

When are Assessment Activities at UNC Considered Research?

When conducting assessment, UNC units collect data, analyze data, and make changes to programming based on the findings. Data are typically collected from students, staff, faculty members, and other participants. Usually assessment work is conducted to help programs work internally to understand their programming and to inform people in their units and other UNC decision-makers. Sometimes, units see value in sharing their assessment findings with audiences outside of UNC. For example, units may write an article for their discipline describing their assessment efforts or units may present their assessment work at conferences. When UNC units think that their assessment work may be useful for an audience outside of UNC then that assessment work must be reviewed and approved by the UNC Institutional Review Board, the entity that oversees protection of human participants in research at UNC.

In what situations would assessment activities (collecting assessment data, analyzing assessment data, reporting assessment results) be considered research and need to be approved by the UNC Institutional Review Board?

Assessment efforts may be considered research if a unit intends to share data findings from assessment efforts with audiences outside of UNC and/or at the UNC Research Days. IRB approval may be necessary if a unit intends to share assessment efforts with audiences outside of UNC. Audiences outside UNC include but are not limited to non-UNC conferences and in non-UNC publications. Assessment efforts shared outside of UNC may be considered research.

From the UNC "Procedures for Involving Human Participants"
<http://www.unco.edu/osp/doc/irb/procedures.pdf>:

"The Code of Federal Regulations (CFR), which governs much of UNC's policy regarding research with human participants, contains the following definition: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. --- 45 CFR §46.102 (d)

UNC's IRB considers "generalizable knowledge" as research or evaluation results that are published, bibliographically available (e.g., theses and dissertations), presented outside the university (e.g., professional conference), or developed for others to build upon (e.g., pilot data for an investigator from another institution)"

When is IRB approval needed in unit/program assessment activities?

The unit should seek approval **before** data collection and analysis. Before initiating data collection and analysis, a unit should decide how the assessment data will be used and with whom the assessment efforts will be shared. If the unit decides that assessment efforts will only be used internally and will not be shared with non-UNC audiences then IRB approval may not be needed. However, if a unit decides that there is value in sharing their assessment efforts with non-UNC audiences then IRB approval is needed.

What if a unit has already collected assessment data and then realizes that there is value in sharing the assessment efforts with non-UNC audiences?

There are a few options in this situation and it is recommended that the unit work directly with the UNC IRB to determine which option to pursue.

Option 1: The unit can seek IRB approval for additional data collection. Once approved, the unit would conduct another round of data collection and analysis. The results from this additional data collection would be shared with non-UNC audiences. However, previously collected data would not be shared with non-UNC audiences.

Option 2: The unit can seek IRB approval to have the previously collected data considered existing data. In this situation, the unit would need to meet certain requirements related to existing data records. Approval for the use of existing data is not guaranteed; therefore, units are encouraged to seek approval before data collection occurs.

Written by Julie Sexton, Assistant Director of Assessment. Feedback on this document was provided by Megan Babkes Stellino, Co-Chair, UNC Institutional Review Board.

For more information about the IRB process at UNC, visit
<http://www.unco.edu/research/research-integrity-and-compliance/institutional-review-board/>