

Guidelines for Student Work Involving Human Participants Not Requiring IRB Review

The following guidelines are provided for projects for which it has been determined at the academic-unit level—in consultation with the IRB representative of that unit or the IRB—that an IRB review is not required:

Changes in the project – The instructor must monitor the project to ensure that any changes over the course of the class would not change the project in such a way that would require IRB approval. The decision about whether a project requires IRB approval due to a change should take place in consultation with the academic unit’s IRB representative.

Belmont Report and CITI Training – Even if the project does not rise to the regulatory definition of research, it should be conducted in accordance with the ethical principles that govern the protection of human subjects in research as outlined in the *Belmont Report*: respect for persons, beneficence, and justice. The corresponding applications of these three principles consist of informed consent, assessment of risks and benefits, and selection of subjects. Projects should not expose participants to more than “minimal risk,” meaning no more risk than everyday life. All instructors and students with projects that involve human participants should read the *Belmont Report* and complete human subjects protection training (Collaborative Institutional Training Initiative, CITI).

Fully informed – Human participants have the right to be fully informed of the nature and purpose of the project, the collection of any personal information, and all procedures to be performed or followed. This includes receiving a full description of any risks, discomforts, or inconveniences reasonably expected from participation, as well as any benefits they may reasonably expect from participation. Participants have the right to ask any questions they may have about the project. All information related to the project must be provided to the participants in a language understandable to them and in a way that ensures complete comprehension.

Consent – Obtaining informed consent is essential to the ethical conduct of projects. Participants have the right to adequate time to consider whether or not to participate in the project and to make a decision free from any explicit or implicit coercion. Instructors should be aware of existing power relations and design a consent process that avoids potential undue influence by the participant’s supervisor or others who occupy a position of authority.

Withdrawal at any time – Participants have the right to be informed how they may withdraw from the project, at any time, without any reprisal nor affecting their existing rights.

Personal information – The project should limit to the extent possible the collection of personal information. Any personal information collected should be safely stored to protect confidentiality and destroyed upon project completion.

Beyond the *Belmont Report* – While the *Belmont Report* has become a cornerstone in the ethical conduct of research involving human subjects, it only constitutes a baseline standard. The report was proposed as an “analytical framework,” and its “principles cannot always be applied so as to resolve beyond dispute particular ethical problems.”¹ Similarly, some common disciplinary practices and industry standards may not meet the level of ethical conduct to which the USD community aspires. Accordingly, instructors with projects involving human participants should critically reflect on all aspects of their project from different perspectives and continually strive to affirm the dignity of every person and contribute to a culture of respect and inclusivity. These guidelines are not exhaustive and should be considered a starting point for developing ethical conduct in projects involving human participants.²

Nonmandatory IRB reviews

If student or faculty researchers are pursuing a non-IRB research project that involves human subjects, or a research project that does not involve human subjects, and wish to submit an IRB application to the USD IRB for review, they may do so through the IRB online application platform. Please note that this type of review will only be done at the academic unit level by the respective IRB faculty representative. For complete instructions on how to submit this type of application, refer to the USD IRB website: <https://www.sandiego.edu/irb/apply.php>.

Suggested reading

Adashi, E. Y., Walters, L. B., & Menikoff, J. A. (2018). The Belmont Report at 40: Reckoning with time. *Public Health Ethics, 108*(10), 1345–1348.

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. (1976). The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

Marshall, E. (1986). Does the moral philosophy of The Belmont Report rest on a mistake? *IRB: Ethics & Human Research, 8*(6), 5–6.

Saunkeah, B., Beans, J. A., Peercy, M. T., Hiratsuka, V. Y., & Spicer, P. (2021). Extending research protections to tribal communities. *The American Journal of Bioethics, 21*(10), 5–12.

Shore, N. (2006). Re-conceptualizing the Belmont Report: A community-based participatory research perspective. *Journal of Community Practice, 14*(4), 5–26.

Siddiqui, W., & Sharp, R. R. (2021). Beyond the Belmont Report. *The American Journal of Bioethics, 21*(10), 1–4.

¹ The *Belmont Report* is available online at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

² For some examples of ethical considerations that go beyond the Belmont Report, see the suggested reading included with these guidelines.