SOP-E-005: TC IRB Standard Operating Procedures (SOP) for Documentation of IRB Meetings: Agenda, Discussions, Decisions, and Findings

Purpose

This document outlines the standard procedures for convened IRB meetings, including agenda preparation, distribution of review materials, documentation of discussions and decisions, drafting and finalizing meeting minutes, and ensuring compliance with regulatory and institutional requirements for record-keeping.

Definitions

Quorum: A quorum is the minimum number and type of IRB members that must be present at a convened meeting (>50%). To review proposed research at a convened meeting, a majority of the members of the IRB must be present, including *at least one member whose primary concerns are in nonscientific areas* (45 CFR 46.108(b); 21 CFR 56.108(c)). If a majority of the IRB membership is not present, or if a nonscientist is not present, then a quorum has not been met, and IRB business cannot be conducted.

Policy

1.0 When creating the agenda for an IRB meeting, the IRB office ensures that:

1.1 Items are assigned to an agenda only when the IRB members who will attend can provide sufficient expertise to determine whether the applicable criteria for IRB approval are met. This expertise may be supplemented by the involvement of an external consultant.

1.2 Items involving vulnerable populations will be placed on the agenda only when at least one individual (IRB member or consultant) who is knowledgeable about or experienced in working with the population will participate in the meeting (or a consultant has been obtained).

2.0 External consultants may be asked to provide information and expertise, as needed to ensure an appropriate review. Consultation may be provided in person at an IRB meeting or through a consultant's written comments distributed to the IRB.

3.0 IRB members are provided with sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

4.0 Review materials are provided to all IRB members at least **7 business days** before meetings, except in special circumstances:

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4.1 A meeting will be rescheduled or canceled if it becomes apparent that meeting requirements (quorum, sufficient expertise, participation of a non-scientist member) will not be met.

Procedures

1.0 IRB Meeting Schedule

The IRB office establishes the IRB meeting schedule each semester, considering holidays, the academic calendar, and special circumstances. Additional meetings may be scheduled on an *ad hoc* basis. The schedule is distributed to all IRB members and posted on the IRB website accessible via the Meetings & Deadlines link.

2.0 Meeting Requirements

In advance of each meeting, approximately 7 days, the IRB office confirms which IRB members will be present.

Referring to the IRB Membership Roster, the IRB office verifies that the following regulatory requirements for an IRB meeting will be met:

2.1 **Quorum:** For TC, *the total number of active (primary) IRB members is 12; therefore quorum, calculated by using the "half-plus-one" technique, is 7.*
2.2 **Non-scientist member:** At least one member who is identified as a "non-scientist" on the membership roster will be present.
2.3 **Sufficient expertise:** The members in attendance have sufficient expertise to determine whether the applicable criteria for approval have been met. This includes, when relevant, expertise with a vulnerable population involved in the research.

3.0 Preparation of the meeting agenda- IRB Staff

3.1 Select the items for the agenda.

3.1.1 In all cases, the availability of sufficient expertise is the primary consideration for the selection of items.
3.1.2 If it is determined that appropriate expertise is not available within the IRB, or should be augmented, a consultant will be considered.
3.1.3 If expertise with a specific vulnerable population is needed but not available from the IRB members, a consultant may be obtained for expertise.
3.1.4 The agenda document is prepared as described in the *TC IRB Meeting Agenda Preparation Procedures* document.

4.0 Preparation of the meeting materials - IRB Staff

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The IRB office prepares the materials for IRB members, referring to the *TC IRB Meeting Materials for Review* document to ensure that all appropriate materials are provided.

5.0 Disseminating meeting materials

The IRB office disseminates meeting materials via the Mentor IRB online management system.

6.0 Urgent items

Items requiring urgent review may be provided to the IRB office after an agenda has been completed and distributed with review materials. The IRB office will use best judgment (and may consult with the Chair) to decide whether the urgent item can and should be placed on the already-distributed agenda for a pending IRB meeting. The following factors are considered:

6.1 Availability of an appropriate expertise and/or consultant
6.2 Number of days before the IRB meeting and whether the time is sufficient for IRB members to complete a thorough review.
6.3 Size and complexity of the late materials
6.4 The urgency of the issue. Examples of urgent issues include but are not limited to:
- Subject welfare and safety
- Funding considerations
- Timing and dependency of research procedures on factors such as a school year, availability of subjects/resources/investigator, etc.

6.5 The workload for the IRB members concerning the pending meeting

Emergency meetings

The IRB may convene a special meeting for matters that fall outside the regular agenda or meeting deadlines. In scheduling these meetings, the same factors mentioned above will be considered.

7.0 Make meeting arrangements (meeting room, virtual meeting logistics, etc.), as needed.

TC IRB Related Documents
TC IRB Meeting Materials for Review
TC IRB Meeting Agenda Preparation Procedures

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TC IRB Meeting Agenda Preparation Procedures

Purpose

This section includes standard procedures used to prepare the agenda for an IRB meeting. This occurs after the agenda items, order, and attendees have been assigned.

Policy

The meeting agenda document is used to communicate pertinent information about upcoming IRB meetings to members of the IRB. The meeting agenda outlines the human subject research activities subject to review by a convened meeting of board members. Submission of a research protocol must satisfy all the requirements necessary for the comprehensive review of all the protocol materials before the convened meeting. However, there could be instances where a protocol is added to the convened meeting agenda primarily due to its complex nature and its potential impact on existing SOPs, highlighting the challenge of always satisfying all procedural requirements. Such situations underline the necessity for the board's intervention, especially in emergencies where protocols may initially not align with our standards. Additionally, the agenda provides a listing of any discussion items relevant to the operations of the human subject protection program.

Procedures

1.0 Meeting Agenda

The Research Compliance Director prepares the meeting agenda. Additionally, relevant review materials are distributed via Mentor IRB to all board members at least **7 business days** before the scheduled meeting.

The agenda shall include the following items:

A. Date of meeting
B. Minutes from the previous meeting
    a) The IRB Regulatory Compliance Analyst and Reliance Agreement Specialist draft the meeting minutes and send them to the Research Compliance Director for review and posting in Mentor IRB.
    b) The minutes are then approved at the convened meeting.
C. Adverse Events/Unanticipated Problems
D. Protocol Deviations
E. Closed/expired protocols
F. Protocol Reviews (noted for informational purposes)
    i. Exempt protocols
    ii. Expedited protocols
    iii. External IRBs
G. Administrative Reviews
H. Research Compliance
I. Old/New Business

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J. Information/Education

2.0 Agenda Distribution

The IRB utilizes the Mentor IRB system to compile and prepare the agenda for the IRB meeting. When preparing the agenda, the Regulatory Compliance Director ensures all necessary items and protocols are included for discussion. Following the preparation of the agenda, the Director distributes it to all IRB members via email. The email contains clear instructions on how to access and review the agenda within the Mentor IRB system.

3.0 Maintenance and revision of meeting agenda templates

The IRB office utilizes a meeting agenda template to prepare the meeting agenda for each IRB meeting. The agenda template is created in the Mentor IRB online management system and includes items listed in section 1.0 above.

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TC IRB Meeting Materials for Review

Purpose

This section includes standard materials provided to the IRB for review purposes.

Policy

TC IRB review materials are provided to IRB members seven (7) calendar days in advance of convened meetings, except in special circumstances described in the *TC IRB Meeting Preparation Procedures* document. IRB members may request additional information or supporting documents at any time by emailing the Research Compliance Director at IRB@tc.edu.

Procedures

1 IRB Review Procedures

1.1 Reviewers

All IRB members receive access to the IRB agenda in Mentor IRB, the previous month's minutes for approval, appropriate IRB application(s), informed consent (or request to waiver informed consent), recruitment materials, site permission forms, surveys/questionnaires, or any other study-related documents. Relevant materials are to be provided for all types of IRB review including initial review, continuing review, and modifications for review at the convened meeting.

2 Materials Provided to IRB Members for Review
- 2.0.1 Meeting Agenda
- 2.0.2 Minutes for previous meetings
- 2.0.3 Report of completed expedited reviews.
- 2.0.4 Educational materials (as applicable)

3 Initial Applications – Materials provided by the investigator (as applicable)
- 3.0.1 IRB Application form
- 3.0.2 Application supplements
- 3.0.3 Consent/assent
- 3.0.4 Recruiting materials
- 3.0.5 Data collection instruments
- 3.0.6 Financial Conflict of Interest disclosure/management plan
- 3.0.7 Other materials relevant to the study or deemed useful by the IRB

4 Continuing Reviews
- 4.0.1 Continuing Review form.
- 4.0.2 Updates to IRB Application.
- 4.0.3 Consent/assent documents.

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- 4.0.4 Relevant post-approval reports (e.g., Data Safety Monitoring reports)
- 4.0.5 Any other materials provided by the investigator.
- 4.0.6 Other materials relevant to the study or deemed useful by the IRB.

5 Amendments

- 5.0.1 Amendment Review form.
- 5.0.2 Modified protocol
- 5.0.3 Modified consent/assent
- 5.0.4 Modified recruitment materials
- 5.0.5 Modified investigator brochure/package insert.
- 5.0.6 Other modified study documents

TC IRB Related Documents

TC IRB Meeting Preparation Procedures
TC IRB Meeting Agenda Preparation Procedures

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TC IRB Meeting Minutes Drafting Procedures

Purpose

This section includes standard policies and procedures for creating IRB meeting minutes.

Background

TC IRB must comply with HHS and FDA regulations in 45 CFR part 46, and 21 CFR parts 50 and 56, respectively when reviewing research subject to those regulations. Both the HHS regulations at 45 CFR 46.115(a)(2) and the FDA regulations at 21 CFR 56.115(a)(2) specifically require that an institution, or when appropriate, an IRB, prepare and maintain adequate documentation of IRB activities, including minutes in sufficient detail to show:

1. Attendance at the meetings.
2. Actions taken by the IRB.
3. The vote on these actions, including the number of members voting for, against, and abstaining.
4. The basis for requiring changes in or disapproving research; and
5. A written summary of the discussion of controverted issues and their resolution.

These five items **must** be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

Scope

This document applies to IRB staff and other compliance designees.

Policy

The IRB meets at least once a month on a regularly scheduled day. Scheduled meetings may be canceled by the IRB Research Compliance Director due to the inability to secure a quorum for attendance, or other reasons that may arise that make a scheduled meeting unnecessary or otherwise inappropriate. The IRB office maintains an electronic IRB address book used to notify members of meetings and other pertinent IRB information.

One week before the convened meeting, all members of the IRB shall be provided access to all submitted materials to facilitate adequate discussion of the protocol and determine the appropriate action during the convened meeting. All members of the IRB are expected to familiarize themselves with meeting materials to contribute to the IRB's deliberations.

The IRB meeting minutes document all actions that occur during an IRB meeting. The minutes are a critical document demonstrating an appropriate human research review.

1.0 *Minutes Requirements*

The IRB minutes are required to document the following information by the IRB:

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A. Actions taken by the IRB.
B. Separate deliberations for each action.
C. Votes for each research project as numbers for, against, or abstaining.
D. Attendance at the meeting for each action, including any early departures.
E. When an alternate member replaces a primary member.
F. The basis for requiring changes in research.
G. The basis for disapproving research.
H. A written summary of the discussion of controverted issues and their resolution.
I. Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the TC-approved sample consent documents.
J. For initial and continuing review, the approval period.
K. The names of IRB members who recused themselves from the meeting due to a conflict of interest along with the fact that a conflict of interest was the reason for the recusal.
L. Determinations required by the regulations and research project-specific findings justifying those determinations for:
    i. waiver or alteration of the consent process.
    ii. research involving pregnant women, human fetuses, and neonates.
    iii. research involving prisoners.
    iv. research involving children.
    v. research involving participants with diminished capacity to consent.
M. The determination of the level of risk
N. Attendance of members or alternate members who participate through videoconference or teleconference.
O. The approval of research is contingent on specific minor conditions by the IRB Chair or IRB Chair's designee (to be documented in the minutes of the first IRB meeting that takes place after the date of the approval)
P. Whether reports of protocol deviations and unanticipated problems involving risk to participants or others (1) **are or are not** determined to be unanticipated problems involving risk to participants or others and (2) are or are not due to serious or continuing noncompliance
Q. Information that pertains to action that must be taken by the Investigator.

2.0 Meeting Minutes Preparation

The preparation of the meeting minutes begins with the preparation of the meeting agenda. Each item submitted to the IRB for review is posted on the agenda. Refer to the *TC IRB Meeting Agenda Preparation Procedures* document for guidance.

3.0 Information Documented

The minutes of IRB meetings shall be compiled by the Research Compliance Analyst or Specialist, following the IRB meeting minutes template. The following specific information shall be recorded in the meeting minutes:

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A. Attendance is recorded by first/last name.
B. Approval of previous minutes
C. Adverse Events/Unanticipated Problems action
D. Protocol Deviations
E. List of closed/expired protocols
F. List of approved exempt and expedited approved protocols and specific citations for the expedited review category.
G. External IRB submissions
H. Actions taken by the IRB on initial, modifications, and continuing review applications. If applicable, specific measures taken to protect vulnerable populations and requests for alterations to the informed consent process or form (e.g., Waiver or Alteration of Elements of Informed Consent; Waiver of Documentation of Signed Informed Consent; and/or Waiver of the Informed Consent Process)
    i. Recorded votes on these actions # for, #against, #abstained
    ii. The basis for requiring changes in or disapproving research
    iii. Summary of controverted issues
    iv. Required IRB findings and determinations
I. Research Compliance
J. Old/New Business
K. Information/Education

The minutes shall record when a member enters/leaves the convened meeting as evidence of proper quorum. The minutes shall record any presence of conflict of interest or abstention.

3.0 Documentation of Protocol-Specific Findings (as applicable)

When the IRB makes specific findings at convened meetings, the IRB Research Compliance Analyst or Specialist documents these findings in the minutes of the meeting and includes protocol-specific information justifying each finding. Examples of specific findings include, but are not limited to:

1. **Alteration or Waiver of the Informed Consent Process:** When the convened IRB reviews a procedure that alters or waives the requirements of informed consent, the minutes document the IRB's determinations required by federal regulations (45 CFR 46.116).
2. **Waiver of Documentation of Informed Consent:** When the convened IRB reviews a procedure that waives the requirements for obtaining a signed informed consent document, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.117).
3. **Research Involving Deception:** When the convened IRB reviews research involving deception, the minutes document that the IRB made the findings in accordance with 45 CFR 46.116.
4. **Research Involving Prisoners:** When the IRB reviews research involving prisoners, the minutes indicate that the research meets the findings required by 45 CFR 46.305(a) and represents one of the categories of research permissible under Health and Human Services (HHS) regulations required by HHS 45 CFR 46.306(a).

Teachers College, Columbia University
Institutional Review Board
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   a. *At least one member of the IRB is a prisoner or a prisoner representative with the appropriate background and experience to serve in that capacity.*
5. **Research Involving Children:** When the IRB reviews research involving children, the minutes document that the IRB made the findings in accordance with IRB policy and federal regulations (HHS 45 CFR 46 Subpart D, 46.404-46.407).
   a. **Wards of the State or Other Agency:** When the IRB reviews research involving children who are wards of the state or any other agency, institution, or entity, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.409).
6. **Research Involving Pregnant Women, Human Fetuses, and Neonates:** When the IRB reviews research involving pregnant women, human fetuses, and neonates, the minutes must document that the IRB made the findings in accordance with federal regulations (45 CFR 46 Subpart B).
7. **Research Involving Individuals with Impaired Consent Capacity or with Economically or Educationally Disadvantaged Persons:** When the IRB reviews research involving individuals who are determined to be cognitively impaired and/or lack consent capacity, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.111(b)), and local policy.

Procedures

1.0 Development of IRB Meeting Minutes

The IRB Research Compliance Analyst identifies all reviews and comments from the meeting and utilizes this information to prepare the convened meeting minutes.

2.0 Meeting Minutes Approval & Distribution

The minutes are presented at the next appropriately convened IRB meeting for review and approval. The IRB office posts minutes in Mentor IRB for review in advance of the convened meeting. The chair leads the meeting of the convened IRB. This includes calling the meeting to order, leading the IRB through the agenda, and calling for motions and votes. The chair ensures that all members have an opportunity to express their opinions and concerns on the research under review.

The IRB Research Compliance Analyst distributes copies of approved minutes, as appropriate, to the Institutional Official (IO) and others as deemed appropriate by the IRB.

Regulatory Resources

DHHS Office of Human Research Protections: Guidance on Written IRB Procedures
45CFR 46.107
45 CFR 46.108
45 CFR 46.111
45 CFR 46.115 (a)(2)
45 CFR 46.116
45 CFR 46.117
45 CFR 46.305(a)

Teachers College, Columbia University
Institutional Review Board
525 W. 120th St. Box 151, New York, NY 10027
212-678-4105 | IRB@tc.edu | RH 13 | tc.edu/IRB

45 CFR 46.306(a)
45 CFR 46.409
45 CFR 46 Subpart B
45 CFR 46 Subpart D

TC IRB Related Documents
TC IRB Meeting Preparation Procedures
TC IRB Meeting Agenda Preparation Procedures
TC IRB Meeting Minutes Template
TC IRB Reviewer Guidance for Protocol Specific Findings

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TC IRB Meeting Minutes Template

TC IRB Meeting [Date] Minutes
[Version – *where applicable*]

[minutes should not include member identifiers as able]
The Institutional Review Board (IRB) meeting was held on [date], called to order at [start time], and adjourned at [end time]. All members attended via Zoom or teleconference and had virtual access in Mentor IRB to all pertinent materials in sufficient time to review before the meeting. IRB Members were able to participate in the discussion of all action items actively and equally.

No member of the IRB was permitted to participate in the review, deliberation, or vote of any project in which he/she/they had a real or perceived financial or non-financial conflict of interest (COI).
All IRB members and guests are required to respect and preserve the confidentiality of information he/she/they receive as a member of the IRB, and use, discuss, and/or disclose such information only for purposes related to deliberations or other assigned business of the IRB.

A. Attendance

[Insert table] [use the IRB Meeting Attendance Tracking Sheet]

Attendance Notes

- Consultant (enter name) was in attendance during this IRB Meeting with expertise in (enter area of expertise) *[For example research involving pregnant women, human fetuses, and neonates; prisoners; children; participants with diminished capacity to consent]*. He/She/They did not vote.
- Guest(s): (e.g., IRB support staff who are not IRB members, the investigator whose study is being reviewed, study coordinator)
- *You may indicate general meeting attendance (XX arrived late at [time][review order], XX left early at [time], left from [time][review order] to [time][review order]) – specifics regarding voting should only be included under each item where applicable.*

B. Announcements and Education *(copied from agenda, expand if needed)*

- [list]
- The IRB Chair/Vice-Chair reminded board members that attendees with a conflict of interest may be present during the discussion to provide insight or answer any questions; however, during the deliberation and vote they must recuse themselves. They were also reminded to verbally state the recusal and the reason for the recusal.
- The IRB Chair/Vice-Chair reminded board members that when not speaking, board members are expected to mute their devices to reduce any unintended noise from occurring.
- The IRB Chair/Vice-Chair reminded board members that should they need to step away from the meeting, they should make a verbal announcement or leave a note in the chat box before doing so. They may hide their Zoom camera and keep their microphone on mute. This announcement of departure will allow IRB staff to ensure the quorum is being met throughout the meeting.
- The IRB Chair/Vice-Chair reminded attendees that the meeting is being audio recorded and the recording is available only to IRB staff to benefit the accuracy of recording the meeting minutes. Once

Teachers College, Columbia University
Institutional Review Board
525 W. 120th St. Box 151, New York, NY 10027
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the minutes are approved by the Research Compliance Director, the audio recording will be destroyed and a copy of the document version of the meeting minutes will be filed in Mentor IRB.

- **Exempt/Expedited Agenda Review Policy Reminder:** Each month the IRB office reviewed protocols at the Exempt/Expedited level. As part of the review process, we ask all Full Board members to engage in a quality assessment of that agenda to make notations or offer comments at the convened meeting. Board members are not required to review the protocols on this Exempt/Expedited agenda, rather just provide insights into the protocols that had been reviewed that month.

C. Previous Meeting Minutes

The IRB [Chair/Vice-Chair] presented the minutes from the IRB meeting held on [date].

Choose one:

No issues were raised. A motion was made to approve the minutes followed by a vote.

Voting notes: *[Delete entire section if n/a.]* [Name] - abstained from voting on the minutes as they were not present at the previous meeting.

For	Against	Abstained

or

The following concerns/suggestions were raised by an IRB member(s):

- *[Concisely list]*

A motion was made to amend the minutes to reflect the suggested changes and approve *[or otherwise]* followed by a vote.

Voting notes: *[Delete entire section if n/a.]* [Name] - abstained from voting on the minutes as they were not present at the previous meeting.

For	Against	Abstained

D. New Protocols *(please number)*

Protocol Number:
Protocol Title:
PI:
IRB Member COI: *[Write "none" when applicable]*
Submission Package:
Sponsor/Funder:
Current Risk Level:

The [IRB Chair/Vice-Chair/assigned reviewer] presented a summary of the submission.

Discussion, Controverted Issues, and Resolutions: [Choose one]

Teachers College, Columbia University
Institutional Review Board
525 W. 120th St. Box 151, New York, NY 10027
212-678-4105 | IRB@tc.edu | RH 13 | tc.edu/IRB

There was no discussion, no controverted issues, nor resolutions discussed.
OR
[Provide a summary of each discussion point and/or controverted issue (what it was, what was discussed, how it was resolved; if modifications or additional information are needed, note that the discussion point resulted in a modification or information request as described below.) Also, indicate here if the board determines notification or reconsent is needed and why.]

Primary Investigator Consultation Report
[This section is dedicated to documenting any consultations between IRB staff members and Primary Investigators (PIs) prior to IRB meetings. These consultations are intended to provide additional insights into the protocols under review and facilitate a deeper understanding of the specifics of each study, which may not be fully captured within the standard agenda] [N/A entire section if not applicable]

Modifications Required to Secure Approval:
[*list*]
If n/a, delete this section

IRB DETERMINATIONS
Criteria for Approval: *[choose one and delete the others]*
The Board determined all criteria for approval continue to be met per 45CFR46.111/21CFR56.111.
The Board determined all criteria for approval per 45CFR46.111/21CFR56.111 will be met once required modifications are made.
The Board did not have enough information to determine that all criteria for approval continue to be met per 45CFR46.111/21CFR56.111.

Period of Review: The IRB recommended a 12-month approval.
OR
The IRB recommended an approval period of (e.g., six months) due to (specify reasons such as the degree of risk involved in the research).

Future Review: The board decided that future reviews of this study will remain full board OR can occur using expedited procedures under category #. The board decided that future reviews can occur using expedited procedures under category # *[include expedited category]*. *[include a statement regarding a change of risk level and justification if applicable].*

Researcher Conflicts of Interest: *[N/A entire section if not applicable] [Describe acknowledgment and management of conflicts of interest disclosed by researchers.]* The IRB staff reports that *[name]* has a COI relating to this study. The IRB has been provided with the < conflict management plan ***OR*** relevant sections of the conflict management plan > for review and <finds it acceptable ***OR*** requires the following additional conditions to mitigate the conflict: *[detail]* >. In addition, <the disclosure has been added to the Informed Consent document (s) and found to be acceptable ***OR*** the disclosure must be added to the consent (s)>.

Teachers College, Columbia University
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Who May Review and Verify Modifications: *[Delete entire section if there are no modifications.]* IRB staff / any voting member / primary review / IRB Chair / return to the full board. *[Do not refer to a member by name.]*

Voting notes: *[Delete entire section if n/a.]* [Name] - recused due to a conflict of interest - indicate which alternate member(s) was/were voting in place of a primary member(s) where applicable. For example: Alternate board member [name] voted in place of [absent/recused] primary member [name].

Determination: A motion was made to [approve, require substantive modifications, require directive modifications, disapprove] followed by a vote.

For	Against	Abstained

E. Amendments *(please number)*

Protocol Number:
Protocol Title:
PI:
IRB Member COI: *[Write "none" when applicable]*
Enrollment Status: [subjects currently enrolled, closed to enrollment, long-term follow-up, etc.]
Expiration Date:
Submission Package:
Sponsor/Funder:
Current Risk Level:
Summary: [Include a concise justification as to why this amendment is coming to the full board]
The [IRB Chair/Vice-Chair/assigned reviewer] presented a summary of the protocol and proposed change(s).
Discussion, Controverted Issues, and Resolutions: [Choose one]
There was no discussion, no controverted issues, nor resolutions discussed.
OR
[Provide a summary of each discussion point and/or controverted issue (what it was, what was discussed, how it was resolved; if modifications or additional information are needed, note that the discussion point resulted in a modification or information request as described below.) Also, indicate here if the board determines notification or re-consent is needed and why.]

Example language: The Board determined that re-consent is not required/is required [indicate timeframe]."
The Board determined that participant notification is not required/is required [indicate timeframe].

Primary Investigator Consultation Report
[This section is dedicated to documenting any consultations between IRB staff members and Primary Investigators (PIs) prior to IRB meetings. These consultations are intended to provide additional insights into the protocols under review and facilitate a deeper understanding of the specifics of each study, which may not be fully captured within the standard agenda] [N/A entire section if not applicable]

Modifications Required to Secure Approval:

[*list*]
If n/a, delete this section.

IRB DETERMINATIONS

Criteria for Approval: *[choose one and delete the others]*
The Board determined all criteria for approval are met per 45CFR46.111/21CFR56.111.
The Board determined all criteria for approval per 45CFR46.111/21CFR56.111 will be met once required modifications are made.
The Board did not have enough information to determine that all criteria for approval were met per 45CFR46.111/21CFR56.111.

Period of Review: *[Only include this section if the Board determined a different approval period for the protocol as a result of the amendment.]*
The IRB recommended an approval period of (e.g., six months) due to (*specify reasons such as the degree of risk involved in the research)*.

Future Review: *[Only include this section of the board determined a different level of review is now appropriate as a result of the amendment.]* The board decided that future reviews can occur using expedited procedures under category # *[include expedited category]*. *[include a statement regarding a change of risk level and justification if applicable].*

These requested changes did not change any previous determinations.
OR [*include the new determination(s) below.]*

Researcher Conflicts of Interest: *[N/A entire section if not applicable] [Describe acknowledgment and management of conflicts of interest disclosed by researchers.]* The IRB staff reports that *[name]* has a COI relating to this study. The IRB has been provided with the < conflict management plan ***OR*** relevant sections of the conflict management plan > for review and <finds it acceptable ***OR*** requires the following additional conditions to mitigate the conflict: *[detail]* >. In addition, <the disclosure has been added to the Informed Consent document (s) and found to be acceptable ***OR*** the disclosure must be added to the consent (s)>.

Who May Review and Verify Modifications: *[Delete entire section if there are no modifications.]* IRB staff / any voting member / primary review / IRB Chair / return to the full board. *[Do not refer to a member by name.]*

Voting notes: *[Delete entire section if n/a.]* [Name] - recused due to a conflict of interest - indicate which alternate member(s) was/were voting in place of a primary member(s) where applicable. For example: Alternate board member [name] voted in place of [absent/recused] primary member [name].
Determination: A motion was made to [approve, require substantive modifications, require directive modifications, disapprove] followed by a vote.

For	Against	Abstained

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F. Continuing Reviews *(please number)*

Protocol Number:
Protocol Title:
PI:
IRB Member COI: *[Write "none" when applicable]*
Enrollment Status: [subjects currently enrolled, closed to enrollment, long-term follow-up, etc.]
Expiration Date:
Submission Package:
Sponsor/Funder:
Amendment: *[yes/no – provide a summary, and where applicable, include a concise justification as to why this is coming to the full board in the instance where the CR alone would have been reviewed expedited]*

Previous Determinations: *[including current risk level] [include a statement regarding a change of risk level and justification if applicable. Justifications or protocol-specific findings need to be reiterated]*

The [IRB Chair/Vice-Chair/assigned reviewer] presented a summary of the submission *(with proposed changes)* and reviewed the status of the study.

Discussion, Controverted Issues, and Resolutions: [Choose one]
There was no discussion, no controverted issues, nor resolutions discussed.
OR
[Provide a summary of each discussion point and/or controverted issue (what it was, what was discussed, how it was resolved; if modifications or additional information are needed, note that the discussion point resulted in a modification or information request as described below.) Also, indicate here if the board determines notification or re-consent is needed and why.]

Example language: The Board determined that re-consent is not required/is required [indicate timeframe]."
The Board determined that participant notification is not required/is required [indicate timeframe].

Primary Investigator Consultation Report
[This section is dedicated to documenting any consultations between IRB staff members and Primary Investigators (PIs) prior to IRB meetings. These consultations are intended to provide additional insights into the protocols under review and facilitate a deeper understanding of the specifics of each study, which may not be fully captured within the standard agenda] [N/A entire section if not applicable]

Modifications Required:
[*list*]
If n/a, delete this section.

IRB DETERMINATIONS
Criteria for Approval: *[choose one and delete the others]*
The Board determined all criteria for approval continue to be met per 45CFR46.111/21CFR56.111.

The Board determined all criteria for approval per 45CFR46.111/21CFR56.111 will be met once required modifications are made.
The Board did not have enough information to determine that all criteria for approval continue to be met per 45CFR46.111/21CFR56.111.

Period of Review: The IRB recommended a 12-month approval.
OR
The IRB recommended an approval period of (e.g., six months) due to *(specify reasons such as the degree of risk involved in the research)*.

Future Review: The board decided that future reviews of this study will remain full board OR can occur using expedited procedures under category # *[include expedited category]*. *[include a statement regarding a change of risk level and justification if applicable].*

Researcher Conflicts of Interest: *[N/A entire section if not applicable] [Describe acknowledgment and management of conflicts of interest disclosed by researchers.]* The IRB staff reports that *[name]* has a COI relating to this study. The IRB has been provided with the < conflict management plan ***OR*** relevant sections of the conflict management plan > for review and <finds it acceptable ***OR*** requires the following additional conditions to mitigate the conflict: *[detail]* >. In addition, <the disclosure has been added to the Informed Consent document (s) and found to be acceptable ***OR*** the disclosure must be added to the consent (s)>.

Who May Review and Verify Modifications: *[Delete entire section if there are no modifications.]* IRB staff / any voting member / primary reviewer / IRB Chair / return to the full board. *[Do not refer to a member by name.]*

Voting notes: *[Delete entire section if n/a.]* [Name] - recused due to a conflict of interest - indicate which alternate member(s) was/were voting in place of a primary member(s) where applicable. For example: Alternate board member [name] voted in place of [absent/recused] primary member [name].
Determination: A motion was made to [approve, require substantive modifications, require directed modifications, disapprove, suspend, terminate] followed by a vote.

For	Against	Abstained

G. Reportable Events *(please number) [delete section if not applicable]*

Protocol Number:
Submission Number:
Protocol Title:
PI:
IRB Member COI: *[Write "none" when applicable]*
Enrollment Status: [subjects currently enrolled, closed to enrollment, long-term follow-up, etc.]
Expiration Date:
Submission Package:

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212-678-4105 | IRB@tc.edu | RH 13 | tc.edu/IRB

Sponsor/Funder:
Current Risk Level:

IRB Staff presented the reportable event. *[Provide incident details that were presented at the meeting, including root cause, applicable PI risk assessment, how the incident was discovered, and Corrective and Preventative Action (CAPA) plan/risk-mitigating actions the Board reviewed in its assessment of the Reportable Event.]*

Discussion, Controverted Issues, and Resolutions: [Choose one]
There was no discussion, no controverted issues, nor resolutions discussed.
OR
[Provide a summary of each discussion point and/or controverted issue (what it was, what was discussed, how it was resolved; if modifications or additional information are needed, note that the discussion point resulted in a modification or information request as described below.) Also, indicate here if the board determines notification or re-consent is needed and why.]

Example language: The Board determined that re-consent is not required/is required [indicate timeframe]."
The Board determined that participant notification is not required/is required [indicate timeframe].

Primary Investigator Consultation Report
[This section is dedicated to documenting any consultations between IRB staff members and Primary Investigators (PIs) prior to IRB meetings. These consultations are intended to provide additional insights into the protocols under review and facilitate a deeper understanding of the specifics of each study, which may not be fully captured within the standard agenda] [N/A entire section if not applicable]

[Include the following if not enough information was available to the Board to make an assessment as to whether an incident constitutes serious noncompliance/continuing noncompliance/an unanticipated problem.]

The Board agreed that additional information about the incident, as described in Modifications Required below, is needed to assess whether the incident constitutes *[serious noncompliance/continuing noncompliance/an unanticipated problem involving risks to subjects or others].*

[Include as applicable.] The Board agreed that this incident *[does/does not]* constitute serious noncompliance for the following reason(s):
1. [List reasons]

Voting notes: *[Delete entire section if n/a.]* [Name] - recused due to a conflict of interest - indicate which alternate member(s) was/were voting in place of a primary member(s) where applicable. For example: Alternate board member [name] voted in place of [absent/recused] primary member [name].
A motion was made that this incident *[does/does not]* constitute serious noncompliance followed by a vote.

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[Include as applicable.] The Board agreed that this incident *[does/does not]* constitute continuing noncompliance for the following reason(s):
1. [List reasons]

Voting notes: *[Delete entire section if n/a.]* [Name] - recused due to a conflict of interest - indicate which alternate member(s) was/were voting in place of a primary member(s) where applicable. For example: Alternate board member [name] voted in place of [absent/recused] primary member [name].
A motion was made that this incident *[does/does not]* constitute continuing noncompliance followed by a vote.

For	Against	Abstained

[Include as applicable.] The Board agreed that this incident [does/does not] constitute an unanticipated problem involving risks to subjects or others for the following reason(s):
1. [List reasons]

Voting notes: *[Delete entire section if n/a.]* [Name] - recused due to a conflict of interest - indicate which alternate member(s) was/were voting in place of a primary member(s) where applicable. For example: Alternate board member [name] voted in place of [absent/recused] primary member [name].
A motion was made that this incident *[does/does not]* constitute an unanticipated problem involving risks to subjects or others followed by a vote.

For	Against	Abstained

Noncompliance *[was/was not]* identified as a component of the unanticipated problem involving risks to subjects or others.
[Choose one of the following to indicate whether the Board assessed the CAPA plan/risk-mitigating actions taken were appropriate to manage the incident.]

The Board agreed that additional information about *[the CAPA plan (use if noncompliance)/risk-mitigating actions (use if AE)]*, as described in the Modifications Required below, is needed to assess if *[it is/they are]* appropriate to manage this incident.
OR
The Board agreed that the *[CAPA plan is/risk-mitigating actions are]* appropriate to manage this incident.

Modifications Required:
[*list*]
If n/a, delete this section

IRB DETERMINATIONS

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Voting notes: *[Delete entire section if n/a.]* [Name] - recused due to a conflict of interest - indicate which alternate member(s) was/were voting in place of a primary member(s) where applicable. For example: Alternate board member [name] voted in place of [absent/recused] primary member [name].

Who May Review and Verify Modifications: *[Delete entire section if there are no modifications.]* IRB staff / any voting member / Original reviewer / IRB Chair / return to the full board. *[Do not refer to a member by name.]*

[Choose ONE of the following:]
Determination: A motion was made to require modifications for the reportable event followed by a vote.

For	Against	Abstained

[OR]

Determination: A motion was made to acknowledge the reportable event followed by a vote.

For	Against	Abstained

TC IRB Related Documents

- TC IRB Meeting Preparation Procedures
- TC IRB Meeting Agenda Preparation Procedures
- TC IRB Meeting Minutes Drafting Procedures
- TC IRB Reviewer Guidance for Protocol Specific Findings

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