

## **Human Subject Research**

The University of San Diego, guided by its Catholic identity, is committed to the dignity and fullest development of the whole person. As part of its pursuit of ethical conduct and compassionate service for all members of its community, the University is committed to safeguarding the rights and welfare of human subjects involved in University research projects. The University expects human subject researchers to be guided by the University's mission, core values, applicable laws and regulations, and generally accepted ethical principles for human subject research.

The University has adopted the report of the national Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research", which is commonly known as The Belmont Report. All human subject researchers at the University should be familiar with The Belmont Report and should use it to guide their treatment of human subjects.

USD's Policy on the Protection of Human Subjects provides specific guidance to USD researchers regarding their ethical obligations as set forth in The Belmont Report and their administrative obligations under USD's Institutional Review Board (IRB). USD's Policy on the Protection of Human Subjects can be found at: <http://www.sandiego.edu/legal/policies/community/research/humansubjects.pdf>

The Belmont Report can be read in its entirety here: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

Most human subject research conducted at USD must be approved by USD's Institutional Review Board (IRB). Additional information regarding the IRB's specific requirements related to human subject research can be gathered by contacting the IRB directly: <http://www.sandiego.edu/irb/>

Other helpful resources for human subject researchers:

- The Federal Policy for the Protection of Human Subjects (the Common Rule) governs human subject research that is funded by the federal government. The Common Rule can be found at 45 CFR part 46 (<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>), and includes subparts that specify the additional protections necessary where the research involves pregnant women, human fetuses, prisoners, or children. Research that involves any of these protected categories must comply with all of the requirements of the Common Rule as well as the requirements of the relevant subpart.

- The Department of Health and Human Services' Office for Human Research Protections (OHRP) oversees compliance with the Common Rule. OHRP's website is a good resource for learning more about the Common Rule and its requirements related to human subject research. OHRP's website can be found here: <https://www.hhs.gov/ohrp/>.

For more information about human subject research at USD, please contact the IRB.