

APPLICATION INSTRUCTIONS  
INSTITUTIONAL REVIEW BOARD

### **The IRB Proposal Includes:**

1. All documents, other than the informed consent form, should be understandable to an informed lay-person (ie, the non-clinician/non-scientist members of the board should be able to understand the documents without reference to outside assistance).
2. A brief (10 page maximum, 12 pt. Times New Roman, 1” margins) description of the scientific background, and merits, of the proposal project.
3. A full description of all research procedures and devices, providing reference to the literature when appropriate.
4. A full reference bibliography.
5. A brief CV (2 page maximum) for each major research participant in the study. The CV should clearly outline the expertise this person brings to the project, and the qualifications of this person to perform any specialized task.
6. If applicable, an Informed Consent form that summarizes the research purposes and procedures in simple language (6<sup>th</sup> grade reading level).
7. If applicable, a HIPAA Research Authorization form that authorizes the use and disclosure of protected health information.
8. If applicable, any text for subject recruitment/advertising. (e.g. brochures, flyers, radio ads, etc.)

### **The Researcher's responsibility includes:**

1. Providing a written annual report of research progress, and/or a final report. The annual report constitutes an application for a one-year extension of the research application. The report must include 2 copies of recent subject consent forms, a description of any adverse subject reactions that may have occurred during the study period, and the actions you took to address those reactions.
2. Depending upon the nature of the research project, and its potential hazards or benefits, the IRB may require reports on a more frequent basis.
3. Prompt notification of any change in research methods, procedures, and key personnel. This notification must be accompanied by an appropriately revised IRB application and IRB Amendment Form.
4. Prompt notification about subjects that reacted negatively to the research procedure. Not every adverse reaction needs to be reported immediately, only the severe or unexpected ones. As a general guideline, you should report to the IRB
  - (A) Anytime a subject has a strong negative reaction to the research procedure, whether or not this type of reaction was listed as a potential negative side effect in the informed consent form. A strong negative reaction includes anything which causes a reasonable concern about the health and welfare of the subject.
  - (B) Anytime a subject specifically contacts you about a negative reaction to the research procedure (no matter how minor this reaction may seem).
  - (C) Anytime a subject exhibits a negative reaction that was not documented as a possible side effect in the original IRB proposal.
5. The researcher must allow the subject a minimum of 24 hours to read, and review, the informed consent form before data collection begins. The requirement will be waived only when the IRB is convinced that it would seriously undermine the goals of the research project without creating unacceptable risk for the subjects.
6. The researcher must keep all consent forms on file, and available for inspection, for a period of at least three years from the date of the last data collection.
7. The researcher must make all current research results available for inspection by the IRB, or its appointed representatives, while data is being collected.
8. The researcher must allow on site inspection of the laboratory, data, and data collection procedures by the IRB, or its appointed representatives.

*\*This document will be sent to the Investigator when his/her protocol has been approved. A copy must be signed by the investigator and returned to the Research Office.\**

INSTRUCTIONS FOR SUBMITTING A PROTOCOL  
TO THE INSTITUTIONAL REVIEW BOARD (IRB)

FULL REVIEW

1. Complete the attached GENERAL INFORMATION SHEET. This form must be typed. The space on the top of the page is for IRB use only. The IRB number will be assigned upon submission of the application.
2. Prepare a description of the research protocol by answering the questions which are listed on the attached RESEARCH DESCRIPTION INSTRUCTIONS SHEET. Each response should be numbered to correspond with the applicable question. PLEASE NOTE: THE RESEARCH DESCRIPTION SHOULD NOT EXCEED 10 PAGES, WITH 1" MARGINS, 12 PT. TIMES NEW ROMAN FONT
3. Read carefully the INSTRUCTIONS FOR DOCUMENTATION OF INFORMED CONSENT. Using the sample format, submit the consent form that you propose to use.
4. If the research is part of a National Institutes of Health (NIH) MULTICENTER CLINICAL TRIAL, NIH requires that the local IRB receive a copy of the NIH-approved sample informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the investigator and approved by the IRB. For trials sponsored by the National Cancer Institute (NCI), investigators must forward copies of such IRB-approved changes, with their justifications, to the appropriate Cooperative Group headquarters. The NIH-approved consent document and any justification for changes in the Risks and/or Alternatives sections should be submitted as part of the application packet.
5. If your research project involves subjects under the age of 18, read carefully the DESCRIPTION OF REQUIREMENTS FOR RESEARCH INVOLVING CHILDREN which is attached. If appropriate, submit the assent form that you propose to use. (Please remember that this document should be written in language easily understood by children.)
6. If the research project involves the use of approved drugs, investigational new drug(s) or an approved drug for an unapproved use, complete the DRUG INFORMATION FORM.
7. If the research project involves the use of investigational new device(s), complete the DEVICE INFORMATION FORM.
8. If the research project involves the use of radioactive materials, complete the RADIATION SAFETY INFORMATION FORM.
9. If prisoners are to be included as subjects in the research project, notify a Research Subjects Office staff member. The federal regulations have special membership requirements with which the IRB must comply when reviewing research involving prisoners.
10. If subjects from other organizations external to New York Chiropractic College are to be recruited for the study, written approval should be obtained from an authorized official of that institution. (A statement of any preliminary contacts with the appropriate officials should be attached to the materials submitted for review.)
11. If the research project is to be submitted to either an external or internal funding source, two copies of the grant, contract proposal, or device protocol should be submitted to the IRB OR if the research involves the administration of drugs, three copies of the detailed drug research protocol and three copies of the physician's brochure (if applicable) must be submitted to the IRB.
12. If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales must be included in the application. (NOTE: If standardized scales and/or questionnaires are to be used, submit two copies to the IRB.)
13. Obtain the appropriate signatures as specified on the SIGNATURE ASSURANCE SHEET. If the principal investigator is also the director of the department, the dean or equivalent should review and sign the signature assurance sheet.
14. Before submitting the research protocol application to the IRB, the requested information **MUST BE COLLATED** in the following order:
  - a. General Information Sheet
  - b. Research Description Summary
  - c. Informed Consent Form
  - d. NIH-Approved Sample Informed Consent Document, if applicable
  - e. Assent Form, if applicable

- f. Instrument to be used for data collection, if applicable (e.g., questionnaire, interview questions or assessment scales)
  - g. Drug Information Form, if applicable
  - h. Device Information Form, if applicable
  - i. Radiation Safety Form, if applicable
  - j. Signature Assurance Sheet
  - k. HIPAA Research Authorization Form, if applicable
15. Submit the following collated materials to the Research Department Office.
- a. 2 (two) copies of the IRB Research Protocol (See #14 above for a description of items to be included in the Research Protocol. Note that in an effort to decrease the number of pages, the investigator is encouraged to submit two-sided copies, if at all possible.)
  - b. 2 (two) copies of the grant, contract, or device proposal, if the protocol does not involve administration of drugs
  - c. 3 (three) copies of the detailed drug protocol and physician's brochure, if the protocol involves administration of drugs.
  - d. 1 (one) Electronic version sent to the IRB administrative assistant (asimolo@nycc.edu)

Please note that the IRB meets on a monthly basis. Protocols should be submitted two weeks before a scheduled IRB meeting. Protocols are assigned on a "first come, first served" basis and will be placed on the next available agenda. You are encouraged to submit your protocol as early as possible. Investigators are encouraged to submit their applications by NOON on the submission deadline.

Full reviews require that the Principal Investigator (PI), or a representative knowledgeable in the protocol, attend the meeting at which the application is reviewed. A review date will be assigned to the protocol at the time of submission. If the PI is not available on this date, this should be made clear to staff of the Research Subjects Office at the time of submission.

Note that incomplete IRB applications will not be scheduled for review but returned to the PI.

If you have questions concerning submission of a research protocol for IRB review, please call the Research Department Office at (315) 568-3868.

## INSTRUCTIONS FOR DOCUMENTATION OF INFORMED CONSENT

Informed consent is one of the primary ethical considerations underlying research with human subjects. It is too often forgotten that informed consent is an ongoing educational process that takes place between the investigator and prospective subject; it is not just a piece of paper that must be signed. Nevertheless, in most cases the federal regulations require that informed consent be documented. It should be reiterated, however, that the consent document does not substitute for discussion or subjects' education.

Below are instructions for preparing the written consent form. Please follow the instructions carefully.

1. Use the standardized consent form in your application packet. Items with asterisks may be deleted if not applicable
2. The language in the form should be aimed at a sixth-grade reading level. Do not use medical or technical jargon.
3. In addition to the information included on the standardized form, when appropriate, one or more of the following items should be included on the consent form:
  - a. Anticipated circumstances under which the subjects' PARTICIPATION may be TERMINATED by the investigator without regard to the subject's consent.
  - b. The CONSEQUENCES of a subject's decision to WITHDRAW from the research, and procedures for orderly termination of participation by the subject.
  - c. The APPROXIMATE NUMBER OF SUBJECTS involved in the study
4. If the RESEARCH INVOLVES THE PARTICIPATION OF MINORS (under 18 years of age), please read the "Description of Requirements for Research Involving Children". Additional requirements concerning the parental consent forms and children assent forms are discussed.
5. If the RESEARCH ACTIVITIES ARE DIRECTED TOWARD PREGNANT WOMEN, both the mother and father must give consent after having been fully informed regarding the impact of the research on the fetus. (NOTE: the federal regulations do specify certain conditions under which the father's consent is not necessary. For a list of those conditions contact the Research Department.)
6. If the RESEARCH COULD POSSIBLY PUT AT RISK (1) AN UNBORN CHILD, (2) A MAN OR WOMAN'S ABILITY TO PROCREATE, (3) A WOMAN'S ABILITY TO CONCEIVE OR CARRY A CHILD, the following statement(s) (revised to meet the needs of your particular study) should be included in the consent form.
  - a. "If I am pregnant, I cannot participate in this study. If I am a woman who could have children, it will be necessary to have a urine (or serum) test to see if I am pregnant before I start this study. If I am a sexually-active male or female, I agree to take precautions to avoid the possibility of impregnation because it is not known how this drug (treatment, device, etc.) will affect an unborn child. If I am a woman and become pregnant during the course of this study, I will notify the principal investigator of this fact as soon as possible."
7. If the research is part of an NIH-sponsored multicenter clinical trial, a copy of the NIH-approved sample informed consent document must be included in the application packet.
8. For research involving HIV screening and/or AIDS research, there are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Contact the Research Office at (315) 568-3868.