Policy Statement: Human Subjects Research

I. Preamble:

Scholarly research is a primary method for furthering the College's goals of increasing knowledge and serving the community. When research involves human subjects, however, concerns about protecting the rights and interests of the subjects must be addressed. This policy sets general guidelines to be used by the Human Subject Review Committee (HSRC).

II. Principles:

Any appeal to or use of members of the College community as subjects in research must be approved by HSRC. Any appeal to use human subjects in research, by individuals acting as members of the LFC community, must be approved by HSRC.

For the purpose of this policy, 'research' will be conceived broadly, to include any use of individuals as subjects (e.g., through testing, surveying, or interviewing), in efforts to gather information that the investigator will use in scholarly work.

There is a distinction here between <u>research</u> (which is designed to gather information that an investigator will use) and <u>class projects</u> (where participation is itself a pedagogical tool and the purpose of the activity). Full reviews by HSRC will be expected for any <u>research</u> involving human subjects, undertaken by LFC faculty or staff, outside investigators, or students undertaking independent study research projects (e.g., senior theses). The use of human subjects as part of <u>projects</u> required for regular classes will ordinarily not face full review. However, (1) students undertaking such projects must be informed of the standards appropriate for their endeavors (as evidenced by this policy) and (2) faculty overseeing such projects must ensure compliance with the relevant standards contained in this policy. If HSRC becomes aware of concerns about the appropriate use of human subjects in such class projects, it can require a full review. If faculty members or students have concerns about compliance, they can request a review by HSRC.

Educational or Social Value:

The use of human subjects must serve the goals of the institution as an educational and research organization. A research program must be well-designed and likely to achieve its goals. Members of HSRC may appeal to faculty experts on campus for advice.

The ideals of increasing knowledge and serving the community are subordinate to concerns about the welfare of subjects.

Voluntariness:

Participation in research must be completely voluntary.

Researchers must take steps to avoid the appearance of pressure to participate as subjects in research. If subjects are solicited during class time, voluntariness must be especially stressed.

Confidentiality:

Confidentiality of any information gained in the course of research must be assured. Whenever possible, strategies for separating names of subjects from personal information gained in the course of the research must be employed.

Consent that represents an informed decision:

Researchers must provide potential subjects with (1) information about nature and goals of the research, including the ways the information gathered will be used, (2) names, qualifications and affiliations of the researchers, (3) the reason to appeal to members of the LFC community, (4) an account of the types of questions or tests to be administered, (5) an explanation of the risks and benefits to the subjects, and (6) an account of the effort or time subjects would be expected to devote to the research. The voluntary nature of participation must be emphasized. Potential subjects must be informed that they can quit at any time.

For interviews, testing, and any research in which anonymity is not assured, researchers will be expected to gather explicit evidence of informed consent, e.g., through a signed statement that includes the essential information listed above.

For anonymous surveys, researchers must provide potential subjects with a cover letter providing the information described above.

For studies where certain information about the nature of the research (i.e., information in point (1) above) cannot be presented without compromising the research, HSRC still must see all such information and be able to assess the value of the study.

Any deception in the course of research must be reasonable and justified. HSRC will expect to see an explanation of the necessity of such deception and the risks associated with it.

Potential subjects must always be given as much general information as is consistent with the goals of the study, as well as all other information described above. While details may have to be withheld, no false claims can be made at the consent level (i.e., either on the informed consent form or the cover letter accompanying anonymous surveys). It is especially important that subjects understand that they can quit at any time. Subjects must be informed about the nature of the research either at the end of the testing session or, if necessary, at the conclusion of the research. Every effort will be made to keep track of participants and to get the information to them. For anonymous surveys, this may imply public disclosure through the same channels used to solicit subjects. HSRC will expect to see an account of the debriefing to be employed to provide subjects with accurate information about the research.

III. Information required for HSRC Review

Researchers must provide:

- 1) an account of goals of the research and its methodology
- 2) names qualifications, and affiliation of the individual(s) directing the research and those undertaking the research
- 3) representative samples of testing instruments (e.g., survey, questionnaire, interview questions, test materials)
- 4) description of how subjects will be solicited, how many will be needed
- 5) account of how confidentiality will be guaranteed
- 6) account of how informed consent will be gained (e.g., cover letter for surveys, information and informed consent forms to be provided to potential subjects)
- 7) account of the risks to subjects
- 8) account of debriefing (where appropriate)
- 9) duration of the research

In addition, researchers who are not members of the LFC community must provide:

1) evidence of review and approval by the home institution's equivalent of HSRC and

2) explanation of the need for the use of subjects from the LFC community

IV. Administrative Policies:

1) HSRC approval will cover a period of up to one year. At the end of one year, if the research is to continue, HSRC must approve a request for an extension. Such a request should briefly summarize the research and elaborate on any changes in procedures.

2) All researchers will be expected to comply with (i) provisions of this policy and (ii) any specific requests made by HSRC. Researchers will be expected to maintain records demonstrating compliance (e.g., signed informed consent forms) for review by HSRC or other appropriate College committees or officials.