

## SOP-P-003: TC IRB Standard Operating Procedure (SOP) for Over-Enrollment in Research Studies

### Purpose

This SOP outlines the procedures for managing over-enrollment in research studies to ensure consistency and compliance with regulatory requirements.

### Scope

This SOP applies to all studies reviewed and approved by the Teachers College Institutional Review Board (TC IRB).

### Definitions

- **Enrolled Participant:** An individual who is eligible for participation (i.e., meets the inclusion criteria for the study), has given informed consent and participated in some or all of the study procedures (excluding screening procedures where applicable).
- **Screened Participant:** An individual who has given informed consent and participated in screening procedures to determine eligibility.
- **Screen Failure:** An individual who has given informed consent and participated only in screening procedures to determine eligibility but was determined to be ineligible to take part in the study.
  - **NOTE:** Screen failures are not considered to have enrolled in the study.
- **Withdrawals:** An individual who has given informed consent and participated in some study procedures, but who withdrew or was withdrawn from the study.
- **Over-Enrollment:** Enrollment of participants beyond the number approved by the IRB.
  - **NOTE:** Participants who enroll but later withdraw, or are withdrawn, are counted in the total number enrolled and cannot be “replaced” by enrolling more than the original approved number.
- **Minimal Risk (MR) Study:** A study where the probability and magnitude of harm or discomfort anticipated are not greater than those ordinarily encountered in daily life.
- **Greater Than Minimal Risk (GTMR) Study:** A study where the probability and magnitude of harm or discomfort anticipated are greater than those ordinarily encountered in daily life.
- **Significant Over-Enrollment:** Over-enrollment exceeding 20% of the initially approved participant number, any increase in participant number that introduces new risks or significantly alters the existing risk profile of the study, or situations where the additional participants strain the study's logistical capabilities or challenge the ethical management of the study.

### Procedures

#### I. Monitoring Enrollment

- Primary Investigators (PIs) must monitor the number of participants enrolled and ensure it does not exceed the approved limit.
- Any potential for over-enrollment should be communicated to the IRB as soon as identified.

- **CASE SCENARIO:** The IRB-approved enrollment number for the study is 150 participants. So far, the study team has enrolled 115 participants with 10 screen fails, bringing their total enrollment number to 105 (115-10= 105) Therefore, the current enrollment is 105 which means that 105 of the 150 “spots” have been taken. The study team may enroll (consent and pass screening) an additional 45 participants (150-105= 45). If enrollment is anticipated to go above 150, an amendment needs to be reviewed and approved by the IRB prior to enrolling more subjects.
    - Investigators conducting research may not enroll more participants than the number specified on the approved IRB application until a modification to increase that number is approved.
- 2. **Reporting Over-Enrollment**
  - If over-enrollment occurs, the PI must submit a detailed report to the IRB, including:
    - The number of participants enrolled beyond the approved limit.
    - Justification for the over-enrollment.
    - Assessment of any additional risks to participants.
    - Steps taken to ensure compliance in the future.
- 3. **Review and Classification**
  - *Increased Risk Assessment:* Staff should use the following criteria to determine if over-enrollment leads to increased risk:
    - New or amplified physical harm.
    - Increased psychological distress.
    - Extended exposure to study procedures.
    - Data security and privacy concerns.
    - Strain on resources and support systems.
  - **NOTE:** please refer to the [TC IRB Staff Risk Assessment Checklist for Over Enrollment](#) to complete this assessment.
    - *Minimal Risk (MR) studies:* The IRB will review the over-enrollment report and classify it based on risk assessment:
      - **Minor Over-Enrollment:** If the additional participants do not introduce new risks, the IRB may allow the study to continue with an amendment to the approved participant number.
      - **Significant Over-Enrollment:** Defined as over-enrollment exceeding 20% of the initially approved participant number, any increase in participant number that introduces new risks or significantly alters the existing risk profile of the study, or situations where the additional participants strain the study's logistical capabilities or challenge the ethical management of the study. A protocol deviation must be submitted, and the study may be subject to full board review.

Significant Over-Enrollment Calculation Example

Percentage Increase=

$(\text{Actual Enrollment} - \text{Approved Enrollment} / \text{Approved Enrollment}) \times 100$

**CASE SCENARIO:**

- **Approved number of participants: 8,000**
- **Actual number of participants enrolled: 10,000**
  1. **Subtract the approved enrollment from the actual enrollment:**  $10,000 - 8,000 = 2,000$
  2. **Divide the difference by the approved enrollment:**  $2,000 / 8,000 = 0.25$
  3. **Multiply by 100 to get the percentage increase:**  $0.25 \times 100 = 25\%$

In this example, the percentage increase is 25%, which would be considered significant over-enrollment since it exceeds the 20% threshold.

- *Greater than Minimal Risk (GTMR) studies:* Any over-enrollment in GTMR studies will be classified as significant and must be submitted as a protocol deviation. This deviation will be reviewed by the full board to assess any new risks and determine necessary actions.

#### 4. Amendment Process

- For minor over-enrollment, the PI must submit an amendment request, including revised estimates and any necessary adjustments to study procedures.
- The amendment must be approved by the IRB before enrolling additional participants.

#### 5. Protocol Deviation

- For significant over-enrollment, a protocol deviation must be submitted, detailing the impact on the study and participant safety.
- The deviation will be reviewed by the full board to determine necessary corrective and preventive actions, including but not limited to:
  - PIs and study coordinators must undergo training on monitoring and reporting enrollment.
  - Regular audits will be conducted to ensure compliance with enrollment limits.

#### 6. Responsibilities

- **Primary Investigators:** Monitor enrollment, report over-enrollment, and submit necessary amendments or deviations.
- **IRB:** Review reports of over-enrollment, classify the severity, and approve amendments or deviations as necessary.

#### 7. References

- [TC IRB Staff Risk Assessment Checklist for Over Enrollment](#)
- [TC IRB Reportable New Event Reviewer Checklist](#)
- [Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance \(2007\)](#)
- [OHRP, Guidance on Continuing Review \(2010\)](#)
- DHHS 45 CFR §46.103(b)(4)(iii).
- FDA 21 CFR §56.108(a)(4).

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- 21 CFR §56.108(b).
- 21 CFR §812.150.