When do new course proposals need to get RCS/IRB review and approval?

Introduction
The design and intent of course activities determine whether or not the activities require Research Compliance Services (RCS) and Institutional Review Board (IRB) review/approval. Below is an explanation of what does not, and does, typically require IRB review and approval. Whenever instructors assign or encourage activities that necessitate IRB review, they should inform students of the IRB review and approval requirement in the course syllabus (the IRB review process can be lengthy; researchers are advised to submit their application six to eight weeks in advance of the anticipated start date for human subjects activities).

New courses with individual activities
In general, student interaction with individuals (or individually identifiable data) that occurs for the purpose of fulfilling a single course requirement does not require RCS/IRB review and approval because it does not meet the definition of “human subjects research,” as that term is defined in the federal regulations on research with human subjects. According to the federal definition of that term, research means:

“a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Activities undertaken for fulfillment of a single course requirement often do not meet the threshold of being “a systematic investigation,” and/or are not “designed to develop or contribute to generalizable knowledge” since they aren’t expected to be shared beyond the course for the purpose of expanding a body of scholarship.

New courses with individual activities that might be used beyond the classroom
However, there are times when students do engage in “human subjects research” as part of fulfilling a course requirement that requires IRB review and approval. Whenever a student interacts with individuals (or individually identifiable data) with the intent of sharing their findings beyond the classroom (e.g. in a paper, conference presentation, video, etc.) for the purpose of expanding a body of knowledge, the interaction could constitute human subjects research requiring RCS/IRB review and approval.

When creating course requirements or opportunities for student interaction with individuals/identifiable data, instructors should inform students that if at any point they know that they would like to use data they obtain for a publishable paper, their thesis/master’s project, a conference presentation, etc., they should contact the RCS/IRB office right away because they likely will need IRB review/approval. If someone is ever unsure about whether or not they need RCS/IRB review/approval, they should consult with someone in RCS.
Sometimes, students and faculty start activities involving individuals/identifiable data without expecting to use any of it for the purpose of contributing to generalizable knowledge, but then decide they want to do so. When that happens, students should halt all interactions with the individuals/identifiable data and contact RCS to initiate the IRB review/approval process. Once IRB approval is obtained, students can resume the data collection activities.

**New courses designed as research data collection and analysis**

If an entire course is designed around the collection of data to help answer a research question, it is the responsibility of the course instructor to contact RCS/IRB before the course proposal comes before the UOCC. If the RCS/IRB determines that the course requirements constitute “human subjects research”, then the instructor will need to complete the IRB protocol process as the Principal Investigator (PI) and list all of the students as Co-PIs.

**Course activities that appear to involve human subjects research**

If there is a possibility that the course activities listed in the course syllabus and new course proposal will involve human subjects research, submitting departments should send the new course proposal and syllabus to RCS. RCS will assess the course description and syllabus and determine whether or not the entire course or specific course assignments do require IRB review and approval. Individual instructors and departments cannot claim “self exemptions”.

Examples of course activities that appear to involve human subjects research are:

- interviews for research projects and archives,
- audio or videotaping individuals which require model release forms,
- focus groups,
- online surveys,
- participant observation (including in online environments), and
- use of existing data sets

New course proposals using any of these methods should include documentation from RCS indicating whether or not IRB review is needed for the course or any course activities. If IRB review and approval is needed, the proposing department and instructor will need to submit the IRB approval letter with the rest of the package.

Ultimately, the department and instructor proposing the course are responsible for ensuring there are no human subjects research violations.