IRB Submissions: Common Reasons For Returns

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Human Research Protection Office
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Objectives

• Discuss IRB pre-review process objectives and what the IRB staff

• Review data comparisons for 2021 vs. 2022

• Discuss most common findings
Outcomes of Pre-review

• Exempt
  – Log in/approve or return to study team
• Expedited/Other
  – Return to study team
  – Log in for IRB member or HRPO staff review
• Expedited: may proceed to approval or return
• Other: may proceed to be assigned for convened review or return; may be returned after a meeting
• Return items marked as ‘required y/n’
Data Snapshot

• Last data review done in October 2021 (presented at a previous MIM)

• Data compiled from Rascal system of all Tasks for Events returned in May 2022

• 522 Events [roughly = studies] represented

• 3916 Tasks entered into Rascal (Last MIM 4804 tasks)

*Same task may be communicated more than one time if not addressed
## Section and Number of Tasks Identified

<table>
<thead>
<tr>
<th>Sections</th>
<th>September 2021</th>
<th>May 2022</th>
<th>Improved?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attributes</td>
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<td>Background</td>
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<td>Biological Specimens</td>
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<td>Child Involvement</td>
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<th>Improved?</th>
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<th>May 2022</th>
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</thead>
<tbody>
<tr>
<td>Research Aims/Abstracts</td>
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<td>Subjects</td>
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May 2022 Tasks
Attributes—who will review the study?

• The CU IRB typically does not enter into reliance arrangements unless there is a funding or policy requirement. Since no such requirement exists for this protocol, please update the IRB of Record field to reflect that the CU IRB will only provide approval for CU researchers.

• Please note that, per federal regulations, an US-institution cannot cede IRB review to an international IRB, as proposed for this protocol.

• As per the 2018 Revised Common Rule: "U.S. institutions engaged in cooperative research must rely on a single institutional review board (IRB) to review and approve the portion of the research conducted at domestic sites. See 45 CFR 46.114(b). The compliance date for the single IRB requirement is January 20, 2020."

• If any procedures will be occurring at CU, you must also indicate "Columbia is a study site"
Consent Form

• Add elements, e.g., key information section up front, procedures, statement of consent, cost, compensation, voluntary
• Resolve inconsistent information
• Remove sections that do not apply, e.g., IF
• Signature lines inconsistent with participant cohort
• Risks not prioritized
• Data presented is hard to read; too wordy
Documents

• Need pdf versions to stamp
• Archive older versions
• Submit documents as described in application
• Unclear which version of consent document to use
• Inconsistencies between documents and protocol
• Duplicate docs submitted – cannot identify current version
• Need documentation from non-CU entity that was not attached
• Forgot to attach a document before submitting
Personnel

• Training not completed
  – TC0019
  – TC0087

• Other trainings not completed as required
  -FDA, Minors, genetic, GCP

• Refresher training

• Question regarding PI eligibility

• Waiver of consent but personnel ‘obtaining IC’

• New personnel not added; listed in mod summary

• Research Roles or engagement inaccurate/unclear
Data Privacy and Security

• System information lacking/incorrect

• Discrepancies in form of data

• Incorrect assessment of Sensitive Data

• Confidentiality of data not distinguished from privacy of participants

• Need description of confidentiality or privacy protections

• Details of data storage/transmission lacking, incomplete or inconsistent
Procedures

• Additional details about the analysis conducted on specimens
  - Will you be conducting any sequencing (whole genome/exome or RNA) or use an assay/platform?
• Genetic testing answer unclear/unable to evaluate
• Unclear which procedures are being done for research purposes
• Incorrect NCT number or other documentation (data sometimes references the wrong study)
• No description of where procedures will occur
• Biospecimen marked as ‘no’ but listed in the protocol
Recruitment and Consent

• Description of how will participants be identified
• How will consent be obtained
• Letter of support if CU/NYP affiliates will be recruited
• No justification for waiver criteria
• Details not provided, esp for special cases
• Wrong options selected or request denied
• Compensation details not provided
Subjects

• Vulnerable subjects responses incorrect
• Numbers do not add up
• Response to screening question incorrect
• Status (e.g., data analysis only) inconsistent with subject information (e.g., 370 remain on study)
• Component information incomplete or inaccurate
• Demographics inaccurate, do not explain if non-English speaking will be enrolled
Summary

• Returns take time/effort for both researchers and HRPO staff

• Careful review of datasheet and all attached documents strongly recommended before submission – accuracy, completeness, consistency

• Select task ‘completed’ only if fully addressed

• Explain unusual situations in memo/letter attached to Event if necessary-this can help clear up confusion
Contact HRPO

Website: research.columbia.edu/irb

or

search for ‘IRB’ on main CU website

Email: irboffice@columbia.edu

Main phone line: 212.305.5883