Work closely with the UCHC faculty member who will serve as the principal investigator. (PI must also have completed training in human subject protections.)

Prepare and submit the informed consent form using the sample ICF for guidance and the ICF checklist, or submit the form, with the questions thoroughly answered, to request a waiver or alteration to consent.

Prepare and submit the appropriate HIPAA document. For international studies, if identifiable data will be brought to the UCHC, execute a HIPAA Authorization, if only de-identified data will be brought back execute a certificate of using de-identified data.

If you state that data is de-identified or anonymous, **do not link** pre and post data **with assigned codes**. An acceptable way to link pre and post data is for the subjects to create and retain their own code. Subjects must be instructed that the code cannot be comprised of any of the HIPAA identifiers. At no point during the conduct of the study can the researcher know what code is linked to what individual, nor can the researcher ever re-establish that link, e.g. a master file linking codes and names cannot be maintained by anyone on the research team.

When applicable, **indicate plans and provide documents** to obtain consent of the parent and assent of the child when minors are to be involved in the study.

When applicable, **obtain and submit School Board approval** for studies that will be conducted within school systems.

When applicable**, provide** the IRB **translated versions** of documents for review and approval *prior to use*. Use either a professional translation service or back-translation.

For studies to be conducted in foreign countries, **submit proof** that an individual from that country possessing appropriate expertise has reviewed the proposed study and found the content and design acceptable for the local culture.

IRB Review

All research involving human subjects must be approved by the IRB **before** it is initiated. Applications may be reviewed under one of the following three review categories. The investigator may request a specific type of review but the IRB makes the final determination.

Full Board Review: Protocols are reviewed by the full board when the study involves greater than minimal risk to a population of voluntary participants. Protocols must continue to be reviewed by the Board at least annually.

Most student projects will qualify for expedited review or exempt status. The IRB will make that determination. Expedited review means that only one IRB member is required to review the application, it **does not** mean a faster response time.

Expedited Review: This typically is granted when there exists no more than a minimal risk to subjects and the research falls into a specified category described in federal guidance. Protocols must continue to be reviewed by the Board at least annually. Categories of research that may qualify for expedited review are listed on the IRB website.

Exempt Review: After initial review, the IRB may provide exemption from further review t. This is usually limited to research designed to examine, existing records, laboratory / pathological specimens, or research involving educational tests surveys and questionnaires. Categories of research that may qualify for exempt status are listed on the IRB website.

Questions or concerns related to human subject research should be directed to:

Institutional Review Board Office
Phone: 860-679-1019
860-679-4851
860-679-4849
Fax: 860-679-1005

For more information on IRB policies and requirements, and to obtain the required forms, visit the IRB web site at:
http://research.uh.uconn.edu

UConn Health Center

Human Subjects Protections Office

&

Institutional Review Board Office

Student Brochure

Remarkable Care Through Research and Education

Ethics in Human Subject Research - Belmont Report

All research involving human subjects carried out by Health Center staff and students must be conducted in accordance with the ethical principles set forth in the Belmont Report and described below.

Autonomy means that the decision of each person of whether or not to participate in research must be respected. Decisions are to be free from coercive elements or undue influence.

Beneficence obligates the researcher to minimize potential harms in a research design while maximizing potential benefits.

Justice requires that the burdens and benefits of human subjects research are distributed fairly among various populations.

The Common Rule Regulation

Federal law (45 CFR 46, known as the Common Rule) mandates that the IRB review and approve any research involving human subjects **prior** to it being initiated. Legally effective informed consent must be obtained from study participants, or the IRB must approve a request to waive or alter the requirements of informed consent.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information, e.g. chart reviews.

Research is defined as a **systematic investigation**, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**.

Therefore, if you **definitely** will not be publishing or presenting results outside of the UCHC, and you are not using identifiable protected health information (defined in the next section) you may not need IRB approval. **Check** with your advisor and / or the IRB if you have any questions. A Master or Doctoral Thesis involving human subject research does require IRB review. Practicum and Selective projects require IRB review if there is **any chance** of publication or presentation.

While the Common Rule may be the most relevant regulation, there are also other regulations governing human subject research, e.g. HIPAA and FDA regulations. Students should also be familiar with internal policies of the IRB which are available on the web site noted on the back of this brochure.

The provisions of the Common Rule generally do apply to research conducted in foreign countries.

The HIPAA Regulation

The Health Insurance Portability and Accountability Act (HIPAA) is a regulation governing privacy issues. Any research project using identifiable protected health information (phi) must comply with HIPAA. Information is considered identifiable if it contains **any** of the following information:

Name	Health Plan #s
E-mail	Medical Record #
URLs	Social Security #
IP Address	Geographic Subdivisions (e.g. Zip)
Phone #s	Dates (except year)
Fax #s	Vehicle Identifiers
Serial #s	Biometric Identifiers
License #s	Device Identifiers
Account #s	Any other unique identifier

Health information pertains to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.

In general, if obtaining informed consent you should execute a HIPAA Authorization form if phi is involved. If you have requested a waiver of informed consent you will generally submit either the form to certify use of de-identified data (i.e. none of the identifiers listed above are included) or the form to request a waiver of HIPAA authorization. If you must retain some identifiers, e.g. from a chart review, but you cannot obtain a HIPAA authorization, you will generally submit the form to request a waiver of HIPAA authorization.

A chart review is an example of a study for which the requirement to obtain informed consent and, if identifiers will be retained, the requirement to obtain a HIPAA authorization might be waived.

Human Subject Research Training Requirement

All investigators and key study personnel must complete training in human subject protections before becoming involved with a study. Information on how to satisfy this training requirement is available on the IRB web site noted on the back of this brochure.

Tips For Students

When preparing an application for the UCHC IRB:

Submit early to allow time for clarification of issues or for full board review if necessary, e.g. if sensitive topics such as drug use or sexual behaviors are involved.

Submit the application checklist with the application.

Answer all questions on the application thoroughly and clearly. Plans for the project, including recruitment strategies, should be well thought out by the time of IRB submission.

Check your student e-mail account for messages from the IRB.

Complete the training in Human subjects prior to submission to the IRB.

Provide a protocol in addition to the abstract asked for within the application. The protocol should describe the entire study, e.g. background information, the hypothesis, the study design, the methods of analysis, references etc.

Submit final versions of survey / interview documents. In the protocol design, **indicate** that the survey or interview forms may have to be "fine tuned" in the field. This allows for minor changes without additional IRB approval. The fine tuned versions must be submitted to the IRB Office for the file with an explanation of the changes. (Major changes need IRB approval prior to use.)

(Tips continued on back.)