

Guidance on Collaboration with Researchers Not Affiliated with Clemson University

The Clemson IRB has certain requirements regarding collaboration with researchers not otherwise affiliated with Clemson University. These requirements vary depending on the institution(s) involved and the level of review needed for the particular protocol.

Team members **not affiliated** with any institution, or affiliated with an institution that does not have its own IRB:

Research eligible for Exempt review – The team members have to be listed on the IRB application but are not required to complete the CITI human subjects training course.

Even though the CITI training is not required, the ethical obligations in the conduct of activities that involve human subjects still apply. We recommend that team members review the Belmont Report, available at <http://www.hhs.gov/ohrp/policy/belmont.html>, or complete the CITI training course, <http://www.clemson.edu/research/compliance/irb/training.html>.

Research requiring Expedited/Full Board review – The non-affiliated research team members must be brought under the purview of an IRB. Most commonly, these individuals will:

- sign an Individual Investigator Agreement (IIA) in order to be covered by Clemson University's IRB, and;
- complete Clemson's human subjects protections training, <http://www.clemson.edu/research/compliance/irb/training.html>, or an alternative training session approved by the IRB.

In rare instances, the institution which the team member is affiliated with may need to obtain a Federalwide Assurance (FWA) and establish its own IRB. More information on FWAs is available on the Office of Human Research Protections (OHRP) website, <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwass/index.html>.

Team members **affiliated** with an institution that has its own IRB:

Research eligible for Exempt review – Both institution's IRB will have to review the protocol. Clemson University's review of the project will only cover the role of Clemson's researchers listed on the protocol. Team members not affiliated with Clemson University will have to consult with their IRB office to determine what is required for their role on the study.

Research requiring Expedited/Full Board review – Researchers must contact the IRB office prior to conducting the study to determine which IRB will be the IRB record for the study. Additionally, an IRB Authorization Agreement (IAA) must be negotiated between Clemson and the other institution. Researchers from the other institution will be required to meet the training requirements set by their own institution's IRB.