IRB Submissions: Common Reasons For Returns

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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

Sections	September 2021	May 2022	Improved?
Attributes	50	41	-
Background	115	68	-
Biological Specimens	64	54	-
Child Involvement	19	36	-
Consent Form	418	366	-
Dept. Approval	1	0	-
Devices	15	0	↓
Documents	1062	802	↓
Drugs/biologics	20	19	-
Exempt/expedited	76	51	-
Existing data	110	59	↓
Funding	35	13	-
Future Use	37	30	-

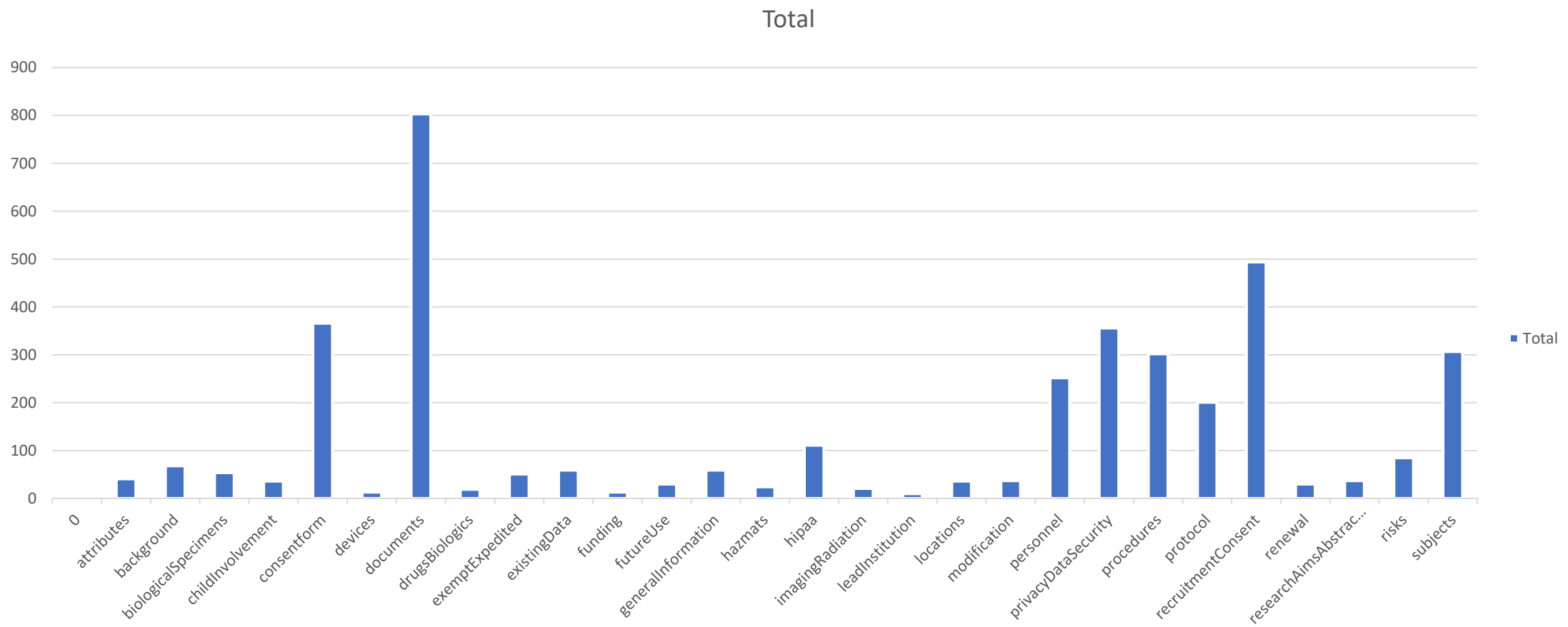
Section and Number of Tasks Identified

	September 2021	May 2022	Improved?
General Information	45	59	↑
Hazmats	20	24	↑
HIPAA	95	111	↑
Imaging/radiation	17	21	↑
Lead institution	4	10	↑
Locations	49	36	-
Modification	40	37	-
Personnel	258	252	-
Privacy/data security	460	356	-
Procedures	346	302	-
Protocol	208	201	-
Recruitment/consent	711	494	↓
Renewal	26	30	-

Section and Number of Tasks Identified

	September 2021	May 2022	Improved?
Research Aims/Abstracts	24	37	-
Risks	114	85	-
Subjects	365	307	↓

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 bring 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