to the**

community. The Crisis Center will use the results of the survey to improve programs to help families, women, children, and partners in need. You and your family are not alone! More than 1 out of every 5 families has suffered violence. **You may experience discomfort by taking part.** The Family Crisis Center has tried to prevent any risk to you. You and the counselor have already talked about things full of emotion for you. In her talk with you in 1 and 6 months, she will listen and spend as much time with you as you want. Most women feel better after talking like that.

No one in the Center tells anyone who has come here to talk or for help. If your partner finds out from others that you were here and asks you what you did, you can say we gave you help about “**women's issues**”; they included child care and transportation to the Clinic.

We will give a list of services and people to call for help about violence in the home. To avoid making any woman's partner angry, that list contains other numbers and programs as well. In fact, it is a list of every social program in the community. There is no sign that the list is related to violence in the home.

You do not have to sign a volunteer consent form to take part. You can agree to take part just by telling us, if you want. You can take a copy of this volunteer consent form with you, but we suggest you do not, to avoid triggering violence by your partner.

The Family Crisis Center has tried to make sure no one else can know what you say. Your name is not on the study form with your answers. Only a space code number is there. Your counselor will keep your code number and name locked up with the Center's records. For even more protection, the Crisis Center also has a Certificate of Confidentiality from the federal government. It was made to protect all information from disclosure, even that ordered by a court, without your written consent. That is, it was made to keep the information private or confidential, like your medical records.

No reports about the survey will contain your name or the name of any volunteer in the study. If you tell the counselor that someone, you or your children, is in danger of great physical harm, she will tell the Clinic to provide protection. The same thing would happen if you gave the same information to a doctor, nurse, or counselor in the Clinic. **Taking part is voluntary.** If you do not take part, you will lose no benefits or services from the Family Crisis Center, or anyone else. The Crisis Center will continue to give you help. You may refuse to answer any question, but we hope you answer as many questions as you can. You may also refuse to take part in the interviews at 1 month and 6 months from now, but we hope you will take part then.

If you have questions about this study, please contact **Mary Doeswell, phone ____ - ____**, or in her office at the Center.

If you have questions about your rights as a volunteer, please contact Ed Ethics CUNY Institutional Review Board (Street, City, State, Zip) (telephone ____ - ____ - ____). Thank you for helping build a better community for all families.

I agree to take part in the Family Crisis Center study about violence in the home. My questions have been answered. I will continue to receive help by the Center whether I agree to take part or not. I may refuse to answer any question I want. I have received a list of helping programs and people, and their telephone numbers.

(Note: The readability of this Consent Form is 8th grade. The text is only 978 words, yet it meets all requirements for Consent Forms for complex research that is greater than minimal social risk.)

Sample Consent Form, #3

Background: This consent form might be used for an innocuous experiment on normal adult behavior. Thus, the research would be no more than minimal risk. Even though a signed consent form is not required in this type of research, the subjects must still be given the same information that they would receive in a consent form. This information should be presented orally and/or in an instruction sheet given to the subjects.

Pattern Recognition Study

Researchers at CUNY are asking you to take part in a study on pattern recognition.

The researchers want to know how people recognize patterns, that is, how they can tell that they have seen a pattern before.

If you choose to take part, we will ask you to look at some patterns on a computer screen. You will see two patterns at a time. The patterns will be of differing colors. We will ask you to pay attention to only one of the color patterns. After you have seen all of the patterns, we will show you some more patterns and ask if you have seen any of them before.

Your responses to all of the questions will remain confidential.

We will not ask you to put your name on any of the response sheets.

Taking part is voluntary.

If you choose not to take part, there will be no penalty and you will receive the credit anyway. You may choose to stop at any time.

If you have questions about the study, please ask the experimenter or contact **Mary Doeswell at CUNY, phone ___ - ___**.

If you have questions about your rights as a volunteer, please contact **Ed Ethics**, Chair, CUNY IRB. Call him at ___ - ___ or visit him at (departmental office).

(Note: The readability of this Consent Form is 8th. grade. The text is only 226 words and ½ of a page, yet it meets all requirements for Consent Forms.)

Sample Consent Form, #4

Background: This consent form might be used for an anonymous survey of adults in which no sensitive information is sought. Thus, the research would be no more than minimal risk. Even though a signed consent form is not required in this type of research, the subjects must still be given the same information that they would receive in a consent form. This information should be presented in an instruction sheet attached to survey.

Health Care Research Study

Researchers at CUNY are asking you to fill out a survey about what services CUNY Clinic patients need. The Researchers want to know what Clinic patients think about the health care services they are receiving and what other services they might need. We will use the results of the survey to plan for better health care services for everyone.

We are asking all adult patients seen by the CUNY Clinic, and parents of children, to fill out the form. There are no risks to you in taking part, because we are not asking for any names and no one can know who filled out a form. It takes about 10 minutes to finish. **Taking part is voluntary.** If you choose not to fill out the survey, there will be no penalty and it will not affect any services or other benefits you might receive from CUNY Clinic. If you do fill out the survey, you may leave any question blank, but we ask you to answer as many questions as you can.

If you have questions about the survey, please contact **Mary Doeswell** at CUNY, phone ____-____.

If you have questions about your rights as a volunteer, please contact **Ed Ethics**, Chair, CUNY IRB. Call him at ____-____ or visit him at (departmental office). Please leave the survey form in the boxes by pharmacy, lab, or medical records.

Please take this cover sheet of explanation with you. Medical records and Mary Doeswell also have copies of the cover sheet and survey.

(Note: The readability of this Consent Form is 8th. grade. The test is only 265 words and 2/3 of a page, yet it meets all requirements for Consent Forms.)

ACKNOWLEDGMENTS

These sample consent forms were developed by Dr. Jeffrey Cohen of SUNY Albany, who granted his permission for their use. They were based, in part, on information from the following sources: The IRB Guidebook, Prepared by The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Levine, Robert J. Ethics and Regulation of Clinical Research, Urban; Schwarzenberg, Baltimore-Munich, 1981. "Sample Volunteer Consent Forms." Prepared by the Indian Health Service (William L. Freeman, MD, MPH, Chair, National IHS IRB)

