

# INSTITUTIONAL REVIEW BOARD PROCEDURES

(Mari Castañeda, Dept of Communication Human Subjects Review Chair, 20092010)

## I. What needs to be reviewed?

All research that involves interacting or intervening with humans needs to undergo review. (Research by undergraduates as part of a class does NOT generally need to be reviewed unless there is “High Risk” involved). For further info – <http://www.umass.edu/research/comply/Guidelines/studentinfo.htm> Applicants are also required to complete the Institutional Training Requirement for the Protection of Human Subjects in Research (CITI). This training is approx 2 hours, only done once, and located online. For free registration visit <http://www.umass.edu/research/comply/citi.html>

## II. Who reviews my human subjects materials?

Reviewed by Departmental Human Subjects Review Committee:

- Faculty research that is not funded by a grant
- Graduate student research (regardless of whether it is part of a course or is a dissertation or thesis project) that is not funded by a grant
- Undergraduate Honors theses or class projects with High Risk

Reviewed by the University Institutional Review Board:

- Research done by faculty members that is funded
- Research done by graduate students that is grant funded
- Any research by faculty and graduate students that is High Risk must also attain University IRB approval
- Please plan accordingly since IRB approval takes 46 weeks

## III. What is the process for review?

Submit the following four items to Professor Castañeda (forms are included in this document):

- 1 Registration Form for Human Subjects Research, including CITI Completion Report.
- 2 Form 441 – On this form, please detail the characteristics of the population you are studying, the risks and benefits of their participation in the research, the necessity of the research, the means by which you will protect their identities, and your short and long term projected uses of the data.
- 3 A highly detailed informed consent form, complete with elements required by the University (For further info <http://www.umass.edu/research/comply/ICinstructions.doc> // For templates <http://www.umass.edu/research/comply/ICtemplate.doc> <http://www.umass.edu/research/comply/assentsamples.doc>

## IV. When will I receive final approval?

Within two weeks, the department level committee will send you a request for changes / revisions or acknowledgment of approval via the Registration Form for Un-sponsored Human Subjects Research. For further info visit <http://www.umass.edu/research/comply/faqshuman.html#02> or email [mari@comm.umass.edu](mailto:mari@comm.umass.edu)

DEPARTMENT OF COMMUNICATION HUMAN  
SUBJECT'S / IRB REGISTRATION FORM

PI Name:

Advisor's Name:

Contact Information:

Is this research funded by outside sources? If so, please list:

Date of completion of online Collaborative IRB Training Initiative (CITI): (Please submit a copy of Course Completion Report or certificate with this application. This is also required for undergraduates conducting research for their Honors Thesis).

TITLE OF PROJECT:

ABSTRACT OF RESEARCH DESIGN:

IRB Approved by: Date: Comments:

DEPARTMENT OF HEALTH, EDUCATION, AND  
WELFARE PUBLIC HEALTH SERVICE ALCOHOL, DRUG ABUSE,  
AND MENTAL HEALTH ADMINISTRATION

PROTECTION OF HUMAN SUBJECTS  
(For Completion by Investigator)

INSTRUCTIONS

"Protection of Human Subjects" is a form that has grown out of our deep concern for human rights and dignity and is intended to provide the reviewers of your proposal with a detailed guide for the evaluation of your project which involves human beings.

The information requested serves as a basis for understanding the methodologies to be used, the precautions to be taken, and the risks involved to the subjects. "An individual is considered to be 'at risk' if he may be exposed to the possibility of harm physical, psychological, sociological [legal], or other as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs" (DHEW Grants Administration Manual).

This form is divided into six (6) categories which basically are using the data. This category also applies if you are using self-explanatory. However, the following examples serve data collected by other investigators. as rationale for the requested information and may assist you in completing the form.

1. CHARACTERISTICS OF GROUP(S) INVOLVED 5. POSSIBLE RISKS INVOLVED

This information serves as a basis by which the reviewers of You are particularly urged to complete this section carefully your project can determine the risks to the subject(s) to be if you foresee any risks whatsoever to human subjects, studied. For example, certain psychological experiments namely, physical, psychological, sociological, legal, or could cause loss of selfesteem in older children, but no such other. loss in younger ones, or they could also cause anxieties in institutionalized persons but not in normal groups. Data as 6. NONBENEFICIAL RESEARCH well as direct involvement of subjects should be considered. Therefore, this information is necessary for assessing the full "NonBeneficial Research" is defined as research involving extent of possible risks. Physiological and psychological investigations of a person,

his body or surroundings, which is devoid of therapeutic

2. SPECIAL GROUPS purpose to that person.

Complete this category if other than "normal" adult groups, This category provides the reviewer with information as to such as children or mentally incompetent will be used as subjects. the reasoning for the use of specific individual(s) and subjects. Whether alternatives were explored.

3. TYPE OF CONSENT In each of the six (6) categories please insert your responses

under each item. If you need additional space, a separate Please be explicit as to the manner in which consent will be sheet will suffice. Please be as explicit as possible in your obtained from subjects. Be especially explicit for minors responses. If there are any questions or comments you and other special groups. would like to make regarding the contents of this form, feel

free to do so on a separate sheet. After you have completed

4. CONFIDENTIALITY OF DATA the form please sign and return to:

This category deals with the safeguarding of data to be collected. Consider both your procedures for protecting confidentiality as well as others that may at some time be

The information contained in the form will be evaluated as a whole determining the adequacy of protection of Human Subjects in your proposal. No ONE answer or any ONE variable will provide immediate acceptance, or rejection of a project. Rather, the questions are designed to assure that relevant factors are considered for safeguarding the rights and welfare of Human Subjects involved in activities supported by grants and contracts from the Alcohol, Drug Abuse, and Mental Health Administration.

PROTECTION OF HUMAN SUBJECTS

PROJECT TITLE:	PROJECT NO.
CHARACTERISTICS OF GROUP(S):	Describe the characteristics of the group(s) to be used: (If additional space is needed for an item, use a separate sheet) a) Sex, race or ethnic group, age range, etc. b) Affiliation of subjects, e.g., institutions, hospitals, general public, etc. c) Subjects' general state of health (mental and physical)
SPECIAL GROUPS:	If human subjects are either children, mentally incompetent, or legally restricted groups give explanation as to: a) The necessity for using these particular groups a) Why adult "normal" groups cannot be used (specifically)
TYPE OF CONSENT:	What precautionary measures will be taken to insure the protection of human subjects on physical, psychological, social, legal and other issues? a) Type of consent to be obtained (written or oral)  b) How and where will permission be recorded? c) If subjects are minors or mentally incompetent, describe how and by whom permission will be granted?
CONFIDENTIALITY OF DATA:	What precautions will be taken to safeguard identifiable records of individuals? These questions also apply if you are using secondary sources of data. a) Consider the long range use of data (by you and others) b) Immediate use of data (by you and others) c) Describe specific procedures to be used to provide confidentiality of data



<p>RISKS TO SUBJECTS:</p>	<p>Describe in detail any physical, psychological, social, legal, economic, or other risks you can foresee, both immediate and long range: a) Immediate risks b) Long range</p> <p>c) Rationale for the necessity of such risks d) Alternatives that were or will be considered</p> <p>e) Why alternatives may not be feasible</p>
<p>NON-BENEFICIAL RESEARCH:</p>	<p>"NonBeneficial Research" is defined as research involving physiological and psychological investigations of a person, his body or surroundings, which is devoid of therapeutic purpose to that person. If you plan to conduct this type of research and feel that there are no other methods available for obtaining the information needed, please describe: a) What other methods were or will be explored</p> <p>b) The extent of the risks (Describe in detail any physical, psychological, social, legal, and other risks you can foresee, both immediate and long range) c) The importance of the knowledge to be gained d) Why do you feel that the value of information to be gained outweighs the risks</p>
<p>ADDITIONAL COMMENTS:</p>	
<p>PI SIGNATURE *Students must have a faculty sponsor (PI) STUDENT SIGNATURE (IF APPLICABLE) DATE</p>	

Please attached additional information, such as survey samples: