IRB Town Hall

Spring Training

- This session will be recorded
- Please use the Chat or Q&A feature to post questions
- Questions will be addressed at the end of each section

April 27, 2021

Margaret Hsieh, MD – IRB Chair
Jean Barone – HRP Director
Melissa Miklos, HRP Associate Director

TODAY'S LINEUP

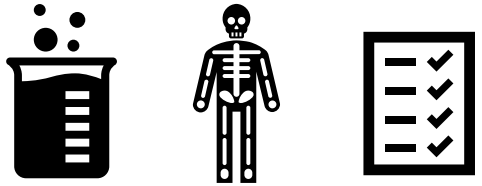
1. Jurisdiction of the Pitt IRB
2. Incoming and outgoing investigators
3. HRP integration and PERIS™
4. COVID-19 related topics
   - Environmental health and safety
   - Starting and restarting research
5. Data security
6. Obtaining informed consent
   - Pitt and UPMC rules
   - Timing of consent
   - Electronic and remote consent

Pitt IRB Jurisdiction

Pitt Research

Rob Rutenbar –
Senior Vice Chancellor for Research

Office of Research Protections



Office of Innovation and Entrepreneurship

Office of Economic Partnerships

Office of Sponsored Programs

Office of Research Computing

Human Research Protections

Bill Yates, PhD
Vice Chancellor of
Research Protections

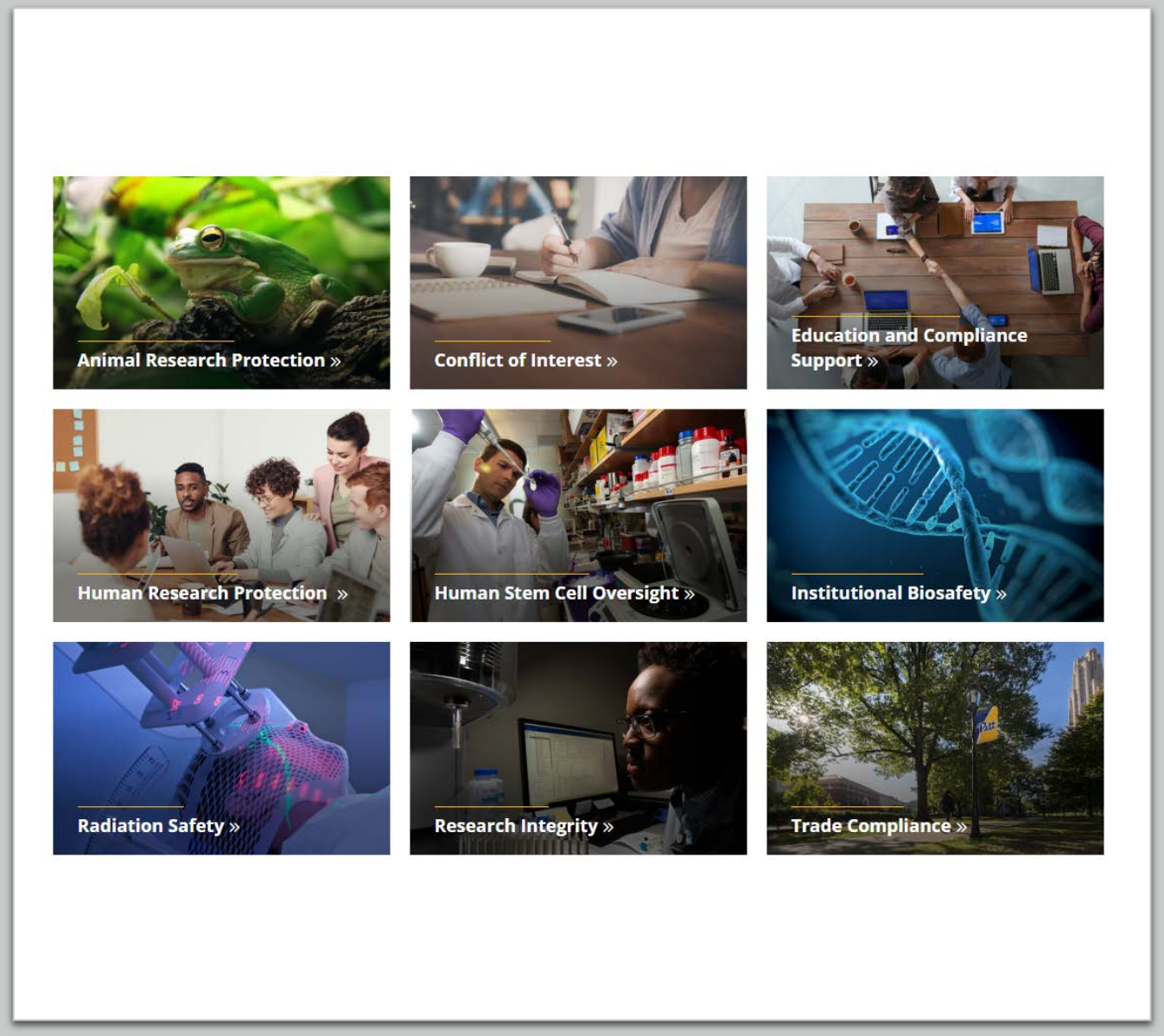
Margaret Hsieh, MD
IRB Chair

Jean Barone, CIP

HRP Director

Melissa Miklos, MSL, CIP

HRP Associate Director



The IRB has the authority to approve, require modifications in (in order to approve), or disapprove all research activities involving human subjects

When Pitt/UPMC faculty, staff or students are engaged in human subject research

It takes place in Pitt/UPMC facilities

It is conducted using the private records of Pitt/UPMC

Single IRB Review (sIRB)

Legal arrangement that allows one IRB to review the research on behalf of other engaged institutions

NIH Policy:

- Effective January 25, 2018
- Applies to NIH funded new grant, renewal, revision or resubmission
- Multi-site
- Non-exempt
- Domestic

DHHS Policy:

- Effective January 18, 2020
- Applies to ANY federally funded new grant, renewal, revision or resubmission
- Multi-site
- Non-exempt
- Domestic

IRB.reliance@pitt.edu

When is reliance appropriate?

Required

- NIH
- DHHS
- Consortium or Network

Optional

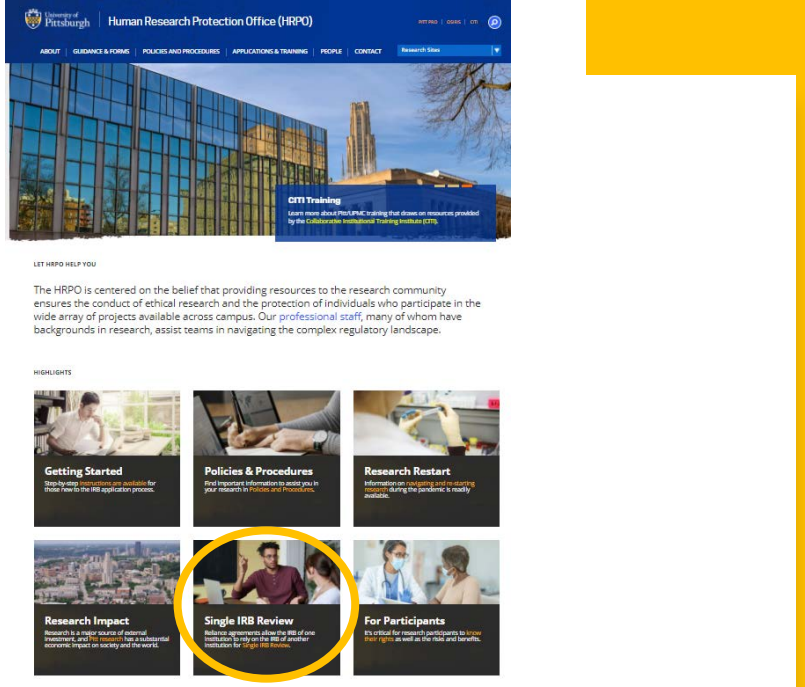
- Engaged collaborator conducting subcontract
- Investigator relocating with previous IRB approval
- Engaged investigator(s) with no IRB

Getting Started with sIRB

1. Select "Single IRB Review" from www.hrpo.pitt.edu
2. Click on "Reliance Request System"
   - Complete list of questions in the Reliance Request System can be found under "Reliance Guidance" in A-Z
3. **Be prepared** and ensure consistency among documents (e.g., same title throughout)

IRB.reliance@pitt.edu

1.



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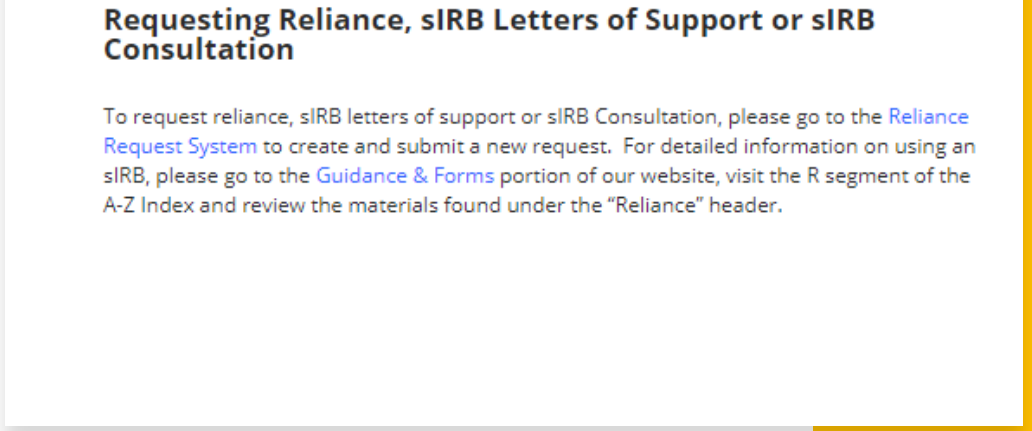
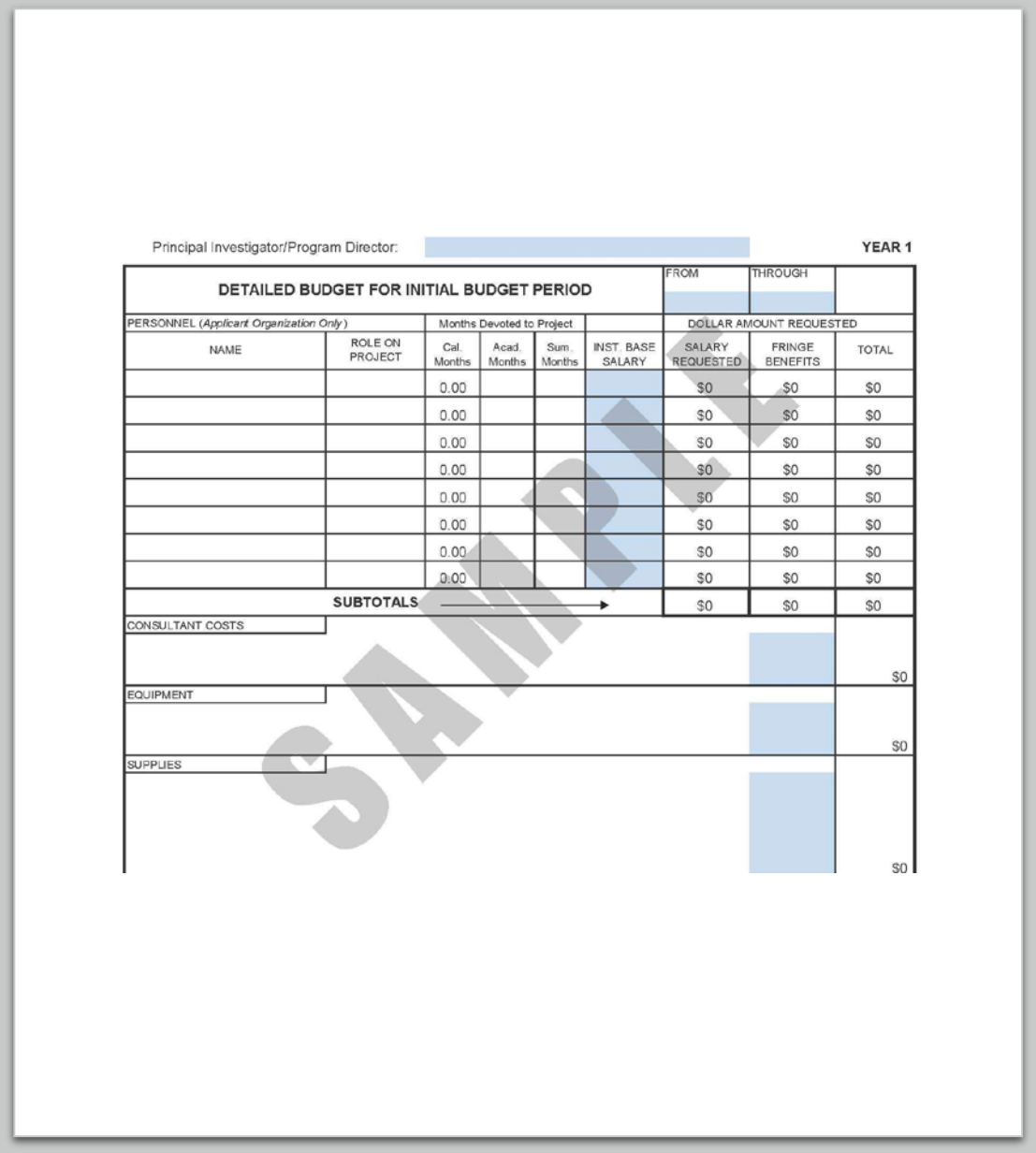


sIRB Budgeting

- Direct costs need to budgeted for IRB services
- Effective after **June 1, 2021**, the new IRB fee structure goes into effect
- Study teams must contact irb.reliance@pitt.edu *at least* four weeks in advance of grant due date to develop the budget
- Failure to budget for these costs may result in Pitt IRB being unable to act as IRB-of-Record



Principal Investigator/Program Director: YEAR 1

DETAILED BUDGET FOR INITIAL BUDGET PERIOD						FROM	THROUGH	
PERSONNEL (*Applicant Organization Only*)		Months Devoted to Project				DOLLAR AMOUNT REQUESTED		
NAME	ROLE ON PROJECT	Cal. Months	Acad. Months	Sum. Months	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
		0.00				$0	$0	$0
		0.00				$0	$0	$0
		0.00				$0	$0	$0
		0.00				$0	$0	$0
		0.00				$0	$0	$0
		0.00				$0	$0	$0
		0.00				$0	$0	$0
		0.00				$0	$0	$0
SUBTOTALS →						$0	$0	$0
CONSULTANT COSTS								$0
EQUIPMENT								$0
SUPPLIES								$0

SAMPLE

Pitt Research

OSPARS:
UPMC Office of Sponsored Programs and Research Support

Purview: Facilitate industry-initiated and sponsored clinical trials of drugs and devices

- Conducted within a UPMC or UPP facility

  or

- Conducted under the direction of a UPMC or UPP staff member in connection with UPMC and/or UPP responsibilities, appointments and clinical privileges

OSPARS@upmc.edu

Pitt IRB or OSPARS Checklist

- ✓ Was any University of Pittsburgh faculty or staff member involved substantially in the development of the clinical trial protocol?
- ✓ Does any University of Pittsburgh faculty or staff member serve as the investigator-sponsor of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) for the experimental drug or device being evaluated in the clinical trial?
- ✓ Is the conduct of this clinical trial being financially supported by any entity other than the industry sponsor and, possibly, the clinical department/division to whom the principal investigator reports?
- ✓ Will the clinical trial procedures be performed exclusively within a University facility without any use of UPMC patients, records, or facilities (i.e., this does not apply to University-owned buildings leased by UPMC)?
- ✓ Does the experimental drug or device being evaluated in the clinical trial 1) emit ionizing radiation; 2) involve a gene transfer intervention; or 3) involve a transgenic xenotransplant?

"NO" to ALL is submitted to OSPARS for processing

Incoming and Outgoing Investigators

Incoming Investigators

Human subject research and grant proposals can be submitted in advance of arrival

Potential activities:

- Open new studies prior to arrival
- Transfer research from another institution
- Execute agreements for other IRBs to maintain jurisdiction

Contacts

- Human subject research needs askirb@pitt.edu
- Office of Sponsored Programs for funding needs www.osp.pitt.edu
- ORP Concierge Tool www.orp.pitt.edu for research needs beyond human subjects

Pitt Research

Preparations that can be done in advance

@pitt.edu

Department Administrators should work to obtain Pitt email and credentials

University of Pittsburgh HSConnect

Set up HSConnect account with Pitt credentials
(DO NOT use Gmail, etc. Case-by-case on other institutional account)

University of Pittsburgh CITI Access Portal

Complete CITI training or link completed CITI training from another institution to Pitt account (https://www.citi.pitt.edu/)

PittPRO | Pitt Protocol Review Online

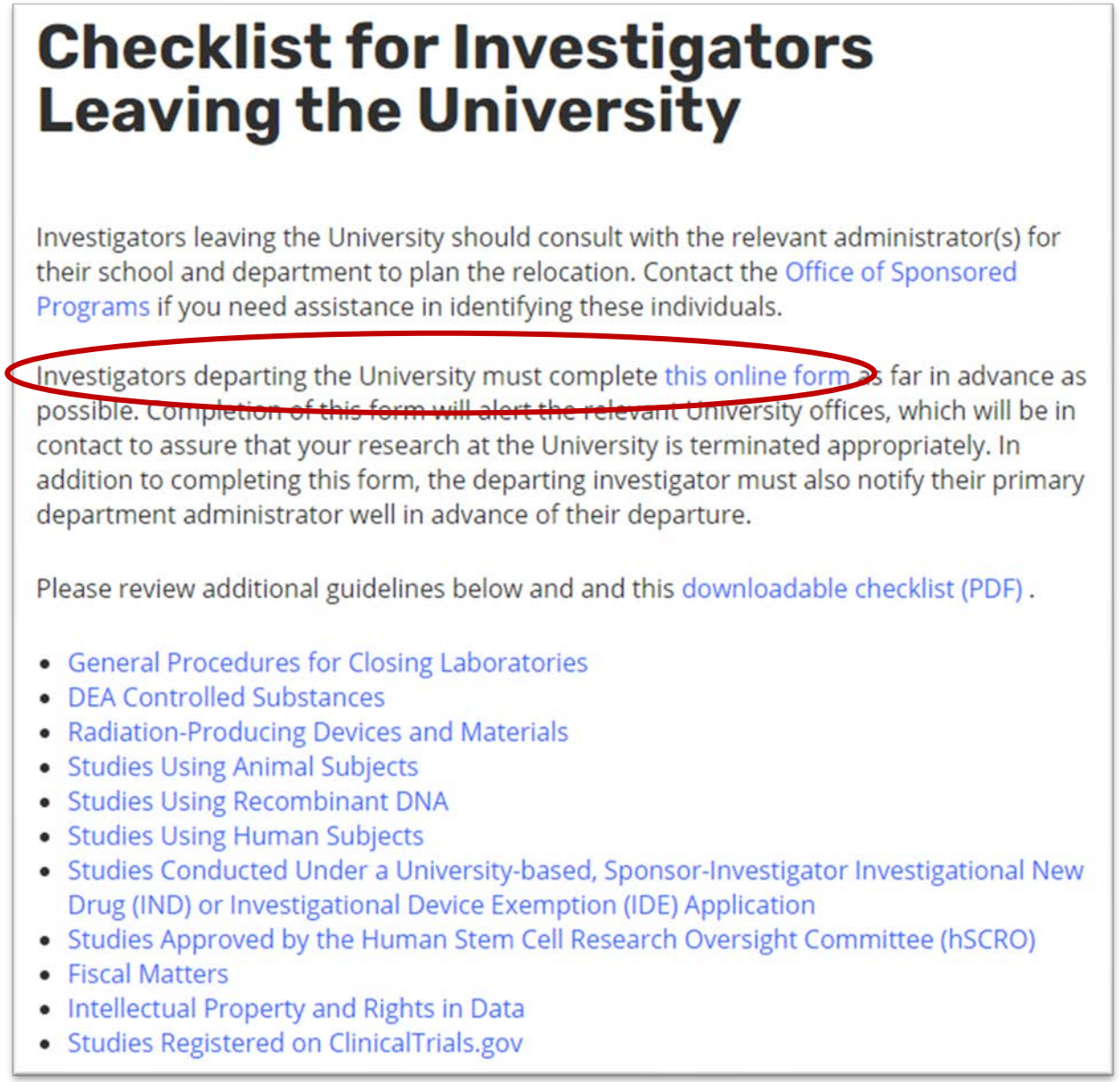
Build submission in PittPRO and submit for approval
(same username and password as HSConnect and CITI)

Outgoing Investigators

Must close or reassign studies prior to departure

Checklist for Investigators Leaving the University: Comprehensive guidelines for activities that must occur with departure

https://www.orp.pitt.edu/resources/checklist-investigators-leaving-university



Checklist for Investigators Leaving the University

Investigators leaving the University should consult with the relevant administrator(s) for their school and department to plan the relocation. Contact the Office of Sponsored Programs if you need assistance in identifying these individuals.

Investigators departing the University must complete this online form as far in advance as possible. Completion of this form will alert the relevant University offices, which will be in contact to assure that your research at the University is terminated appropriately. In addition to completing this form, the departing investigator must also notify their primary department administrator well in advance of their departure.

Please review additional guidelines below and and this downloadable checklist (PDF) .

- General Procedures for Closing Laboratories
- DEA Controlled Substances
- Radiation-Producing Devices and Materials
- Studies Using Animal Subjects
- Studies Using Recombinant DNA
- Studies Using Human Subjects
- Studies Conducted Under a University-based, Sponsor-Investigator Investigational New Drug (IND) or Investigational Device Exemption (IDE) Application
- Studies Approved by the Human Stem Cell Research Oversight Committee (hSCRO)
- Fiscal Matters
- Intellectual Property and Rights in Data
- Studies Registered on ClinicalTrials.gov

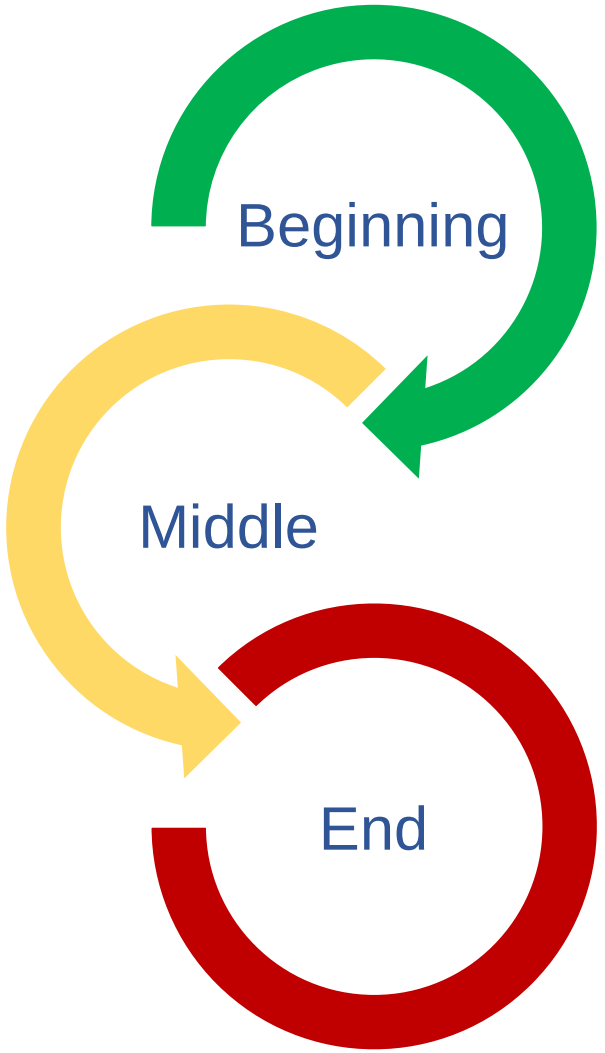
Pitt Research

Closing a completed or terminated study

All studies need to be properly closed: LAPSED and EXPIRED are not appropriate end states!

PittPRO:

- Choose "Create Modification/CR"
- Select first four Milestones
- Click the closure acknowledgement



Pitt Research

Removal of Idle Protocols

Inactive/idle protocols in PittPRO will be discarded by the IRB

Studies in Pre-Submission longer than 4 weeks

Studies in Clarifications Requested after the one month system reminder is sent

Study teams can take the following actions to avoid IRB discard

- **Finalize and submit to IRB for review**
- **Justify extension**
- **Discard**

Note: when a protocol is discarded, the study team can access information but cannot resubmit the project. A new project would need to be submitted for review to be conducted

HRP and PERIS™

PERIS
PITT ELECTRONIC RESEARCH INFORMATION SOLUTION

What is PERIS?

University-wide project to integrate research operations as well as

- Reduce administrative burden for faculty
- Increase efficiency
- Enhance transparency to researchers and administrators
- Create a user-friendly system
- Promote sustainability through electronic processes

Pitt Research

PittPRO | Pitt Protocol Review Online

MyRA my research agreements office of sponsored programs

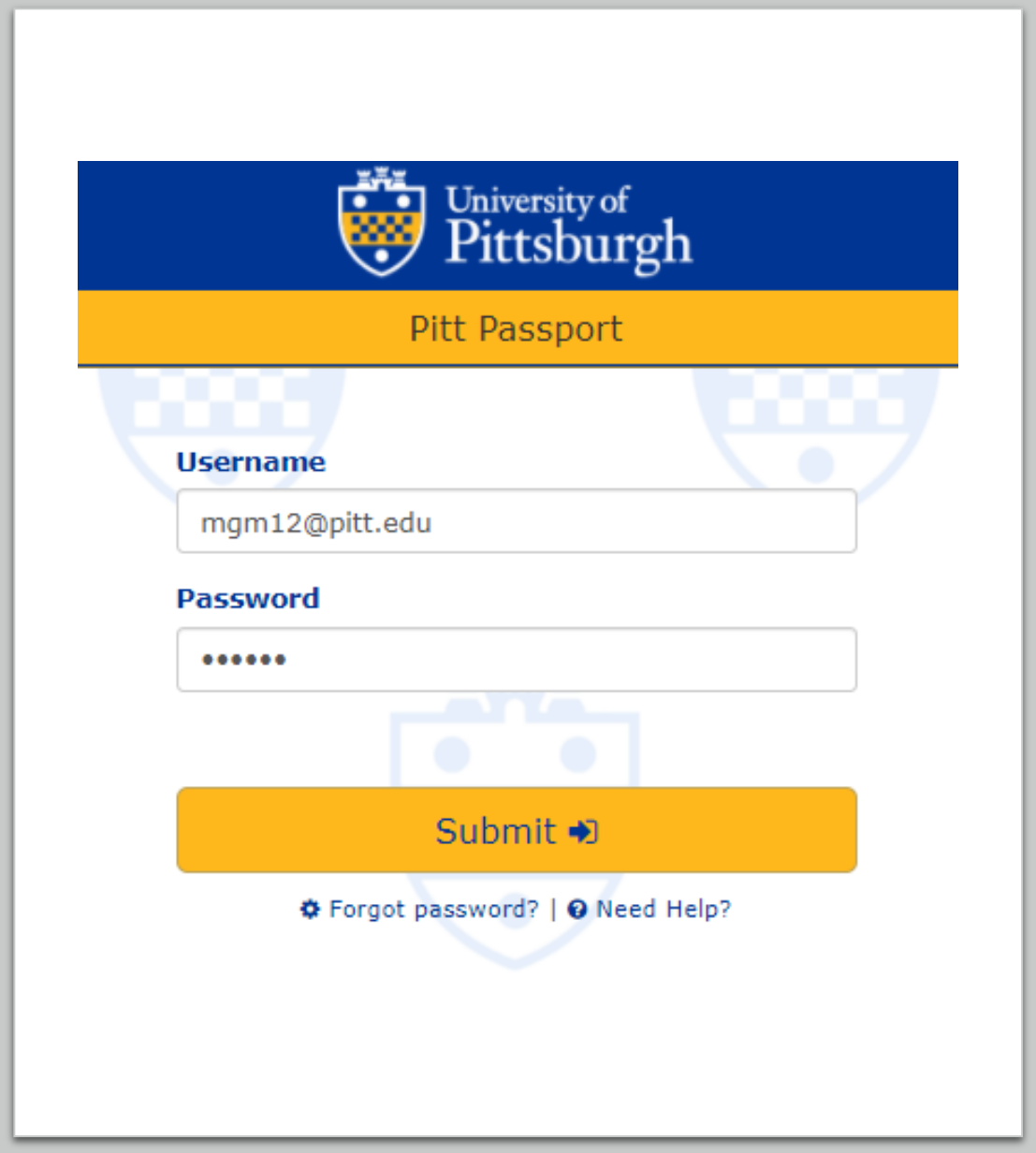
University of Pittsburgh | MyIBC

MyFunding

University of Pittsburgh | Animal Research Online (ARO)

Use Pitt Credentials Whenever Possible!

- Users must log into PittPRO using Pitt or UPMC credentials
- Other systems may only accept Pitt credentials
- Gmail, Outlook, Yahoo, or other independent providers are not acceptable for log in
- Other institutional email addresses *may* be acceptable in certain circumstances



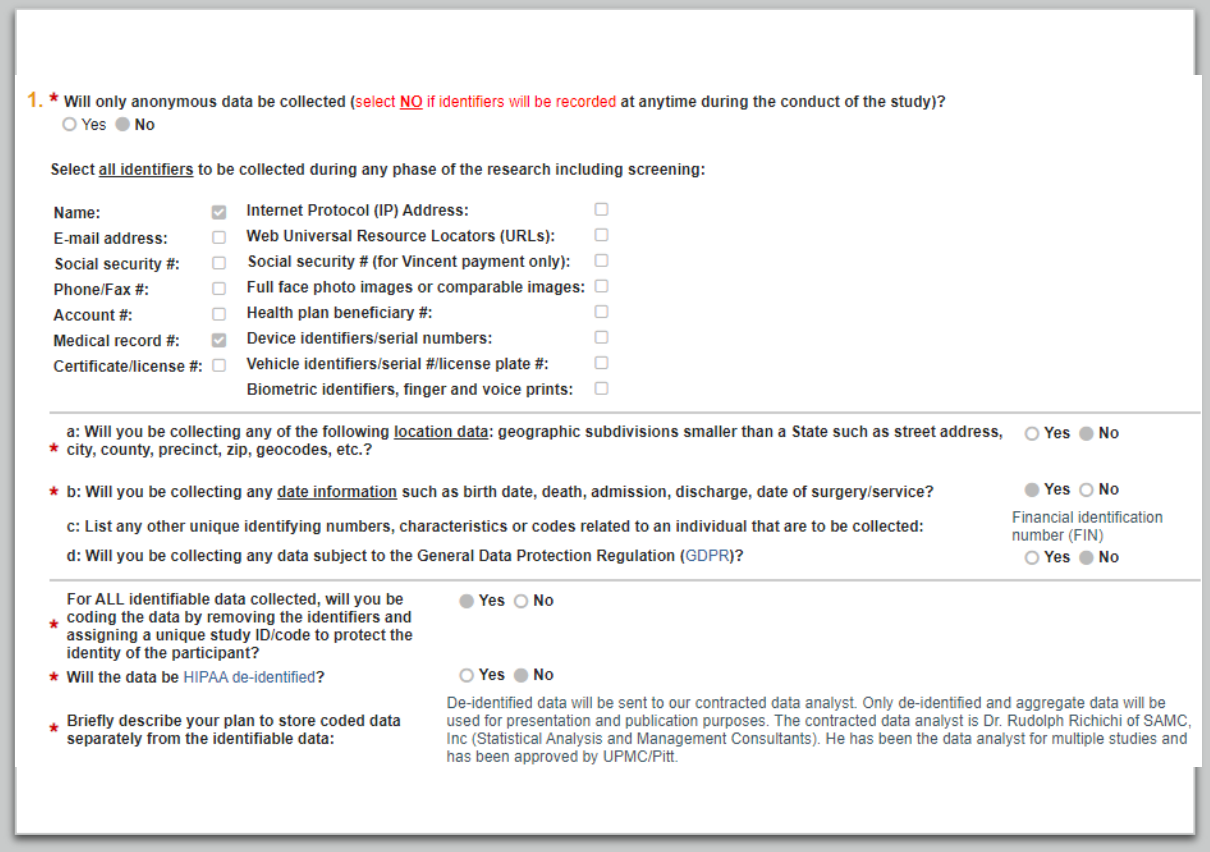
Prepare for a smooth transition

- Ensure accurate information in PittPRO, such as funding sources and investigators
- Ensure streamlined information throughout all research systems for robust dashboard information

Data Security

PittPRO Electronic Data Management

PittPRO asks a series of comprehensive questions to address the sensitivity and security of what is collected, how it is collected, where is it transmitted, and how it is stored



1. * Will only anonymous data be collected (select NO if identifiers will be recorded at anytime during the conduct of the study)?
○ Yes ● No

Select all identifiers to be collected during any phase of the research including screening:

Name:	☑	Internet Protocol (IP) Address:	☐
E-mail address:	☐	Web Universal Resource Locators (URLs):	☐
Social security #:	☐	Social security # (for Vincent payment only):	☐
Phone/Fax #:	☐	Full face photo images or comparable images:	☐
Account #:	☐	Health plan beneficiary #:	☐
Medical record #:	☑	Device identifiers/serial numbers:	☐
Certificate/license #:	☐	Vehicle identifiers/serial #/license plate #:	☐
		Biometric identifiers, finger and voice prints:	☐

* a: Will you be collecting any of the following location data: geographic subdivisions smaller than a State such as street address, city, county, precinct, zip, geocodes, etc.? ○ Yes ● No

* b: Will you be collecting any date information such as birth date, death, admission, discharge, date of surgery/service? ● Yes ○ No

c: List any other unique identifying numbers, characteristics or codes related to an individual that are to be collected: Financial identification number (FIN)

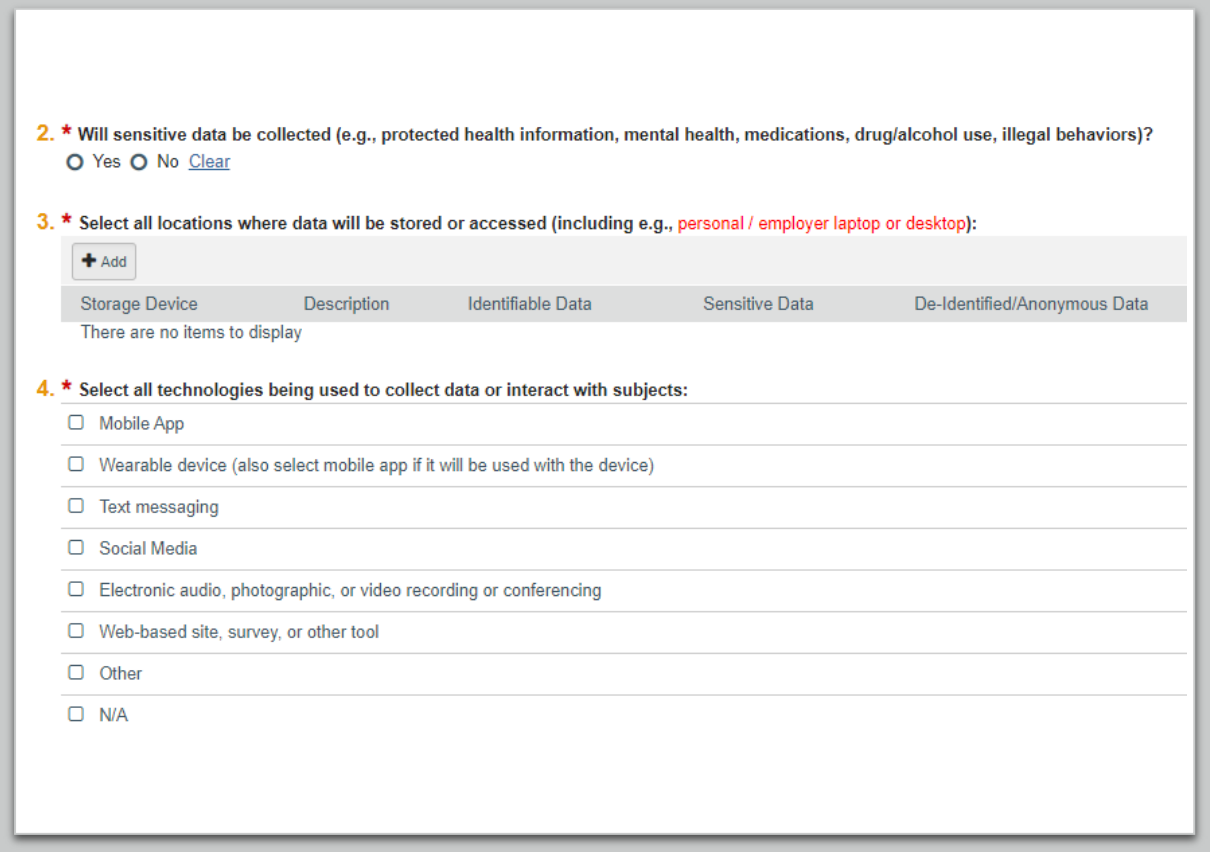
d: Will you be collecting any data subject to the General Data Protection Regulation (GDPR)? ○ Yes ● No

* For ALL identifiable data collected, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant? ● Yes ○ No

* Will the data be HIPAA de-identified? ○ Yes ● No

* Briefly describe your plan to store coded data separately from the identifiable data:

De-identified data will be sent to our contracted data analyst. Only de-identified and aggregate data will be used for presentation and publication purposes. The contracted data analyst is Dr. Rudolph Richichi of SAMC, Inc (Statistical Analysis and Management Consultants). He has been the data analyst for multiple studies and has been approved by UPMC/Pitt.



2. * Will sensitive data be collected (e.g., protected health information, mental health, medications, drug/alcohol use, illegal behaviors)?
○ Yes ○ No Clear

3. * Select all locations where data will be stored or accessed (including e.g., personal / employer laptop or desktop):

+ Add

Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data

There are no items to display

4. * Select all technologies being used to collect data or interact with subjects:

- ☐ Mobile App
- ☐ Wearable device (also select mobile app if it will be used with the device)
- ☐ Text messaging
- ☐ Social Media
- ☐ Electronic audio, photographic, or video recording or conferencing
- ☐ Web-based site, survey, or other tool
- ☐ Other
- ☐ N/A

Data Risk Classification and Compliance

Human Subject Research Data is considered sensitive when the disclosure of information could

- have adverse consequences for subjects or others,
- place them at risk for criminal or civil liability, or
- damage their financial standing, employability, insurability or reputation

https://www.technology.pitt.edu/security/data-risk-classification-and-compliance

Service Security Guide	Maximum Acceptable Data Class	FERPA Non-Directory Student Records	GLBA Financial Aid	HIPAA Protected Health Information	NIST Controlled Unclassified Information	PCI DSS Payment Card Information
Enterprise Cloud Computing Amazon Web Services, Google Cloud Platform, Microsoft Azure	Restricted	✓	⚠	⚠	⚠	⚠
Cloud Storage OneDrive/SharePoint ▪ OneDrive Security Guide ▪ SharePoint Security Guide	Restricted	✓	⚠	⚠	⚠	⚠
Cloud Storage G Suite/Google Drive ▪ Google Drive Security Guide	Public	⚠	⚠	⊘	⚠	⊘
Document Management ImageNow	Restricted	✓	⚠	⊘	⚠	⚠
Electronic Research Notebooks LabArchives	Restricted	✓	⊘	⚠	⚠	⊘
Email	Public	⊘	⊘	⊘	⊘	⊘
Email – Encrypted	Restricted	⚠	⚠	⚠	⚠	⊘
eSignature Service DocuSign	Restricted	✓	✓	✓	⚠	⚠
Learning Management System Canvas	Private	✓	⊘	⊘	⊘	⊘
Online Survey System Qualtrics	Restricted	✓	⚠	⚠	⚠	⚠
Student Information System PeopleSoft	Restricted	✓	✓	⊘	⊘	⊘
Videoconferencing Teams	Restricted	✓	✓	✓	⚠	⚠
Videoconferencing Zoom ▪ Zoom Security Guide	Private	✓	⊘	⊘	⚠	⊘
Videoconferencing Sensitive/HIPAA Zoom	Restricted	✓	✓	✓	⚠	⚠

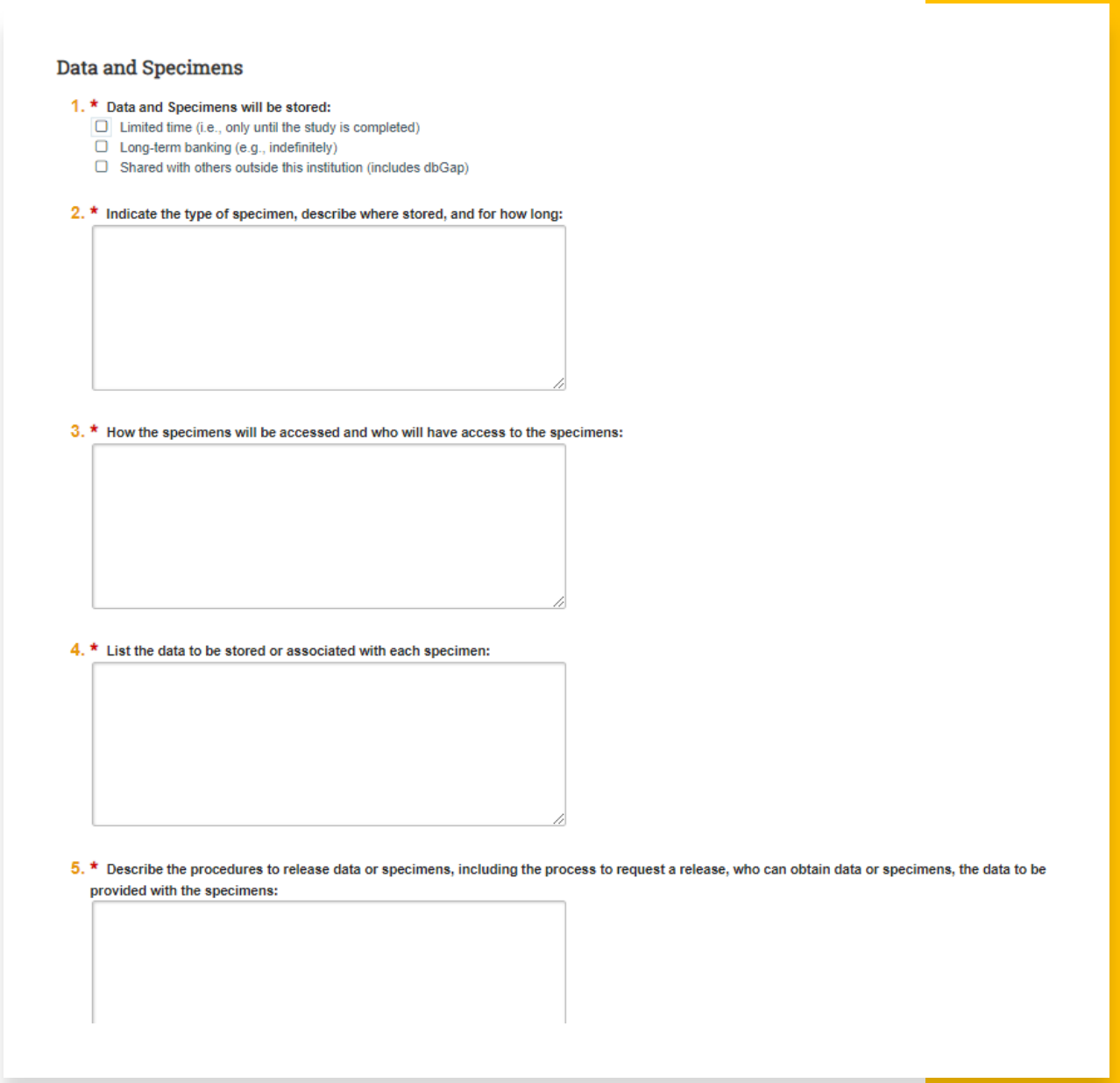
Data Security Resources

- Request a data security consultation:
  - Submit a help request (https://pitt.secure.force.com/ERMServiceDesk/FormCSSDServiceRequest) online using the subject line “Requesting a data security consultation for research” or
  - Call the help desk at 412-624-HELP
- Email askirb@pitt.edu with questions
- Data Risk Classification and Compliance https://www.technology.pitt.edu/security/data-risk-classification-and-compliance
- Call the Pitt technology Help desk at 412-624-HELP and let them know the question relates to the data security of a research study
- Detailed information on file-sharing and storage solution using UPMC MyCloud is available on UPMC INFONET website

Security of Non-Electronic Items

Be sure to put non-electronic information security in the correct section (not in the Electronic Data Management Section)

- Security for paper records belongs in Data and Safety Monitoring #3 (If any research data is collected, stored, or shared in a paper format, address what precautions will be used to maintain the confidentiality of the data)
- Security of specimens belongs on the Data and Specimens page



Data and Specimens

1. * Data and Specimens will be stored:
   - ☐ Limited time (i.e., only until the study is completed)
   - ☐ Long-term banking (e.g., indefinitely)
   - ☐ Shared with others outside this institution (includes dbGap)

2. * Indicate the type of specimen, describe where stored, and for how long:

3. * How the specimens will be accessed and who will have access to the specimens:

4. * List the data to be stored or associated with each specimen:

5. * Describe the procedures to release data or specimens, including the process to request a release, who can obtain data or specimens, the data to be provided with the specimens:

COVID-19 Related Topics

Starting and Restarting Research

IRB Approval

All human subject research being conducted must have IRB approval prior to initiation

-If your research was paused but you have valid IRB approval you may proceed

-Once a study has IRB approval, no further permission from the IRB is required to begin

School / Unit Conduct Plan

Executed by Dean or Associate Dean for Research, Institute Directors, and/or Regional Campus Presidents

-Final authority to approve the start or restart activities of their faculty

Conduct of Research Plan

research.pitt.edu/pitt-researchers/research-operations-during-covid-19-pandemic

Research Operations During the COVID-19 Pandemic

If you did not develop or have an approved Conduct of Research plan prior to August 31, you are required to have one.

The University is using its Resilience Framework **to guide the response to the COVID-19 pandemic.** Operational guidance for research is available to enable Pitt researchers to restart or continue their work, respond with flexibility to changing pandemic conditions and follow all health and safety rules. The University's guidance that all research activities that can be conducted remotely should continue remotely during the pandemic period remains in effect.

Please stay informed by continuing to visit the University's coronavirus response website for real-time updates and precautions taken by the University to build a healthy and resilient community. Additional information on pandemic preparedness for researchers is available through the office of Environmental Health and Safety.

In response to the COVID-19 pandemic, and with very limited exceptions, the offices of Pitt Research will be working remotely and continuing until further notice.

- Implications for Research Activities in Move to Elevated Operational Posture
- Implications for Research Activities in Move to Guarded Operational Posture
- FAQs
- Research Standards and Guidelines
- Research Operations and Governance Standards and Guidelines
- School and Unit Conduct of Research Templates
- PI Checklist
- Research Operations Prioritization Standards and Guidelines
- Human and Animal Research Subjects Standards and Guidelines
- Fieldwork and Research Travel Standards and Guidelines
- Human Resources Information
- Guidelines for Research Trainees During COVID-19 Operations
- Environmental Health and Safety Information
- PPE Guidance
- Visitors and Vendors
- Signage Templates
- August, 2020 Survey Results: Restart Progress

Pitt Research

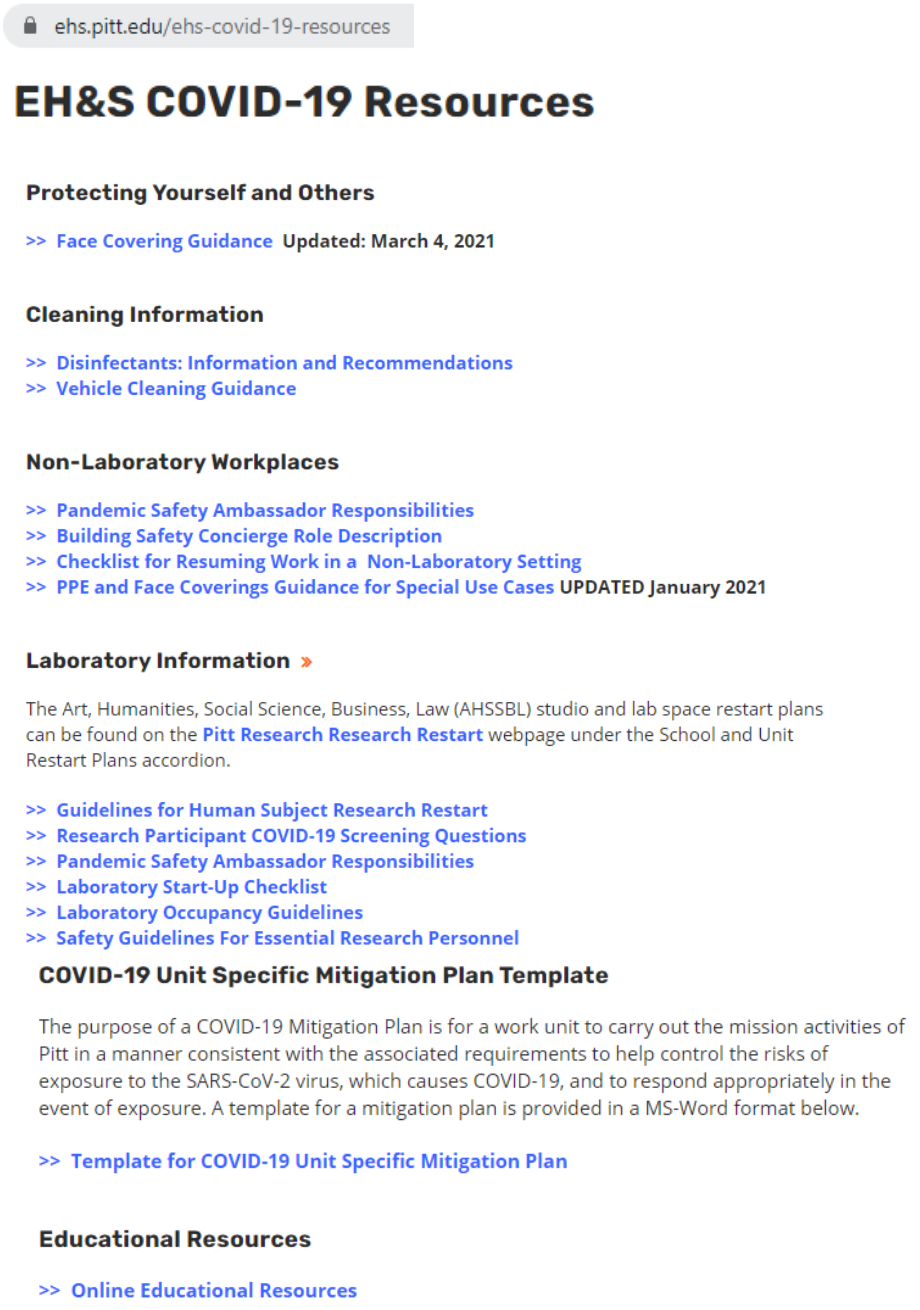
Environmental Health and Safety

Health and Safety Related Information for Research Restart

https://www.ehs.pitt.edu/ehs-covid-19-resources

- Guidelines for Human Subject Research Restart
- Research Participant COVID-19 Screening Questions
- Cleaning Information
- Laboratory Management
- Non-Laboratory Workspace management
- PPE Guidance

Questions? safety@ehs.pitt.edu



ehs.pitt.edu/ehs-covid-19-resources

EH&S COVID-19 Resources

Protecting Yourself and Others

>> Face Covering Guidance **Updated: March 4, 2021**

Cleaning Information

>> Disinfectants: Information and Recommendations
>> Vehicle Cleaning Guidance

Non-Laboratory Workplaces

>> Pandemic Safety Ambassador Responsibilities
>> Building Safety Concierge Role Description
>> Checklist for Resuming Work in a Non-Laboratory Setting
>> PPE and Face Coverings Guidance for Special Use Cases **UPDATED January 2021**

Laboratory Information »

The Art, Humanities, Social Science, Business, Law (AHSSBL) studio and lab space restart plans can be found on the Pitt Research Research Restart webpage under the School and Unit Restart Plans accordion.

>> Guidelines for Human Subject Research Restart
>> Research Participant COVID-19 Screening Questions
>> Pandemic Safety Ambassador Responsibilities
>> Laboratory Start-Up Checklist
>> Laboratory Occupancy Guidelines
>> Safety Guidelines For Essential Research Personnel

COVID-19 Unit Specific Mitigation Plan Template

The purpose of a COVID-19 Mitigation Plan is for a work unit to carry out the mission activities of Pitt in a manner consistent with the associated requirements to help control the risks of exposure to the SARS-CoV-2 virus, which causes COVID-19, and to respond appropriately in the event of exposure. A template for a mitigation plan is provided in a MS-Word format below.

>> Template for COVID-19 Unit Specific Mitigation Plan

Educational Resources

>> Online Educational Resources

Changes made for remote operations

THEN
(March 2020)

In an effort to ease the rapid transition to remote operations, modifications may not have been required in order to move from face-to face

If you are continuing to operate under remote activities where appropriate, protocols need to be updated to reflect how processes are occurring

NOW

To vaccinate or not to vaccinate

- No mandates (Federal, state or otherwise) requiring vaccines
- Study teams do not need to be fully vaccinated to see subjects
- Subjects do not need to be fully vaccinated to enroll in studies
  - Inclusion/Exclusion criteria cannot prohibit unvaccinated individuals from participating unless the study is about the COVID-19 vaccine

Informed Consent Topics

Consent is important! Take your time!

Most common RNI (Reportable New Information) related to consent:

- Conducting research procedures without consent
- Using an improper consent form to obtain consent
- Having the wrong person obtain consent
- Having the wrong person sign informed consent

Who should be there?

What should they talk about? On which form?

Where and how (phone, in-person) should it take place

At what time point is it being obtained?

Timing of consent

Research procedures cannot be performed until after informed consent is obtained (written or verbal with a waiver to document)

Examples of appropriate plans*:	All study procedures are minimal risk and taking place over the phone or electronically → waiver to document consent
	Minimal risk screening procedures take place over the phone and subject is asked to fast prior to first visit → waiver to document for screening and fast, written informed consent at first visit
	Subject is having research procedures done during a clinical visit → written informed consent prior to clinic visit
	Investigator wishes to use data from a clinical visit for research purposes → written consent (or verbal if minimal risk) prior to obtaining the clinical data

Pitt Research

**consenting plans are very dependent on study details*

Who can obtain consent? (Pitt policy)

Minimal Risk Study Not Involving Drug, Device or Surgical Procedure	**Rule**: Listed PI or Co-I must obtain informed consent **Exception**: Justify why listed investigator cannot obtain, include (by position) who will be obtaining informed consent
Study Involving Drug, Device, or Surgical Procedure	**Rule**: Licensed physician PI or Co-I must obtain informed consent **Exception**: Under certain circumstances, justify another PI or Co-I licensed health care professional obtaining informed consent
Greater than Minimal Risk Study Not Involving Drug, Device or Surgical Procedure	**Rule**: Listed PI or Co-I must obtain informed consent **Exception**: No exceptions will be granted

In all scenarios, individual must sign Investigator's Certification at time of involvement

https://www.hrpo.pitt.edu/obtaining-informed-consent-human-subject-research

PA Supreme Court Ruling

The Ruling:

"A physician may not delegate to others his or her obligation to provide sufficient information in order to obtain a patient's informed consent. Informed consent requires direct communication between physician and patient, and contemplates a back-and-forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent."

*-Shinal v. Toms, 31 MAP 2016, 2017 Pa. LEXIS 1385, at *52 (Pa. 2017) (emphasis added). All prior decisions holding otherwise are overruled. Id. at 53.*

What falls under the ruling:

1. Performing surgery, including the related administration of anesthesia
2. Administering radiation or chemotherapy
3. Administering a blood transfusion
4. Inserting a surgical device or appliance
5. Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner

Informed consent must be obtained by a PI or Co-I who has an unrestricted license to practice medicine in the Commonwealth of Pennsylvania

Pitt Research

What about residents and fellows?

ACGME Medical Residents & Fellows

UPMC Medical Education medical residents and fellows in ACGME-accredited training programs are functioning under a Pennsylvania training license and are not considered as licensed physicians for this purpose

→ Consent under PA Law cannot be delegated to them

Non-ACGME Fellows

Fellows in a non-ACGME fellowship who have a Pennsylvania medical license without restriction, DEA license, and appropriate hospital medical staff appointment and clinical privileges may be considered as licensed physicians

→ Consent under PA Law may be delegated to them

Electronic Consent Process and Signatures

Conducting consent and study visits remotely

Method depends on the sensitivity of the information to be disclosed during the visit and if it will be recorded

Pitt licensed versions:

- Skype for Business
- MS Teams
- Zoom (request HIPAA compliant version)
- Vidyo (UPMC)

Data Security:

- Recording storage
- Up-to-date anti-virus protection
- Storage in Pitt/UPMC cloud or University-managed server

NOT one size fits all approach!

Pitt Research

What about HIPAA?

HIPAA Authorization must be obtained prior to the access, use, or generation of past, present or future protected health information (PHI)

- Use of PHI requires written authorization
- Absence of written authorization requires alteration justification
- PHI is rarely exchanged during consent process (i.e. platform does not need to be HIPAA compliant)

What is verbal consent?

- Dialog occurs between the subject and investigator that contains all of the required elements of informed consent.
- Subject states their verbal agreement to participate and does not sign anything
- Investigator documents the conversation in the research record

Is it binding?

Yes. The Common Rule states than an IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects

45 CFR 46.117(c)(1)

Scripts must include all elements of consent!

When can I use it?

In **minimal risk situations** when:

- The principal risk is breach of confidentiality, and the consent form is the only link to the study
- The study involves no procedures for which written consent is normally required outside of research
- Cultural or community norms do not support individuals signing forms

What is an electronic signature?

Electronic sound, symbol or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record (PA 73 PS 2260.103)

Is it legally binding?

Yes. The ESIGN Act and the Uniform Electronic Transaction Act (UETA) establish that eSignatures and records carry the same weight as traditional paper

When can I use it?

Any time written informed consent is required

What methods are there?

- Signature on electronic device
- Validated signature through password protection
- Exchange of traditional consent form through electronic means
- REDCap or Qualtrics
- DocuSign, Adobe

Be sure to discuss methods in Electronic Data Management

Click to Continue

- Does not meet the definition of an eSignature
- Requires a waiver to document informed consent
  - Check "waiver to document consent: in Study Scope #2
  - Justify need and upload script on Waiver to Document page
  - Describe steps on Consent Process page

REMEMBER: consent process still takes place. Only difference is no signature is obtained

Odds and Ends

CITI Training

Required Courses for all

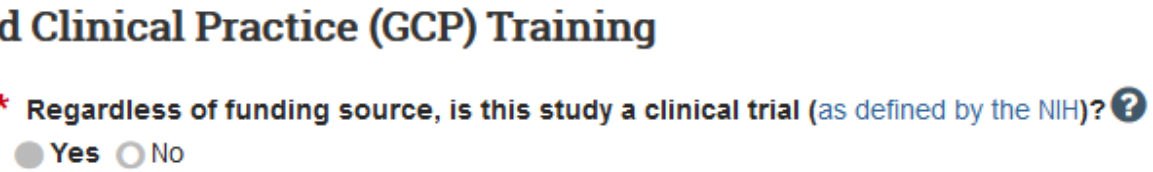
- Responsible Conduct of Research
- Human Subject Protections
  - Biomedical or
  - Social and Behavioral

Must keep up to date for all study personnel

Required based on selection

- Conflict of Interest

- Good Clinical Practice (GCP)



https://www.orp.pitt.edu/training/training-table-list

Phases of Review

- **Pre-Submission** → Researcher is building the protocol
  - Scientific Review takes place when leaving this state
- **Pre-Review** → Ancillary Reviews and IRB review begins
- **IRB Review** → Committee Review or Expedited Review taking place
- **Post-Review** → Final clean-up prior to approval being granted
- **Review Complete** → Active state
- **Clarification Requested** → In Researcher's possession for corrections

	Minor Modification	Major Modification
Definition	A change that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study	Any change that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study
Review Type	**Expedited** (regardless of risk)	**Full Board** (for Greater than Minimal Risk) **Expedited** (for Minimal Risk unless the modification affects the risk level)
Examples	• Changing the timing of visits • Changing the location of visits • Adding a new study coordinator	• Adding a new study group • Changing the drug route of administration • Re-open study after suspension
It depends	• Change in enrollment numbers • Change in primary investigator • Change in battery of assessments	

Exceptions v. Modifications

Exceptions: Prospective permission to deviate from the approved protocol (usually for one or a few subjects only)

- Study visit out of window
- Enroll non-English speaking participant
- Use MRI from prior study for current
- Enroll an ineligible subject

Modification: affects the overall study and/or study population

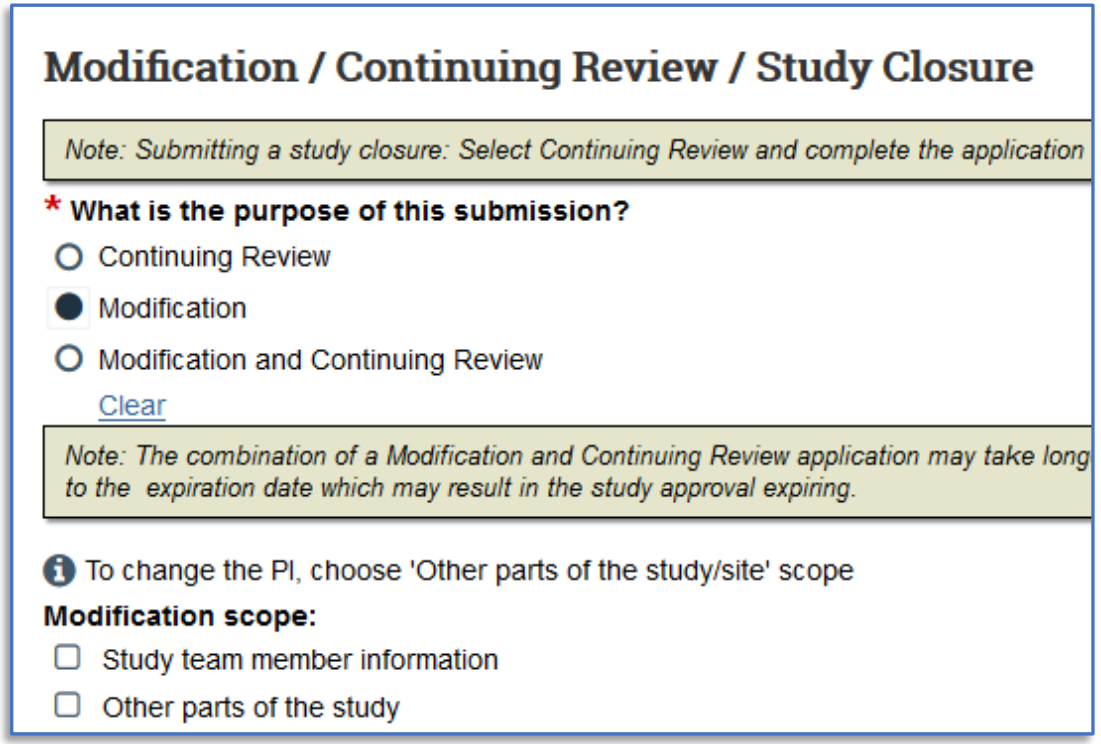
- Change timing of study visits
- Inclusion of special population
- Addition of radiation imaging
- Change eligibility criteria
- Study procedures involve re-consent

General Reminders for Modifications

Modifications must be submitted for IRB review and approval prior to implementation unless:

- Protocol deviation that may be necessary to eliminate an apparent immediate hazard to a subject
  - must be reported to the IRB as soon as possible afterward
- Exempt Studies & No Human Subjects unless the change could alter the Exempt or NHS status
  - Consult with reviewer

- Combined Modification and Continuing Review function:
  - use with caution
  - Can open a Continuing Review and open a separate modification at the same time
  - Can have two mods open at same time (1 study team change & 1 other parts)



Requesting a waiver of consent to review for eligibility

Screening, Recruiting, Determining Eligibility §116(g)

An IRB may approve a protocol where an investigator will obtain information or biospecimens for screening, recruiting, or determining eligibility without informed consent:

- Information is obtained through oral or written communication with the prospective subject or LAR, or
- The investigator will obtain private identifiable information or identifiable biospecimens by accessing records or stored identifiable specimens

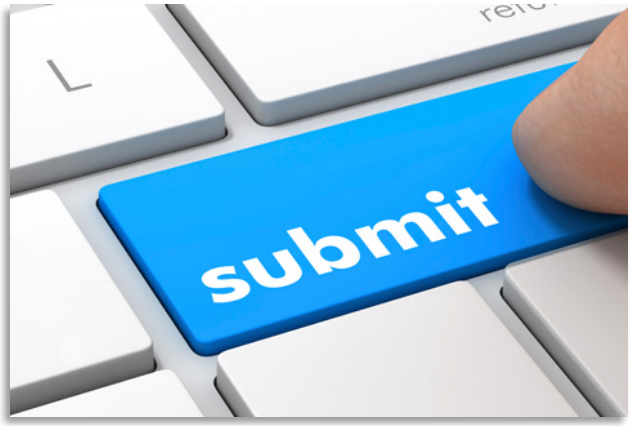
Pitt Research

Be sure to include all elements of HIPAA Authorization

Who is requesting the PHI for research?	We are also requesting your authorization or permission to review your medical records.
Why is this information needed?	To determine whether you meet the conditions for participation in this study, to compare your earlier test results to the findings from this study, and if possible, to use your previous exam results in place of, or in addition to, some of the exams needed for this study.
What will be disclosed?	We will obtain the following information: your diagnosis, age, past medical history, diagnostic procedures, and results of any tissue biopsies or blood tests, including results of genetic tests that were already done as part of your standard evaluation at the Cancer Center.
Will research data be placed in the medical record? If yes, describe.	As part of this research study, some information that we obtain from you will be placed into your medical records held at UPMC, including the results of pregnancy tests (for women of childbearing potential) and other medical tests.
How long will this information be made available to the researchers?	This identifiable medical record information will be made available to members of the research team for an indefinite period of time.
Who (other than the investigators) will receive the PHI, and how will they use it? Note: highlighted element must be included in every consent form.	Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the Food and Drug Administration, the Cancer Oncology Group, the National Cancer Institute, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.
Statement of the potential risk that PHI will be re-disclosed by a recipient:	We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.
How long will this authorization be valid?	This authorization is valid for an indefinite period of time.
Right to revoke authorization; how to revoke:	However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing.
Implications of revocation of authorization	If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.
Implications of not signing form	Note: this need not be stated in the consent form but must be in the IRB application: subjects who do not sign this hybrid consent form (that includes the HIPAA authorization) cannot participate in the study
Signature line should include last phrase (highlighted here)	By signing this form I consent to participate in this research study and provide my authorization to share my medical records with the research team.

https://www.hrpo.pitt.edu/sites/default/files/hipaa_auth_text8.21.18_0.pdf

Don’t forget to hit submit!



Provide details if you have collaborators

- The IRB will determine if agreements are necessary

To help your review to be quick, proofing may help do the trick

- Protocols are often returned because of missing documents, incomplete sections, and placeholders that are left behind

When can I get started?

- After **FINAL** approval is granted by IRB (or after activation if sIRB)
- A formal letter is generated by PittPRO
- Fiscal approval is received (if applicable)
- Retroactive approval cannot be granted

Pitt Research

Call us early and often

412-383-1480
Main IRB number

askirb@pitt.edu
General IRB questions

Irb.reliance@pitt.edu
Central IRB questions (aka sIRB)

orp@pitt.edu
Technical Issues

Pitt Research

Questions?