Radford University Institutional Review Board

Classroom Exercise Guidelines

(Replaces Course Exempt Review Category Instructions)

The Course Exempt Review Category has been removed from the RU IRB review process. Data collections involving human interactions conducted as part of classroom-based activities that do not meet the federal definition of “Research” are now excluded from RU IRB oversight. Such activities are now considered Classroom Exercises. It is recommended that the attached Student/Instructor Classroom Exercise Agreement to be signed between the Student and Instructor as a means of establishing dialog regarding the restrictions associated with those classroom activities that may be conducted without IRB oversight. Reporting of any data obtained through Classroom Exercises is restricted to presentation in the classroom and RU Student Engagement Forum and Masters of Social Work Poster Session only.

“Research” is currently defined by the Office of Human Research Protections (OHRP) as “… a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

Students may still conduct IRB reviewed research as part of classroom activities if desired or required by the instructor, such as when the research design does not fit within the Classroom Exercise restrictions described below.

Key Points Regarding Classroom Exercises:

- Classroom Exercise data collection projects are educational in nature, e.g., they instruct students in research methods as opposed to attempting to generate data intended to contribute to generalizable knowledge.
  
  - While it is recognized that data of interest might be generated from Classroom Exercises, this cannot be the intended purpose of Classroom Exercises. If a proposed student project is believed to be of sufficient value so as to potentially create significant data of interest, IRB review should be sought prior to the initiation of the project so that the resulting data may be used to its fullest (e.g., presented outside of the RU community and/or submitted for publication).

- Please use the criteria presented here and the criteria specified in the Student/Instructor Classroom Exercise Agreement as guidance in determining whether projects qualify as Classroom Exercises and are thus excluded from IRB oversight.

- Please contact the IRB Office or IRB Chair for further clarification if unsure as to whether a classroom data collection activity is considered research.

- Failure to adequately determine whether a project is a Classroom Exercise or human subjects research requiring IRB review leaves the instructor, students, and university open to liability for failure to follow federal guidelines (e.g., non-compliance).

- Failure to obtain prior IRB approval for a project PREVENTS data from being used at later presentations outside of RU. Instructors are encouraged to carefully consider how their students might want to use the results of their projects. If an instructor thinks a student may wish to present their
results outside of the RU community or publish the results in any way in the future, then the student should be directed to request standard IRB approval.

- It is recommended that the attached Student/Instructor Classroom Exercise Agreement be signed by students and instructors as a means of establishing dialog and clarifying the conditions under which Classroom Exercises may be used as opposed to those activities that require IRB submission. If used, the signatures are to be attained below prior to the initiation of any data collection from human interactions as a part of the classroom exercise.

To summarize, Classroom Exercises are those activities involving collecting data from human participants which are used to illustrate some aspect of class material. As such, those Classroom Exercise projects that do not qualify as research, per current federal guidelines for human subjects research, are excluded from IRB oversight. Guidance on this topic includes but is not limited to:

1. Data collection may involve the use of surveys, interviews, observations, or experimental procedures, but may not include interventions, deception or video and/or audio recording of any kind. See the Student/Instructor Classroom Exercise Agreement or the information below for more details on the limits of the Classroom Exercise.

2. Student/Instructor Classroom Exercise Agreements are recommended to be used as a vehicle to facilitate discussion between the instructor and the student(s) regarding the important differences between Classroom Exercises and those activities that require IRB oversight.
   - If used, the Agreement is to be signed by both the individual student and the instructor prior to any human interactions as relating to the classroom exercise.

3. All informational materials (e.g., study descriptions, recruiting advertisements, consent forms, surveys, or debriefing materials) distributed to any participants as a part of a Classroom Exercise MUST be clearly labeled at or near the top of each document or website as “Classroom Exercise” to distinguish the activity from RU IRB approved research.

4. Students may present the results of Classroom Exercises involving data collected through human interaction at the RU Student Engagement Forum and Masters of Social Work Poster Session provided that all criteria set forth in this guideline was observed during data collection.

5. Failure to obtain IRB approval for a project PREVENTS it from later presentation outside of RU. Instructors are encouraged to carefully consider other potential student or faculty uses of a classroom activity to ensure that the project is not inappropriately restricted regarding subsequent use of the results.

6. Each instructor is responsible for determining whether or not to encourage students to submit an IRB proposal for a particular class exercise. Particular attention should be paid by the instructor to other potential uses of the resulting data, such as posters presented at professional meetings.

7. Instructors are encouraged to err on the side of caution and contact the IRB Office if unsure as to whether a classroom exercise should be reviewed.
   - Failure to adequately make this review distinction leaves the instructor, students, and university open to liability for failure to follow federal guidelines (e.g., non-compliance).

8. Specifically, per the agreement signed between instructor and student, Classroom Exercises must meet the following criteria:
   - NO MINORS OR OTHER VULNERABLE POPULATIONS: The project cannot include anyone under age 18 or any other vulnerable populations like pregnant women, prisoners or others whose liberty is
restricted including the occupants of hospitals and long term care facilities, those who lack the capacity to 
consent, and non-English speaking individuals.

- **NO MORE THAN MINIMAL RISK:** "Minimal risk" is the probability and magnitude of harm that is 
normally encountered in the daily lives of healthy individuals. This also precludes the study of any illegal 
activities (e.g., underage drinking, illegal drug use) or the collection of private information that could put 
the participants at risk through a breach of confidentiality.

- **NO INTERVENTIONS:** The class project cannot include any intervention designed to produce long-term 
changes in participants. An intervention includes both physical procedures by which data are gathered (for 
example, venipuncture) and manipulations of the subject or the subject's environment that are performed 
for research purposes.

- **NO DECEPTION:** The class project cannot include any deception. Individuals must be fully informed 
and given the opportunity to voluntarily consent to participate.

- **NO PUBLICATION:** Data from class projects approved under this exemption cannot be used for 
publication or for thesis/dissertation research. Information from the project may not be disseminated 
outside the RU Community, this includes publicly accessible posting on the WWW and use of other media 
for findings dissemination.

- **NO PRESENTATION EXTERNAL TO RU:** Data from class projects approved under this agreement 
may not be used for presentation at any forum outside of the university.

- **NO VIDEO OR AUDIO RECORDING.**

- **NOT AN INDEPENDENT OR DIRECTED STUDY OR HONORS THESIS OR THESIS OR 
DISSERTATION.**

- **ALL MATERIALS CLEARLY LABELED “CLASSROOM EXERCISE”:** All informational 
materials (e.g., study descriptions, recruiting advertisements, consent forms, surveys, or 
debriefing materials) provided to participants must be clearly labeled with “Classroom Exercise” at or 
near the top of each document or website.

**FURTHER,** it is expected that students engaged in the following and related activities **WILL** submit an IRB 
application:

- Classroom activities that require students to collect data in such a manner as to fall outside of the 
parameters set forth in the Student/Instructor Classroom Exercise Agreement, whether or not it constitutes 
research.

- All master's and doctoral theses and dissertations utilizing human subjects.

- Any type of individualized learning experiences involving human subject research, such as Independent 
Study.

The above project types are either too invasive and RU Policy requires RU IRB oversight regardless of the 
research intentions of the project, or are not mere exercises but rather are attempts to teach students the 
intricacies of scientific research. The submission of protocols through the Institutional Review process is an 
integral part of this process.

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1 Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Section 46.102, Definitions, (e).