

Policy Regarding Research Involving Human Subjects

As some members of the Society of Christian Ethics begin to engage research methodologies that include data gathering by means of research involving human subjects, the SCE recognizes that this type of research may fall under the purview of the US Department of Health and Human Services, Office for Human Research Protections and Federal Code Regulations 45 CFR Part 46 (Federal Policy for the Protection of Human Subjects, also known as the “Common Rule”; full text <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>). In order to ensure that the highest standards of research are employed in studies that include the participation of human subjects and consistent with the “Standards of Professional Conduct” of the SCE (http://scethics.org/pro_conduct.html), the SCE requires of its members conducting research with human subjects, which they propose and intend to present at the Annual Meeting or a Regional Meeting of the SCE, that they seek approval from a local Institutional Review Board (IRB) in compliance with the “Common Rule”. The “Common Rule” requires that research involving human subjects undergo scrutiny by and receive approval from an IRB *prior to* the start of study to ensure that subjects are protected from harm (policy approved, SCE Board of Directors, January 8, 2009).

Dedicated to promoting “scholarly work in Christian ethics and in the relation of Christian ethics to other traditions of ethics, and to social, economic, political and cultural problems” (“Purpose,” SCE), the SCE is increasingly aware of the benefits of interdisciplinary initiatives and members have begun to use some of the research methodologies of complementary disciplines. Likewise, SCE members utilize published historical and contemporary studies that address various human rights and social justice issues in national and international contexts as well as pioneering research that depends upon the participation of research subjects. Particularly regarding research in applied ethics, individuals and groups have been consulted, interviewed, and/or observed with a view to the ethicist’s descriptive, analytical, and evaluative research followed by the presentation of findings based in part on the ethicist’s work with human subjects. It is to these methodologies used for research proposed and intended for presentation at Annual or Regional meetings that the SCE policy regarding research with human subjects is directed.

Moreover, rather than being a burden to SCE members, the requirement of IRB approval reminds researchers of their professional responsibility to ensure that appropriate protections are in place *before* they initiate studies that involve human subjects (see *JSCE*, “Publication Criteria,” SCE website <http://www.scethics.org/journal.html> or the Office for Human Research Protections Investigator Responsibility Frequently Asked Questions <http://www.hhs.gov/ohrp/investigatefaq.html>; when in doubt, consult your local IRB).

The SCE is committed to the highest standards of scholarship and conduct among our members and between our members and the communities they serve, and the subjects –personal and theoretical—they investigate. Recognizing the “Standards of Professional Conduct” and the “Purpose” of the SCE, *members of the Society have particular professional commitments and responsibilities; chief among them is the protection of human subjects before, during, and after the conduct of research* that involves methodologies based on data gathering by ethnographic studies, fieldwork, interviews, deliberate observation, etc. Our principal concern is that “our examination of moral issues shall respect the dignity of persons whose practices and positions we study.”

Some examples of scholarly activity to which this IRB Policy applies:

1. Interviews with administrators at religiously-based or secular facilities or agencies (health care, academic, corporate, government, social) on how religious values are incorporated into practice.
2. Surveys of patients or clients asking how their religious views influence(d) their decisions.
3. Assessment of a new curriculum on training providers to perform spiritual or value assessments that involves additional work (focus groups, feedback, etc.) on the part of the students.
4. Comparison of coping skills and/or health status of participants of a weekly Bible study with participants in a secular book club.
5. Longitudinal assessment of students' or participants' spiritual needs or beliefs throughout their educational experience.
6. Ethnographic studies, fieldwork, focus group session(s), deliberate observation and recording of the findings about the human subjects studied, engaged, and/or observed (especially where these findings include identifying marks or information about the persons studied in areas of political or social unrest).
7. Interviews with and/or survey instruments administered to people at and about their work, play, worship, diet, family, and/or about information that is readily identified as sensitive (e.g., regarding race, ethnicity, culture, sexuality, health and/or health status, etc).

Some examples of scholarly activity to which this policy *does not* apply:

1. Analysis, interpretation, and/or constructive theorizing about published sources only.
2. Research using material, including published interviews, already available in the public domain.
3. Research intended to interpret past events, intellectual movements, and/or history and which does not use “live” interviews as one of the means of collecting data.
4. Observation of public behavior that does not include investigator interaction.
5. Research conducted in routine educational settings on instruction strategies or in comparison with alternative techniques for assessment and/or instruction, curricula and/or its development, and/or classroom management methods.

Much of the work among the members of the SCE would qualify as exempt. *However, whenever research involves human subjects as part of the research methodology of collecting data, that research protocol ought to be submitted to a local IRB; the IRB is the party responsible for the determination that a research protocol is exempt from these policy requirements.* For the official/federal guidelines determining research that qualifies as exempt from this policy see 45 CFR §46.101 (b).

45 CFR §46.102 Definitions (abbreviated).

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(f) *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.**