

## Policy on Students as Research Participants

REC\_003

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#### **ADDITIONAL DETAILS** History

#### **Effective:**

**Last Updated:** July 10<sup>th</sup>, 2024

**Responsible University Office:** Spalding Office of Graduate Education

**Responsible University Administrator:** Dean of Graduate Education / Signatory Official

**Policy Contact:** REC Chair

### Scope

Spalding University faculty, students and staff involved in human subjects research, including, but not limited to, study investigators, REC members and school or program chairs or other administrators responsible for overseeing human subjects research activities at Spalding University.

### Policy Statement

This policy outlines procedural considerations for investigators wishing to include Spalding University students (or employees) as participants in human subjects research studies. Investigators must take care to ensure that all research procedures are designed in a way that minimizes risk to participants and reduces the possibility of perceived or actual coercion or undue influence on students (or employees) to participate in research. Though this policy has been developed specifically addressing the inclusion of Spalding students as research participants, the considerations and requirement noted herein may also apply to research involving Spalding employees as participants. This policy may also be extended to apply to research proposing to include students (or other) participants in a status relationship with the investigator, regardless of their affiliation with Spalding.

## Reason for Policy

The purpose of this policy is to ensure that certain procedures are followed to minimize risk to research participants and reduce the possibility of perceived or actual coercion of students (or employees) to participate in human subjects research conducted by Spalding faculty (or students or other employees) or shared by these individuals on behalf of an unaffiliated investigator. In keeping with the FWA under which Spalding University's REC operates, the details of this policy have been developed per the department of health and human [services \(HHS\) guidelines on human subjects research protections at 45CFR46](#).

## Definitions

**Investigator**- anyone involved in obtaining informed consent or with collecting or analyzing participant information for research purposes

**Coercion**- when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, a student considers the relational ramifications of disappointing their professor if they choose not to participate in their research.

**Undue influence**- an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects.

## Policy Requirements & Considerations for Including Students as Research Participants

*OHRP regulations require that the investigator seek consent only under circumstances that minimize the possibility of coercion or undue influence ([45 CFR 46.116](#))*

1. Is the investigator in a position of power (i.e. faculty /instructor, advisor, program chair, etc.) over the participant?
  - a. If yes, additional procedures may need to be implemented as requested by the REC
  - b. If yes, review and approval from additional individuals may be required including, but not limited to, the program or school director / chair, Dean of Graduate Education, Chief compliance officer, or Provost. Additional required approvals will be determined by the REC Chair and University signatory official (Dean of Graduate Education) as needed.
2. Does the investigator have any other relationship to the targeted student population that might represent a conflict of interest (e.g. classmates, colleague, etc.) leading to the perception of coercion or undue influence on students to participate?
  - a. If yes, additional procedures may need to be implemented as requested by the REC
  - b. If yes, review and approval from additional individuals may be required including, but not limited to, the program or school director / chair, Dean of Graduate

Education, Chief compliance officer, or Provost. Additional required approvals will be determined by the REC Chair and University signatory official (Dean of Graduate Education) as needed.

3. **The REC will not approve studies requesting to specifically target Spalding students who are currently enrolled in a course taught by faculty involved in the recruitment, consent or data collection processes of the study.**
  - a. Faculty investigators may recruit student participants after final grades for the class have been posted.
4. **Care shall be taken to ensure that all research related procedures are designed in a way that minimizes the possibility of perceived or actual coercion or undue influence on students (or employees) to participate in research activities.**
5. Extra credit shall not be used to encourage students to participate in research unless explicit written approval is granted by the REC.
  - a. The practice of using extra credit should be treated as an exception rather than the norm. Investigators are strongly encouraged to utilize alternate means of recruiting when possible.
  - b. The REC will consider approval of extra credit for research involving students if and only if the investigator has provided a detailed written description of procedures that adhere to the REC recommended best practices for using extra credit in research (please refer to the best practices document on the REC website).
  - c. If approved, the consent form must explain the nature of the extra credit including non-research alternative(s) for earning extra credit.
6. **Students (or employees) shall not be penalized for refusing to participate in research.**
7. The investigator(s) must provide written approval of the school / program / unit chair / director and/or other appropriate administrator prior to recruiting students (or employees).
  - a. For studies and/or recruitment proposed within classrooms, written permission from the course instructor must also be provided.
8. Other considerations for research involving students (or employees) as research participants:
  - a. Employing procedures that present no more than minimal risk to participants.
  - b. The research presents a potential educational opportunity for the participants when possible.
  - c. The recruitment and consent processes shall be conducted by someone who does not have a status relationship with the potential participants such as a co-investigator or neutral third party (note, anyone involved in recruitment must complete CITI training and be listed as a co-investigator on the study protocol).
  - d. Limit inclusion to individuals that are 18 years of age or older (i.e. do not include students who are still minors as participants)
  - e. If the research is conducted within a classroom setting, the instructor is blinded to the identity of participants when possible.

- f. If the research is conducted in a classroom setting, there must be written justification for time away from class and an alternative activity for students who choose not to participate.

## Procedures NA

### Associated documents / related policies

- Procedures for Sharing requests to recruit Spalding community members to participate in external research (REC\_004)
- REC recommended best practices for using extra credit in research
- Approval Flow for Distributing Research Participation Requests to Spalding Community Members

### History

**Draft proposed and reviewed:** Initial draft-March 1st, 2024; Revisions-April 5, 2024; Approve by REC May 1st, 2024, revised July 10<sup>th</sup>, 2024 per Graduate Dean

**Implemented:** [Click or tap here to enter text.](#)

Last reviewed by Research Ethics Committee: July 12th, 2024

Spalding Administration Review: Reviewed by Dean of Graduate Education (signatory official) on May 15<sup>th</sup>, 2024

Approved in REC Meeting: July 12th, 2024

Approved in Faculty Senate Meeting: [Click or tap here to enter text.](#)