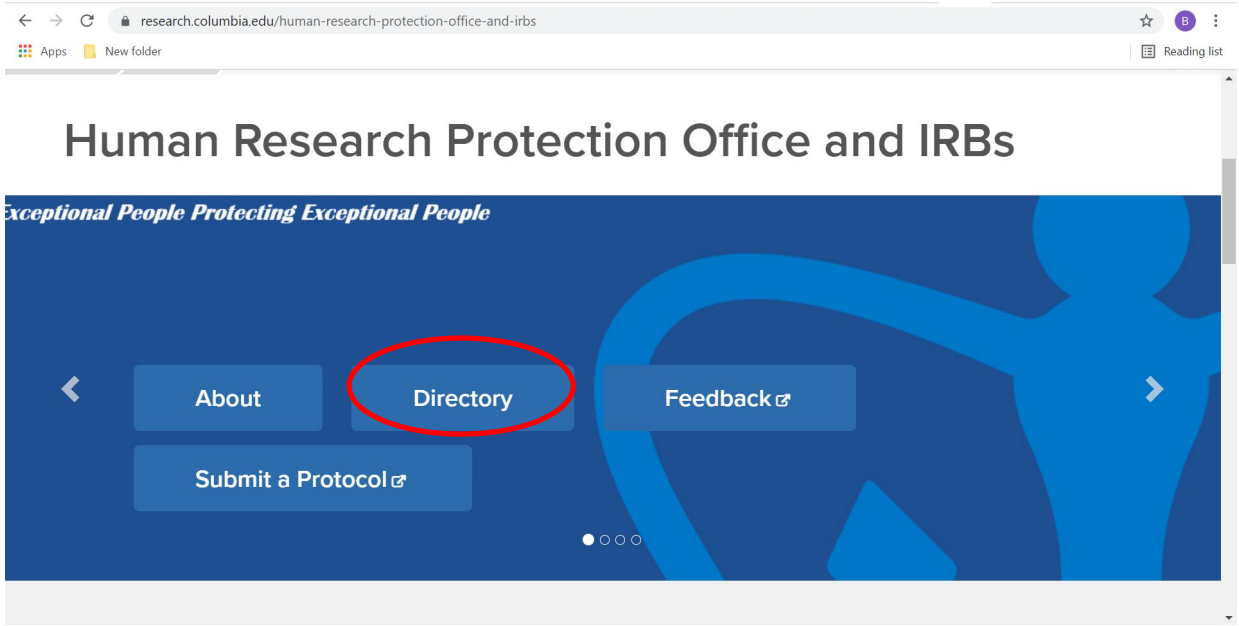
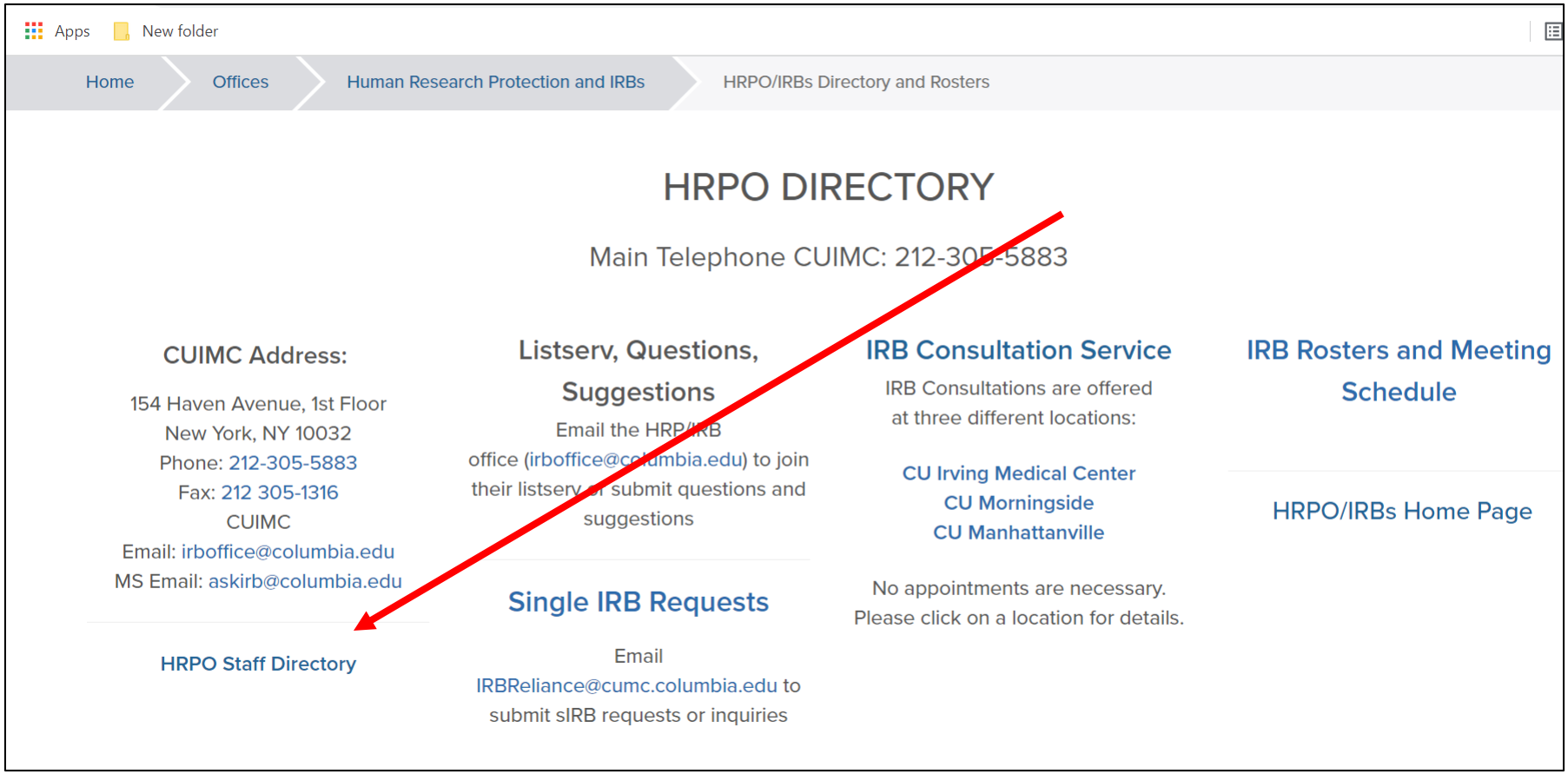
Monthly IRB-Investigator Meeting: HRPO Updates, Common Reasons for Returns, Common Noncompliance Findings

Brenda Ruotolo
AVP for Human Research Protection
October 28, 2021

HRPO Updates

- Website: research.columbia.edu/irb
- Staffing




Apps
New folder
Home
Offices
Human Research Protection and IRBs
HRPO/IRBs Directory and Rosters
HRPO DIRECTORY
Main Telephone CUIMC: 212-305-5883
CUIMC Address:
154 Haven Avenue, 1st Floor
New York, NY 10032
Phone: 212-305-5883
Fax: 212 305-1316
CUIMC
Email: irboffice@columbia.edu
MS Email: askirb@columbia.edu
HRPO Staff Directory
Listserv, Questions, Suggestions
Email the HRP/IRB office (irboffice@columbia.edu) to join their listserv or submit questions and suggestions
Single IRB Requests
Email IRBReliance@cumc.columbia.edu to submit sIRB requests or inquiries
IRB Consultation Service
IRB Consultations are offered at three different locations:
CU Irving Medical Center
CU Morningside
CU Manhattanville
No appointments are necessary.
Please click on a location for details.
IRB Rosters and Meeting Schedule
HRPO/IRBs Home Page

Columbia Human Research Protection Office (HRPO) Staff Directory

NAME	TITLE	DIRECT LINE	E-MAIL	LOCATION
DIRECTORS				
Brenda Ruotolo	*AVP for Human Research Protection*	342-1218	blr2102	154 Haven
Sean Hobson	*Director, Operations*	342-0756	sh4148	154 Haven
Laurence Butaud-Rebbaa	*Director, IRB Management*	773-544-3676	lb2643	154 Haven
Vacant	*Director, Compliance Oversight*	853-0233	TBD	Studebaker
Kimberly Bazylewicz	*Asst. Director, IRB Management*	342-0948	kb3243	154 Haven

154 Haven Avenue, 1st Floor, New York, New York 10032

Main: (212) 305-5883 Email: IRBoffice@columbia.edu Conference Room: (212) 342-1225

NAME	TITLE	DIRECT LINE	E-MAIL	ROOM #
Staff supporting IRB 1				
Diana Lesmes	*Manager*	342-3182	dl3041	102
Catherine Singer	*IRB Specialist*	342-0181	cs4145	102
Staff supporting IRB 2				
Oskar Neyra	*Manager*	342-0033	on2170	102
Vacant	*Assistant Manager*	342-1222	TBD	102
Staff supporting IRB 3				
Stephanie Peña	*Manager*	342-1215	sm4434	102
Vacant	*IRB Specialist*	305-8672	TBD	102
Staff supporting IRB 4				
Qiana Quiles	*Manager*	305-3667	qq2110	102
Jenilee Henriquez	*Assistant Manager*	342-0035	jh2716	102
Martha (Isabel) Bustamante	*IRB Specialist*	342-0038	mir2121	102
Vacant	*IRB Specialist*	305-6485	TBD	102
Staff supporting IRB 5				
Yaritza Collazo	*Senior Manager*	305-1007	yr111	102
Vacant	*IRB Specialist*	342-0031	TBD	102
EXPEDITED/ADMIN				
Ashley Halinski	*Manager*	342-0180	ah3675	102
Carri-Ann Gay	*IRB Specialist*	305-9462	cg2618	102
Janelle Ortega	*IRB Specialist*	305-4144	jo2629	102
Vacant	*IRB Specialist*	305-9008	TBD	102
MORNINGSIDE (MS)	MS Email		askirb@columbia.edu	
Vacant	*Manager*	342-3058	TBD	102
Annie Barry	*Assistant Manager*	342-0034	ab14	101
Stephanie Stanford	*IRB Specialist*	342-0052	ss6344	101
OPERATIONS				
Amanda (Mandi) Fox	*Exec. Asst./QA Specialist*	342-0095	af3053	101
Tasha Smith	*Senior IRB Specialist - Liaison*	342-5136	ts2257	101
Deirdre Lombardi	*IRB Regulatory Specialist*	342-0949	dl2971	101

Studebaker Building, 615 West 131st Street, New York, NY 10027

NAME	TITLE	DIRECT LINE	E-MAIL	FLOOR
COMPLIANCE OVERSIGHT				
Vacant	*Director, Compliance Oversight*	853-0233	TBD	6
Grace Kim	*Research Compliance Manager*	851-7043	gk2477	6
Maryanne McGinn	*IRB Audit Specialist*	851-7041	mm4332	6

10/7/2021

Updates - Rascal

- Task functionality revisions underway
- Adding ‘RHI’ as option for Sensitive Data
- Revising options for storage of electronic Sensitive Data
- Revising Certificate of Confidentiality, GDPR, Imaging-Incidental Findings sections
- Reviewing ‘wishlist’ of enhancements

COMMON REASONS FOR RETURNS

Review Process

- Event (new protocol, modification, renewal, annual report, UP report) is submitted
- HRPO staff conduct 'pre-review'
- Next level review:
  - NHSR and exempt research: HRPO staff
  - Expedited reviews: IRB member or, for administrative modifications, HRPO staff
  - All others: review by convened IRB
  - IRB Executive Committee will review certain items

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’

Analysis of Reasons for Return

- Report from Rascal team of all Tasks for Events returned in September 2021
- 411 Events [roughly = studies] represented
- 4804 Tasks
- Average (mean) 11.7 Tasks per Event
- Caveat: Same task may have been communicated more than one time

Sections/Tasks (by Section)

Attributes	50
Background	115
Biological Specimens	64
Child involvement	19
Consent form	418
Dept approval	1
Devices	15
Documents	1062
Drugs/biologics	20
Exempt/expedited	76
Existing data	110
Funding	35
Future use	37
General information	45
Hazmats	20

HIPAA	95
Imaging/radiation	17
Lead institution	4
Locations	49
Modification	40
Personnel	258
Privacy/data security	460
Procedures	346
Protocol	208
Recruitment/consent	711
Renewal	26
Research Aims/Abstracts	24
Risks	114
Subjects	365

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Tasks for ‘Documents’

- ‘Catch-all Section’
  - Need pdf version – 268 occurrences
  - Archive – 134
  - Submit document ‘as mentioned in application’
  - ‘Revise’ – 72 occurrences (total is higher)
  - Related to consent documents – 76
  - Inconsistencies between document and protocol
  - Duplicate docs submitted
  - Cannot identify current version
  - Need documentation from non-CU entity

Tasks for ‘Recruitment/Consent’

- How will participants be identified
- How will consent be obtained
- Letter of support if CU/NYP affiliates will be recruited
- Waiver criteria not justified
- Details not provided, esp for special cases
- Wrong options selected or request denied
- Compensation – 99 occurrences

Tasks for 'Privacy/Data 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

Tasks for ‘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., RRI or IF
- Signature lines inconsistent with participant cohort
- Risks not prioritized

Tasks for ‘Subjects’

- Vulnerable subjects responses incorrect
- Accrual vs enrollment numbers inaccurate
- 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, e.g., all adults but 100% non-specific

Tasks for ‘Personnel’

- Training:
  - TC0019 – 47
  - TC0087 – 157
  - Other trainings e.g., FDA, Minors, genetic, GCP
  - Refresher training
- PI eligibility – 32
- Waiver of consent but personnel ‘obtaining IC’
- New personnel not added; listed in mod summary
- Roles or ‘engagement’ inaccurate

General

- Returns are costly in terms of researcher and HRPO/IRB time/effort
- Careful review of datasheet and all attached documents strongly recommended before submission – accuracy, completeness, consistency
- Select task 'completed' only if fully addressed; hundreds of 'Task not completed' returns
- Explain unusual situations in memo/letter attached to Event if necessary ("Read me" or "Response to IRB"

COMMON COMPLIANCE FINDINGS

IRB Oversight Responsibilities

- The IRB has the responsibility to oversee the conduct of HS research that is conducted by CU and (certain) NYP personnel
- To meet this responsibility, the HRPO COT may audit such research ('routine audit')
- A 'for-cause' audit or investigation may be conducted in response to an allegation of noncompliance with applicable regulations/laws/policies or IRB determinations

Researcher Responsibility

- Researchers are required to report actual or suspected noncompliance
- Violations (major or minor) and UPs may – or may not – involve noncompliance
- If in doubt about reporting, consult HRPO staff

Common NC Findings

- Informed consent violations
  - Process
  - Signatures
  - Documentation
  - Personnel
- Data security
  - Storage
  - Transfer/transmission
  - Access
- Not following IRB-approved protocol

Future Session

- Common COT findings
- Details including quantitative data
- Best practices to avoid noncompliance
  - Informed consent
  - Study documentation
  - Data security
  - Training

Contact the HRPO

Website: research.columbia.edu/irb

(or search for ‘IRB’ on main CU website)

Email general inbox: irboffice@columbia.edu

General phone line: 212.305.5883