Ph.D. Instructions for Securing Approval of Human Subjects Research

All members of the Fletcher community who are dealing with Human Subjects data or who are observing or interviewing human subjects for a thesis, dissertation or other research agenda need approval from the University’s Institutional Review board (IRB) which in many cases may be secured via Fletcher’s IRB representative in the manner described below. IRB approval and/or review is not optional if humans are the subject of research. Failure to comply with U.S. government regulations could result in the loss of federal funding to the University and potential problems in publication for investigators.

1. Please read these instructions to see if your research is classified as Human Subjects Research (HSR). According to federal guidelines, a Human Subject is “an individual about whom an investigator … conducting research obtains
   (a) data through intervention or interaction with the individual, or
   (b) identifiable private information.”
Research is defined as “A systematic investigation designed to develop or contribute to generalizable knowledge.” (If you are not sure your study is HSR, see faculty advisor.)

2. If the above definitions do not apply, then your work is not HSR and no further action is required on your part.

3. If you are conducting HSR, but think you are eligible for an exemption under the categories in “Exemptions from IRB Review”, complete the Fletcher Human Subjects Review Exemption Form noting the exemption number which applies to you, and attach a research description and oral consent script, and CITI Education Module form. If your request for exemption is approved you will be notified by email; no further action on your part is required.

4. If any one of your answers to questions #2-4 of the HSR Exemption Form is “yes,” or your request for exemption is not approved, you must complete the Tufts IRB Protocol Application (6 pages) and IRB Cover Sheet (2 pgs) Forms (asking for either “expedited” (one IRB member reviews it) or “full” (full IRB Board reviews it) and complete the required CITI Education Module (all 13 modules of the SBER choice) at http://www.tufts.edu/central/research/IRB/Forms.htm

Please see http://fletcher.tufts.edu/IRB website for IRB forms and sample cases.
Exemptions from IRB Review

If you believe that you might qualify for an exemption from HSR, you must request the exemption. The Code of Federal Regulations sets out the following situations where research may be exempted from regular IRB review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. An example of this would be a comparison of the effectiveness of two generally accepted instructional strategies.

2. Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior UNLESS the information is recorded in a manner in which the subject can be identified AND disclosure would place the subject at risk of criminal or civil liability or be damaging to financial standing, employability, or reputation. This does not apply where the subjects are children except where it involves passive observation of public behavior.

3. Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior where subjects are elected or appointed officials or candidates for public office.

4. Research involving the collection or study of EXISTING data, documents, records, or specimens if the sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers or codes. (Note: Even brief use of identifier or code disqualifies the exemption.)

5. Research and demonstration programs designed to study, evaluate, or examine Federal public benefit or service programs

6. Taste and food quality evaluation and consumer acceptance studies involving wholesome foods without additives or with additives or chemicals below established "safe" levels.

**Human Subjects Review Exemption Form**

(Research must be “minimal risk” to qualify for exempt status. This means probability of discomfort or risk, anticipated in research is not greater than that ordinarily encountered in daily life or during routine tests. Risk can include physical or emotional harm, as well as loss of reputation or risk of financial harm.)

1. I believe that my research is exempt from human subjects review due to exemption # __ (see Exemption from IRB Review list on p. 2).

2. I am interviewing and/or observing pregnant women, children under the age of 18, and/or prisoners. YES ____ NO ____

3. I will be using deception (not giving subjects’ complete information or giving misleading information) to conduct my interviews. Yes ____ No ____

4. I will be conducting experiments on the population that may have adverse physical, psycho/sociological, political and/or economic impact. YES ____ NO ____

(If your answer to questions 2-4 is “Yes”, you are not eligible for exempt review and must complete the Tufts IRB Protocol Application and Cover Sheet (see Page 1)

If answers to questions 2 to 4 are “No”, please attach your “Research Description” (at least one page) that includes information on background, objectives, subject population and number, recruitment process, description of how research will be conducted, how confidentiality will be maintained (and if not, why it is not necessary), justification for exemption and why risk to participants is minimal, benefits to participants and to society (if any), conflicts of interest (if any) and explanation of where data will be stored (and if it is identifiable, whether identifiers will be stored with or separate from the data as well as when identifiers would be destroyed) and who will have access to it. Attach any questionnaires, interview instruments, recruitment documents, that will be used in English and for lang.

An official “Written Consent Form” is not required for exempt studies. Just write a paragraph or two explaining the oral consent process. This “informed consent” statement should explain to participants in simple English the purpose of study, procedures, any repercussions and what they’ll be required to do. It should explicitly state that participation is voluntary. Attach foreign language translation if oral consent is not in English.

Is your study funded? Yes ____ No ____ If, yes, have you filed “Conflict of Interest Disclosure” form with the Vice Provost’s Office? __Yes __No __ Not applicable

Return this form to Jenifer Burckett-Picker (for PhD students) Date: _____ Your name: ______________________(typed) __________________ (signature)

Program: PhD _____ MALD _____ MA ____ GMAP ____ Faculty ____

Thesis/dissertation advisor: ______________________(typed) __________________ (signature)

Title of research _____________________________________________________

Research is for:  Dissertation ____ Thesis ____ Other (explain) _________________

Approved:  JBP Signature: ________________________ Date ______

Not Approved: reason/action to take

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