



INSTITUTIONAL REVIEW BOARD

Questions and Answers for Researchers Conducting Human Subjects Research

UNCW Human Subjects Research website:
<http://uncw.edu/sparc/integrity/irb.html>

Online IRB Application System ("IRBIS")
<https://uncw.myresearchonline.org/irb/index.cfm>

Q: I need to make a minor change to a study that was already approved by the IRB. Do I need to notify the IRB?

A: Yes. Any change to an approved protocol, no matter how small (including personnel changes), must be approved by the IRB **prior to** the PI making the change. Please log in to the IRBIS system and submit a modification on the study.

Your approved protocol is an agreement with the IRB to conduct the study as approved. Making a change to your methods, procedures or approved forms without IRB approval is a violation of IRB policy.

Please note that approved amendments do not change the original approval dates for a project. In other words, if your protocol was approved in April 2017 and will expire in April 2018, an amendment to the protocol approved in October 2017 will not extend the expiration date to October 2018.

Q: What do I do if something unexpected happens with a subject during my project?

A: If there is an unexpected adverse event during your human subjects research, the PI is required to report it to the IRB. Please log in to the IRBIS system and submit an Unanticipated Problem/Adverse Event report.

If the problem is very serious, the PI or another responsible person must contact the research compliance manager, Leanne Prete, in Sponsored Programs and Research Compliance (SPARC) at extension 2-7774.

If the event is less serious, the PI does not have to contact the IRB but must submit an Adverse Event Report within five days. For more information on adverse event reporting, please see the IRB policy posted on the IRB website.

Q: If my subjects provide me with health information, am I a covered entity subject to HIPAA?

A: Generally, no. A covered entity is defined under HIPAA as “health plans, health care clearinghouses and health care providers who electronically transmit any health information in connection with transactions for which the Department of Health and Human Services has adopted standards.” UNCW is not a covered entity and the majority of projects conducted by UNCW PIs fall under a research exemption in HIPAA. However, there are some projects that do not fall under this research exemption and require a Business Associate Agreement and data security plan. If you plan to conduct a quality assurance evaluation for a covered entity that involves identifiable protected health information, and you will obtain data directly from the covered entity, please contact Lee Prete in SPARC or General Counsel’s office for guidance prior to entering into a Business Associate Agreement with a covered entity.

Q: What is a Certificate of Confidentiality and when is it a good idea to obtain one?

A: A certificate of confidentiality (CoC) is a document issued by certain U.S. Department of Health and Human Service agencies that allows a researcher to refuse to reveal identifiable research information, even if the researcher is subpoenaed to do so in any civil, criminal, administrative, legislative or other proceeding, whether at the federal, state or local level. A certificate of confidentiality may be awarded whether or not the project is federally funded.

Researchers may want to consider applying for a certificate of confidentiality if they will be collecting information that may be damaging to subjects if it is revealed, for example, damaging the subject’s financial standing, employability, insurability or reputation within the community. Researchers should obtain IRB approval first, then allow at least three months for the CoC application process.

The National Institutes of Health operate an online CoC Kiosk that has more detailed information. This kiosk can be found at:

<http://grants.nih.gov/grants/policy/coc/index.htm>

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Sponsored Programs and Research Compliance