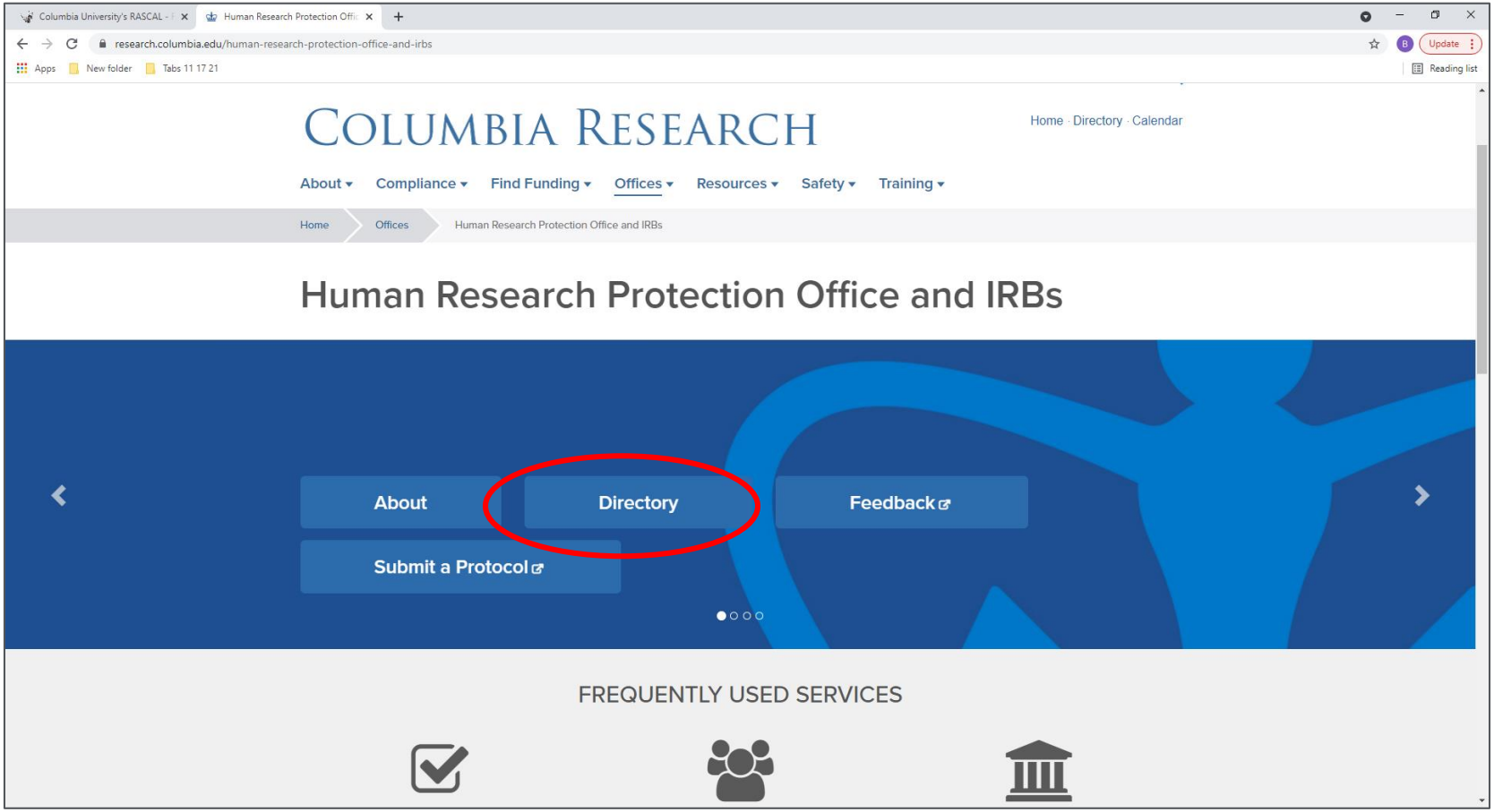
MONTHLY IRB-INVESTIGATOR MEETING – Q AND A

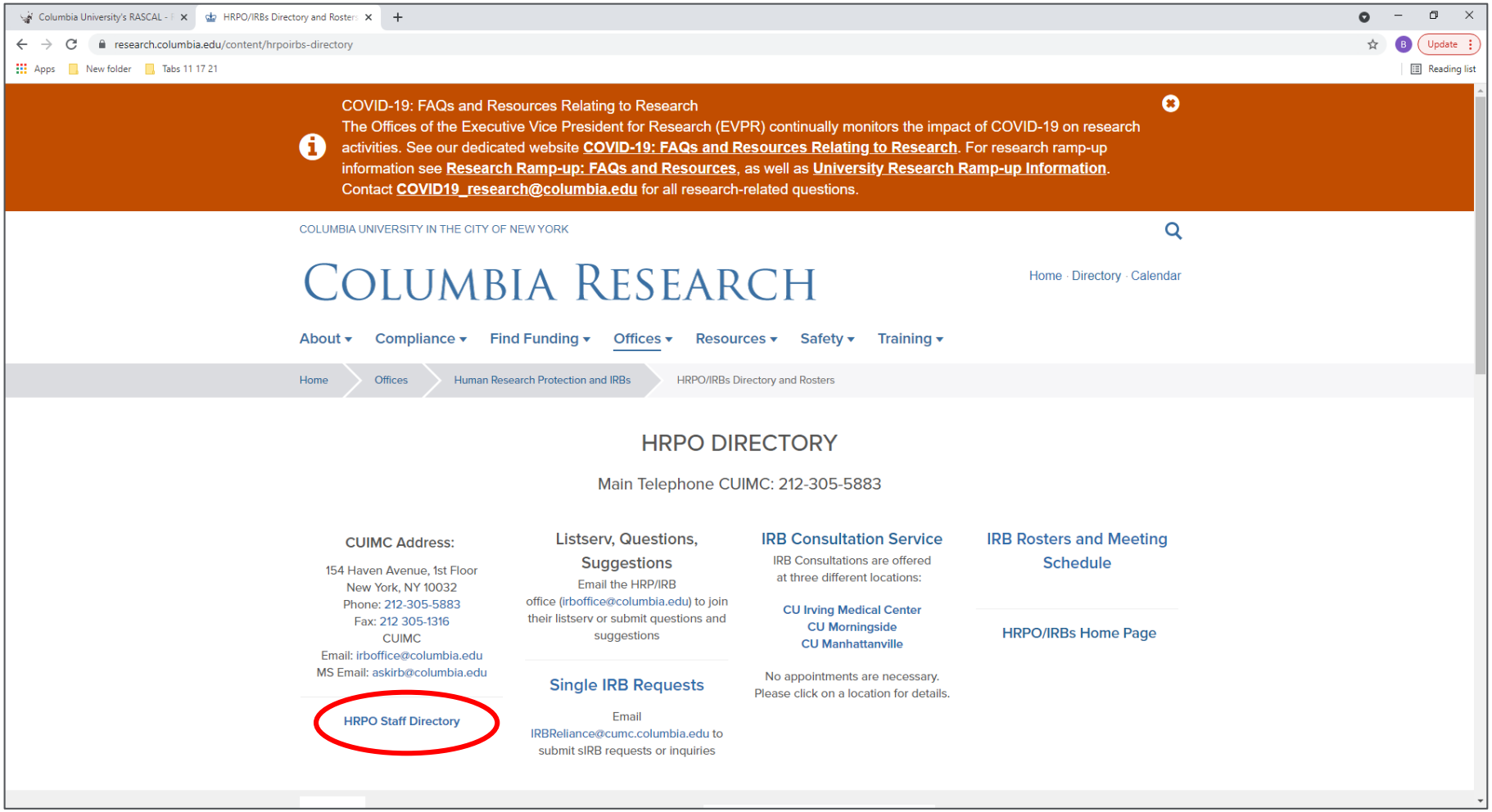
Columbia University
Human Research Protection Office

November 18, 2021

COLUMBIA | COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

Q: There seem to have been many changes among HRPO staff. How do I know who to contact?




Columbia University's RASCAL -
HRPO/IRBs Directory and Roster
research.columbia.edu/content/hrpoirbs-directory
Update
Apps
New folder
Tabs 11 17 21
Reading list
COVID-19: FAQs and Resources Relating to Research
The Offices of the Executive Vice President for Research (EVPR) continually monitors the impact of COVID-19 on research activities. See our dedicated website COVID-19: FAQs and Resources Relating to Research. For research ramp-up information see Research Ramp-up: FAQs and Resources, as well as University Research Ramp-up Information. Contact COVID19_research@columbia.edu for all research-related questions.
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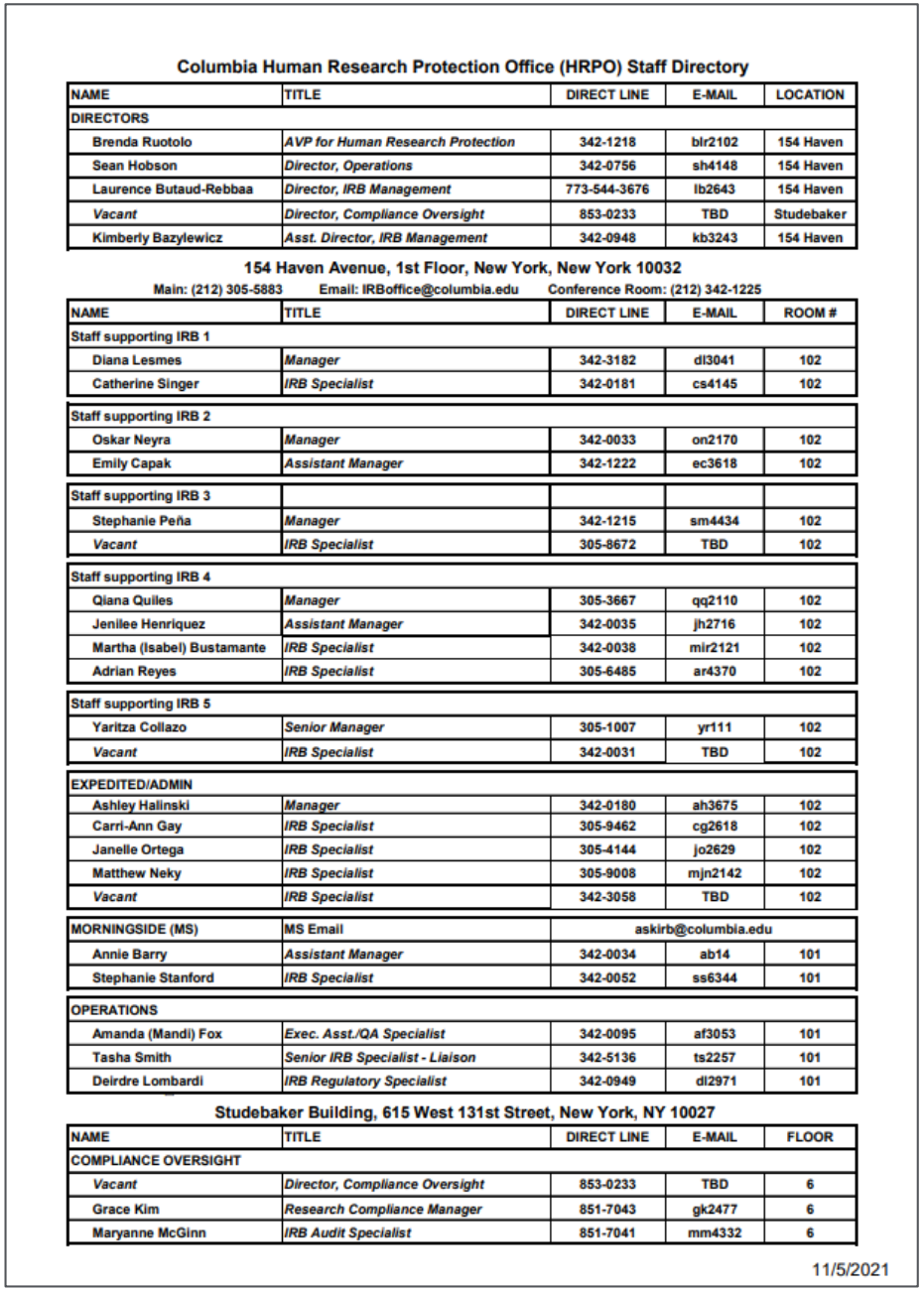
Human Research Protection and IRBs
HRPO/IRBs Directory and Rosters
HRPO DIRECTORY
Main Telephone CUIMC: 212-305-5883
CUIMC Address:
154 Haven Avenue, 1st Floor
New York, NY 10032
Phone: 212-305-5883
Fax: 212 305-1316
CUIMC
Email: irboffice@columbia.edu
MS Email: askirb@columbia.edu
HRPO Staff Directory
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
Emily Capak	*Assistant Manager*	342-1222	ec3618	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
Adrian Reyes	*IRB Specialist*	305-6485	ar4370	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
Matthew Neky	*IRB Specialist*	305-9008	mjn2142	102
Vacant	*IRB Specialist*	342-3058	TBD	102
MORNINGSIDE (MS)	MS Email	askirb@columbia.edu		
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

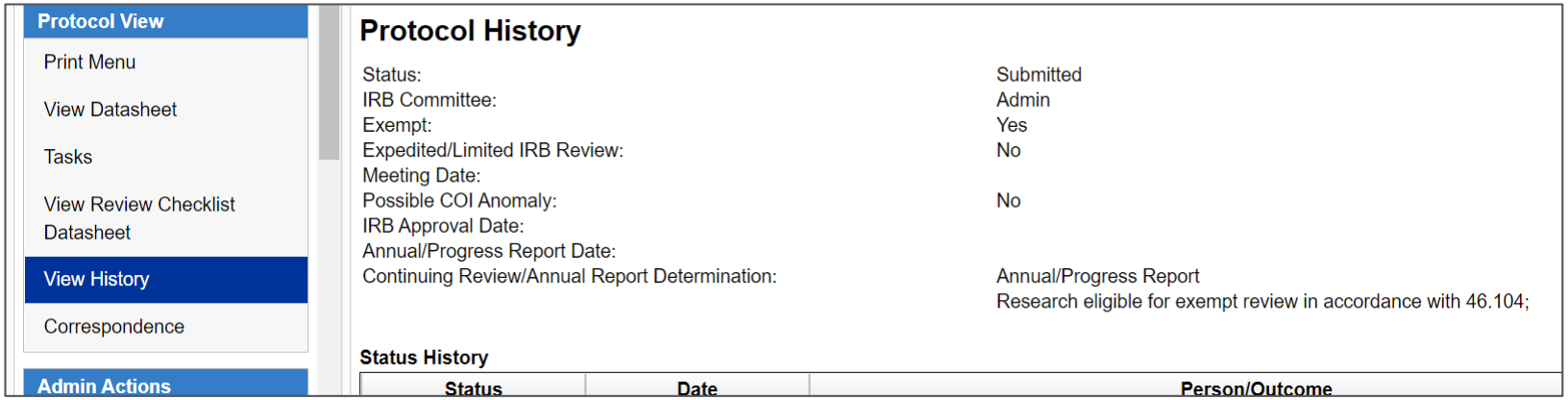
NAME	TITLE	DIRECT LINE	E-MAIL	FLOOR
COMPLIANCE OVERSIGHT				
Vacant	*Director, Compliance Oversight*	853-0233	TBD	6
Grace Kim	*Research Compliance Manager*	851-7043	gk2477	6
Maryanne McGinn	*IRB Audit Specialist*	851-7041	mm4332	6

11/5/2021

https://research.columbia.edu/sites/default/files/content/HRPO/Directories/HRPOStaffDirectory%2011.05.2021.pdf

Who - or what IRB - is reviewing your study?

- When first “submitted”, new study will not be assigned to an IRB
- When study is assigned to staff reviewer: email sent
- At time of first log in or return, assigned to IRB/Admin

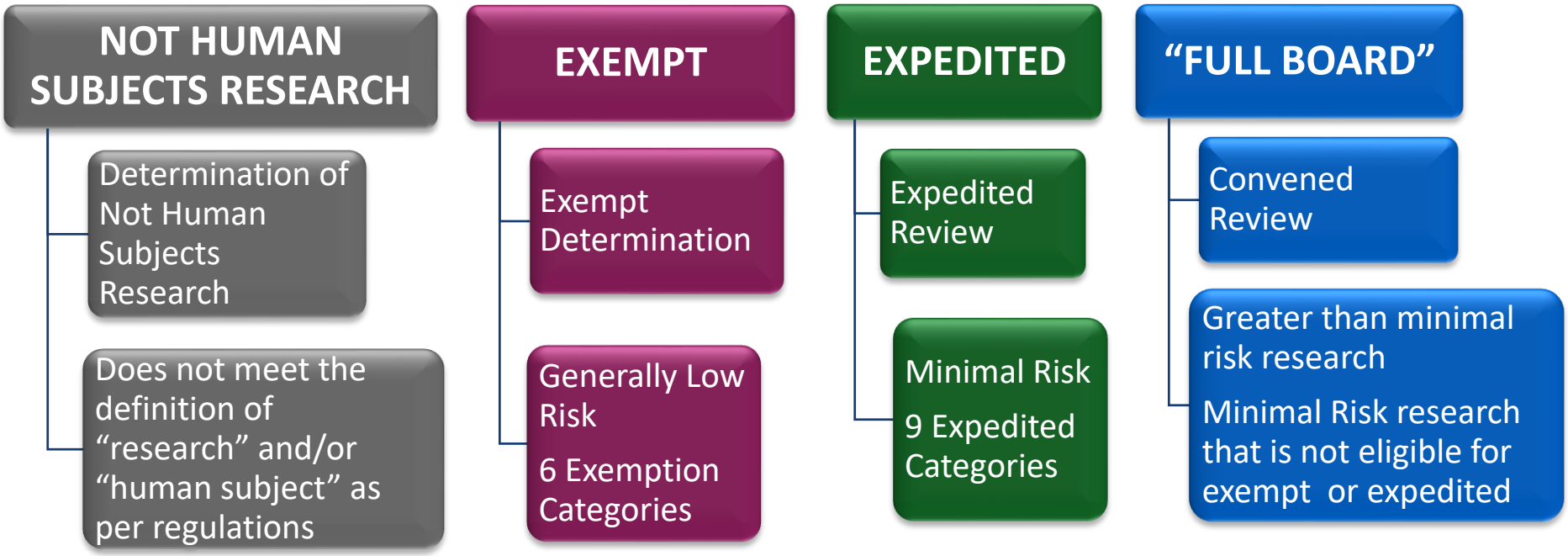


Review Process

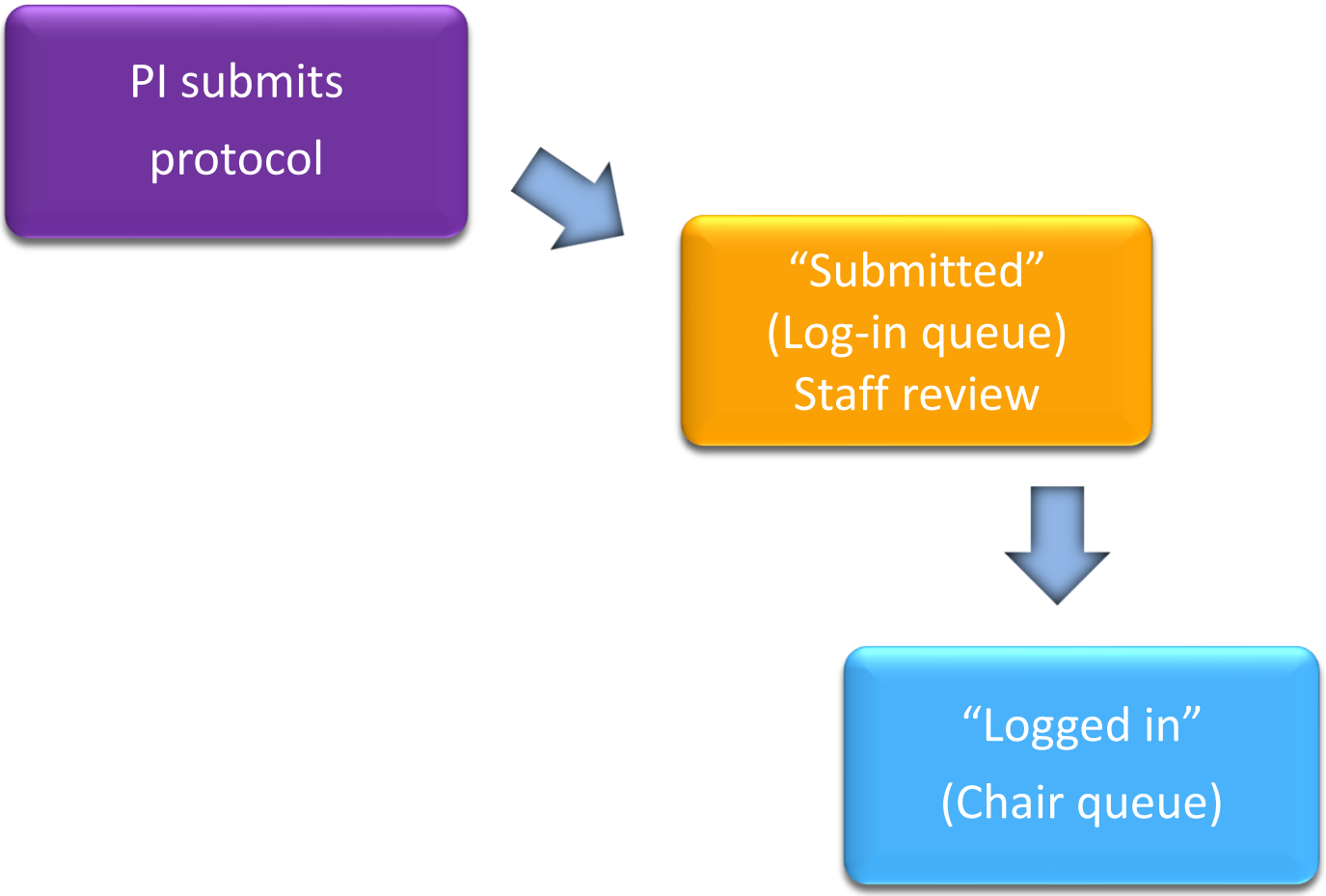
- Submitted = Administrative/regulatory review by HRPO staff
  - Return if incomplete or clarifications are necessary
  - Tasks available in Rascal; correspondence sent
- Determination of level of review
  - NHSR
  - HSR but exempt *from the requirements of the regs*
  - Eligible for expedited review (one IRB member)
  - Requires convened review
- Log in = drops into queue for next level of review
  - HRPO staff; IRB member; assigned to meeting

Regulatory Pathways

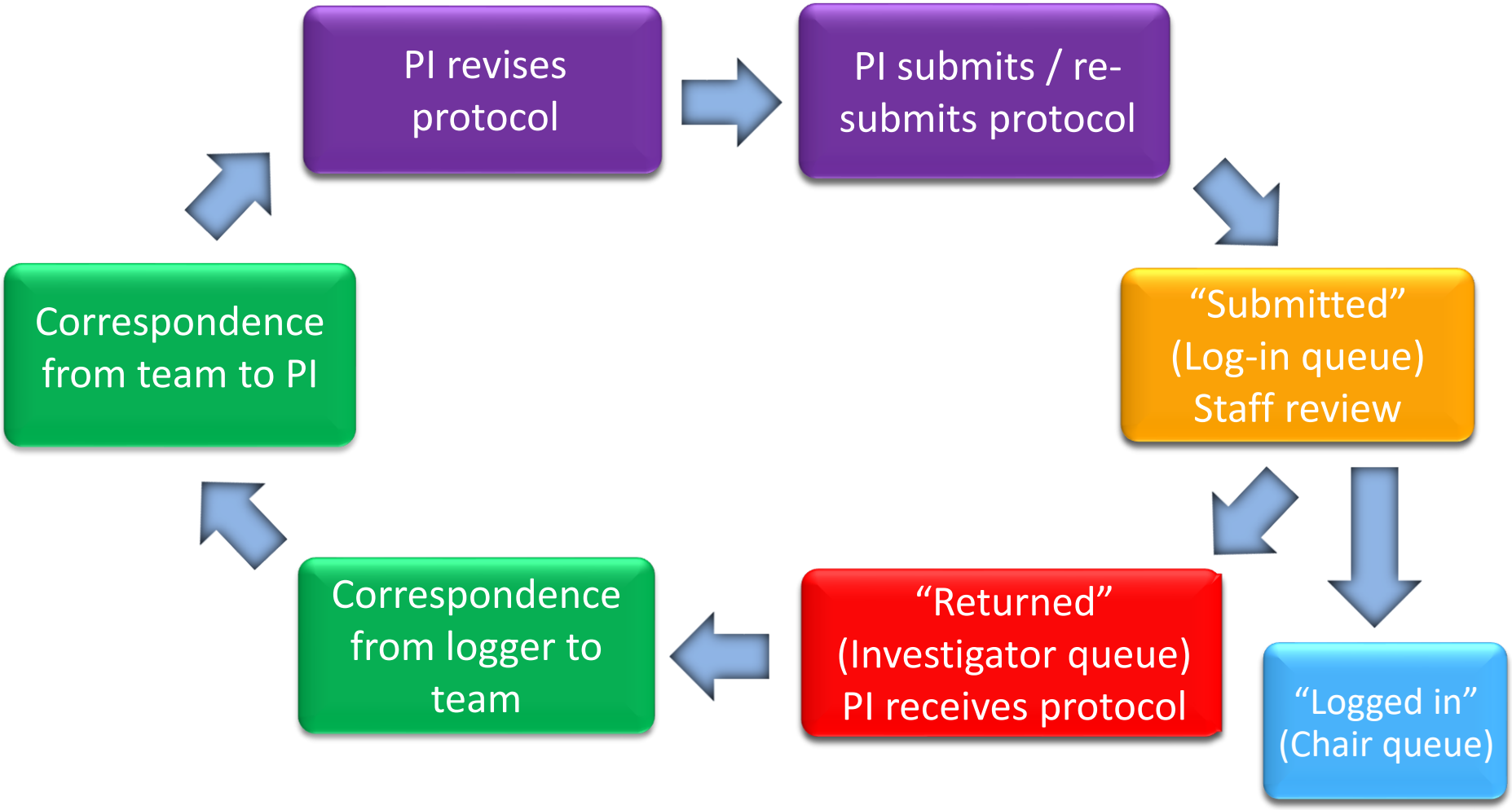
All research projects are categorized based on the level of risks introduced to human subjects and whether they meet the qualifications under specific categories established by the federal regulations at 45 CFR 46.



New Protocol Pathway (Ideal)



New Protocol Pathway (Common)



Q: What is the status of IRB 5? Why was my study moved to another IRB?

- Late August 2021:
  - convened meetings of IRB 5 were suspended due to significant member and support staff changes
  - expedited reviews continued by IRB 5 Chair
- Scope and membership of IRB 5 was revised to meet current research needs
- November 2021:
  - 1st meeting of IRB 5 with new Chair and membership
  - most studies will be moved back to IRB 5

Scope/manager of each Columbia University IRB

IRB 1: non-specific; no cancer-related

HRPO manager: Diana Lesmes

IRB 2: non-specific; no cancer-related

HRPO manager: Oskar Neyra

IRB 3: non-specific; no cancer-related

HRPO manager: Stephanie Pena

IRB 4: cancer-related only

HRPO manager: Qiana-Denise Quiles

IRB 5: non-specific; some cancer-related

HRPO manager: Yaritza Collazo

Q: Is there still a Morningside IRB?

Morningside research that:

- requires convened review is reviewed by IRBs 1-5
  - Faculty and staff from Morningside departments participate in these reviews as necessary
- is eligible for expedited review is currently assigned to the “Morningside IRB” and reviewed by Morningside faculty
- Is eligible for an exempt determination is reviewed by HRPO staff and assigned to the Administrative Review Committee

Q: When is review by the Human Embryonic and Human Pluripotent Stem Cell Research Committee Required?

Reference: Columbia University Policy on the Conduct of Research with Human Embryos and Human Pluripotent Stem Cells.

Effective date: July 6, 2020

URL:

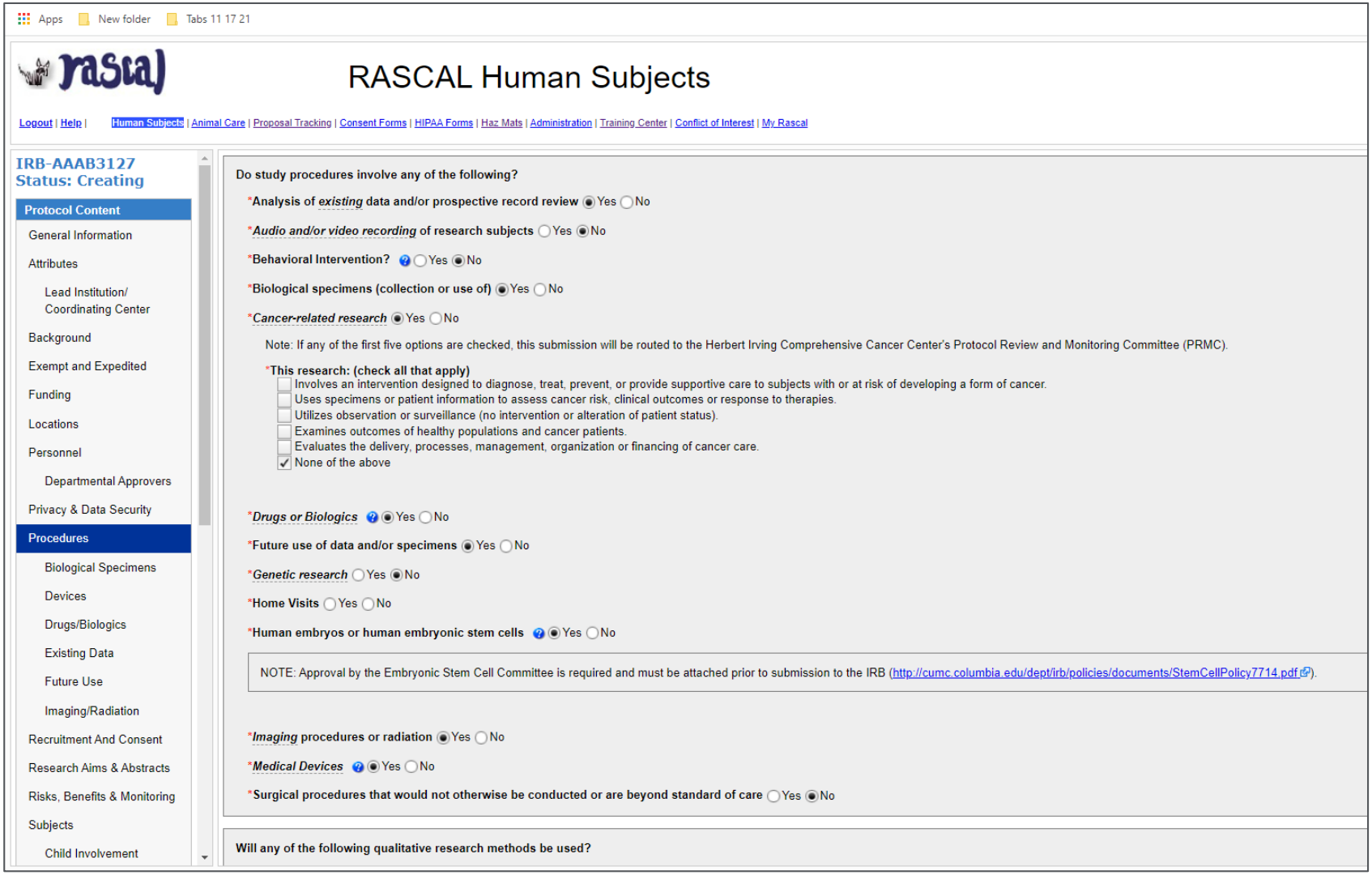
https://research.columbia.edu/sites/default/files/content/HRPO/EmbryoStem%20Cell%20Policy%20DFS%207.6.20.pdf

The following Covered Research (Restricted Research) must be approved by the Committee prior to the commencement of any research procedures:

- Research involving Human Embryos, irrespective of their origin, including the genetic manipulation of Human Embryos or gametes used to make embryos in vitro and the generation of new hPSCs from Human Embryos;
- Research involving the generation of Blastoids;
- Research involving the generation of cerebral Organoids or neural stem cells or tissues derived from hPSC that are implanted into experimental animals; and
- Research involving human-animal blastocyst Chimeras.

Process

- Researchers should contact Debbie Stiles before submitting their protocol to the IRB if they propose to conduct research with Human Embryos and Human Pluripotent Stem Cells, including Human Embryonic Stem Cells as well as Induced Pluripotent Stem Cells and Human Expanded Potential Stem Cells. It also covers Brain Organoids that are initiated from adult stem cells or Pluripotent Stem Cells.
- Documentation of the Committee's approval or Debbie's email that this is not required for a particular protocol should be attached to the IRB submission.


Apps
New folder
Tabs 11 17 21
RASCAL Human Subjects
Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal
IRB-AAAB3127
Status: Creating
Protocol Content
General Information
Attributes
Lead Institution/ Coordinating Center
Background
Exempt and Expedited
Funding
Locations
Personnel
Departmental Approvers
Privacy & Data Security
Procedures
Biological Specimens
Devices
Drugs/Biologics
Existing Data
Future Use
Imaging/Radiation
Recruitment And Consent
Research Aims & Abstracts
Risks, Benefits & Monitoring
Subjects
Child Involvement
Do study procedures involve any of the following?
*Analysis of existing data and/or prospective record review Yes No
*Audio and/or video recording of research subjects Yes No
*Behavioral Intervention? Yes No
*Biological specimens (collection or use of) Yes No
*Cancer-related research Yes No
Note: If any of the first five options are checked, this submission will be routed to the Herbert Irving Comprehensive Cancer Center's Protocol Review and Monitoring Committee (PRMC).
*This research: (check all that apply)
Involves an intervention designed to diagnose, treat, prevent, or provide supportive care to subjects with or at risk of developing a form of cancer.
Uses specimens or patient information to assess cancer risk, clinical outcomes or response to therapies.
Utilizes observation or surveillance (no intervention or alteration of patient status).
Examines outcomes of healthy populations and cancer patients.
Evaluates the delivery, processes, management, organization or financing of cancer care.
None of the above
*Drugs or Biologics Yes No
*Future use of data and/or specimens Yes No
*Genetic research Yes No
*Home Visits Yes No
*Human embryos or human embryonic stem cells Yes No
NOTE: Approval by the Embryonic Stem Cell Committee is required and must be attached prior to submission to the IRB (http://cumc.columbia.edu/dept/irb/policies/documents/StemCellPolicy7714.pdf).
*Imaging procedures or radiation Yes No
*Medical Devices Yes No
*Surgical procedures that would not otherwise be conducted or are beyond standard of care Yes No
Will any of the following qualitative research methods be used?

Q: Information about recruitment of patients seems inconsistent. What are the rules?

- Healthcare providers can reach out to their own patients for recruitment purposes, e.g., during clinical care
- If potentially eligible patients will be identified through medical record information:
  - An approved HIPAA form D (Preparatory to Research) is required to review the records or receive the data
- If contact with a potentially eligible patient will be by a researcher who is not the patient's provider:
  - An approved HIPAA form C is required (Partial or "Recruitment" waiver)

Q: Is it an option to send a letter from all providers in a unit to all patients they (collectively) treat?

Yes, under certain circumstances, if IRB approved:

- The request is reasonable
- This approach is described in the IRB application
- The protocol is presented to all providers
- Providers agree to signing the letter and this agreement is documented
- Providers are given the opportunity to identify patients to whom the letter should not be sent
- The letter clearly states that the listed providers are aware that the letter is being sent
- The letter is sent by the medical director
- There is an approved HIPAA form D (Prep to Research)

Q: What is the status of the consent to contact functionality in Epic?

- Procedures for use of the feature are being developed
  - CTO, DBMI, EVPR, HRPO/IRB, EpicTogether
- Pilot testing of the feature is underway
- Feedback on pilot testing will be important
- An update will be provided early in CY22

Consent to contact for research will not replace a provider's option to introduce studies to his/her patients.

Q: What is the pre-consent status in Epic and what do I have to do to use it?

- "Pre-Consent for Epic Encounter Linking" - Active enrollment status in CTMS and Epic to enable linking of a visit and/or test to research prior to signing consent.
- Potential research subjects may need to be registered in Epic with a medical record number (MRN) and identified in CTMS and Epic as a potential subject prior to signing consent.
- Person has been recruited (perhaps by phone or through discussion with a health care provider), and is eligible.
- Scheduling of the visit and ordering of procedures/tests under a research protocol prior to signing consent in anticipation of the study visit is necessary.

“Pre-consent” procedures

- When scheduling visit/tests with prospective participants, inform them of the medical record creation and linkage to the study.
- Once the participant provides consent, the status should be changed to “Consented-In screening”
- If the person does not come to the visit, or declines to participate, the status should be changed to “Declined”
- Linkage to the study remains in their medical record in Epic, whether person provides consent or declines.

https://research.columbia.edu/sites/default/files/content/HRPO/MIM%20files/MIM%2002%2006%2020%20final.pdf

IRB/Privacy Board requirements

- Describe procedures in Recruitment and Consent section of Rascal
  - Indicate that the pre-consent status will be used
    - Constitutes alteration of authorization
  - Include that notification of linkage in Epic will be provided to prospective participant and participant verbally agrees
    - Document in research record
- Attach necessary HIPAA forms

HIPAA requirements for “Pre-consent” status

Requirements depend on manner of recruitment

Scenario	Study team will initiate contact; Prospective subject is a patient (has MRN in our system) and EHR info will be accessed to identify eligible patients.	Study team will initiate contact; Prospective subject is not a patient or it is unknown if he/she is a patient (i.e., not using EHR to identify eligible individuals).	Prospective subject initiates contact; may or may not be a patient but initiates contact with the study team about the study (e.g., after seeing a flyer etc.).

Scenario	Study team will initiate contact; Prospective subject is a patient (has MRN in our system) and EHR info will be accessed to identify eligible patients.	Study team will initiate contact; Prospective subject is not a patient or it is unknown if he/she is a patient (i.e., not using EHR to identify eligible individuals).	Prospective subject initiates contact; may or may not be a patient but initiates contact with the study team about the study (e.g., after seeing a flyer etc.).
HIPAA	Form D (prep to research) to identify potentially eligible patients Form B (request for waiver of authorization) to use the information to contact if cold calling (note that IRB rarely approves this). Alteration of authorization if obtaining verbal authorization on the phone (IRB would likely require) – patient should be told that there will be information about their potential research participation in Epic Form A (authorization, whether standalone or in CF) at time of study visit.	Alteration of authorization if obtaining verbal authorization on the phone (IRB would likely require) or otherwise before consent is obtained – person should be told that there will be information about their potential research participation in Epic. This would include telling non-patients that a medical record will be created for them in Epic (as it seems necessary for them to have one if tests/labs will be ordered for them through Epic). Form A (authorization, whether standalone or in CF) at time of study visit.	Alteration of authorization if obtaining verbal authorization on the phone (IRB would likely require) or otherwise before informed consent is obtained – person should be told that there will be information about their potential research participation in Epic. This would include telling non-patients that a medical record will be created for them in Epic (as it seems necessary for them to have one if tests/labs will be ordered for them through Epic). Form A (authorization, whether standalone or in CF) at time of study visit.

Questions?

Human Research Protection Office

Reliance related email: irbreliance@columbia.edu

General email: irboffice@columbia.edu

Main office phone: 212-305-5883

Website: research.columbia.edu/irb