

Purpose, Policies and Procedures of the Department of Economics Human Subjects Committee

(September 10, 2004)

Committee Purposes

The Department of Economics Human Subjects Committee (HSC) exists for two purposes:

1. According to “Policies and Procedures of the Committee for the Protection of Human Subjects” by the CSUS Office of Research and Sponsored Projects, “departments in which a significant number of students are engaged in human subjects research [...] are expected to have a department-level committee to review such research” (pp. 4, 5). This department committee will review all research proposals submitted by economics students to assure compliance with federal and university human subjects policies.
2. We also intend to educate economics students that conduct research involving human subjects on these policies and how to navigate the proposal process.

This committee’s activities do not include any oversight of faculty research. Faculty research proposals that include human subjects bypass this committee and go directly to the university-wide Committee for the Protection of Human Subjects (CPHS).

Committee Policies and Procedures

The HSC procedures will be as follows:

1. Students fill out 4 copies of the “Request for Review by the CSUS Committee for the Protection of Human Subjects” form. This form can be found on the Department of Economics website or on the Office of Research and Sponsored Projects website.
2. Students also fill out 4 copies of a departmental “Request for Review” form. This sheet distills the relevant information into one page and provides space for the HSC to approve the research or specify reasons for not doing so. They can find this form on the Department of Economics website.
3. Students submit all copies of their paperwork (including four copies of all attachments to their forms) to the chair of the HSC no later than 1 week prior to a regularly scheduled HSC meeting.
4. The copies will be distributed to the HSC members who will review them independently before the committee meeting and then discuss them at the committee meeting.
5. Proposals will be evaluated on the following five criteria:
 - a) Is the research covered by CPHS policies (see page 2 of “Policies and Procedures of the Committee for the Protection of Human Subjects”)? If not, the proposal does not need HSC approval.
 - b) Are members of vulnerable populations (including minors, prisoners, pregnant women, fetuses, and others who are unlikely to give uncoerced and informed consent) involved in the research project?
 - c) Are the protocols adequately explained?

- d) Can the project be classified as “exempt” or “no risk” by standards set forth on page 6 in “Policies and Procedures of the Committee for the Protection of Human Subjects?”
 - e) Does the project pose any risk to the researcher?
6. Depending on the committee’s decision, the student will receive one of four letters.

Decision-Making Rules

(see page 6 of “Policies and Procedures of the Committee for the Protection of Human Subjects” for the definitions of the different levels of risk)

1. If the research is neither considered “exempt” nor “no risk” or if it involves members of vulnerable populations, then the committee will neither approve nor disapprove a proposal, but rather forward it to the CPHS for a decision (a copy will be kept on file in the department). If revisions or clarifications by the student are necessary then the committee will send a “Departmental Revise and Resubmit” letter (see rule 2 below) to the student before it forwards the proposal to the CPHS even when it is likely that the proposal will not be judged “exempt” or “no risk” or when it involves members of vulnerable populations. If no revisions of the proposal are needed or if all required revisions are done then the department committee will make the additional copies needed for the review by the CPHS, and it will send a “Departmental Referral” letter to the student. It will also inform the CPHS why it forwards the proposal.
2. If the protocols are unclear and need major clarifications, then the committee will return the proposal un-approved. It will send a “Departmental Revise and Resubmit” letter to the student.
3. If the protocols need minor clarifications, then the committee will return the proposal conditionally approved. It will send a “Departmental Conditional Approval” letter to the student. Before starting the research project, the student has to submit one copy of all modified forms to the chair of the committee who determines whether the proposal is unconditionally approved or not.
4. If the research is either “exempt” or “no risk,” if it does not involve members from vulnerable populations, and if it does not need any clarifications, then the committee will approve the proposal. It will send a “Departmental Approval” letter to the student.

Annual Report

At the end of each academic year, the department HSC will submit a report to the university CPHS, in which it lists the protocols it has reviewed, including title of research, names of student researchers and their faculty sponsors, date of approval and level of risk determined by the committee.