Caring

Geisinger

Overview - HRPP, IRB & iRIS

Dorothy Sellers
Deb Henninger
Rosa Sober

November 21, 2016

Caring

Geisinger

Human Research Protection Program (HRPP)

What is ‘HRPP’?

Human Research Protection Program

- seeks to assure the rights and welfare of human subjects participating in research and
- promote excellence in all aspects of human subjects research.

How is HRPP different from an IRB?

- In 2000, oversight for Human Subject Research changed from Office for Protection from Research Risks (ORPP) to the Office for Human Research Protection (OHRP)
- Greg Koski, Director, believed that protecting human subjects was more than an IRB review
- Many IRB offices started calling themselves Human Research Protection Programs (HRPP)
- Real intent was to broaden the protections to include conflict of interest, contracts, etc.,
- AAHRPP set the standards for an HRPP

Geisinger's Human Research Protection Program (HRPP)

Using AAHRPP Model: Three Domains:

I. Institution: Includes all offices which establish a relationship with the research participant:

- Grants
- Contracts
- Office of Research Compliance – Financial Conflict of Interest
- Research Finance

II. IRB Committee

III. Investigators and Study Teams

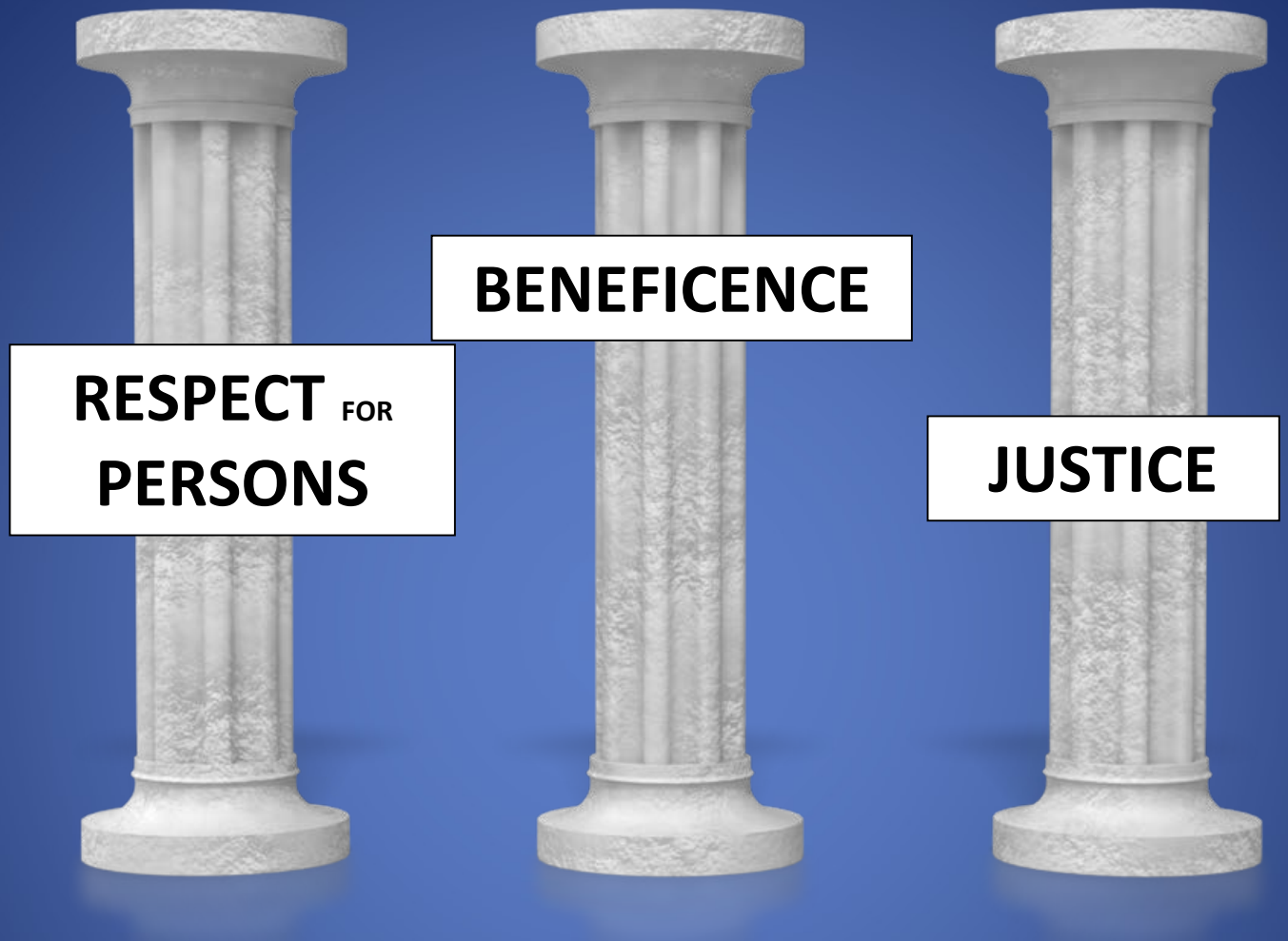
Caring

Geisinger

Institutional Review Board (IRB)

IRB Role §45CFR46

- Health & Human Services (HHS) mandates Institutional Review Board (IRB) oversight of research involving human subjects
- Performs ethical review of all proposed & ongoing research ensuring the protection of the rights, welfare and safety of human subjects
- GHS Research Privacy Board – HIPAA determinations



… eventually referred to as principles

BELMONT

TITLE 45 (PUBLIC WELFARE)
CODE OF FED REGULATIONS
PART 46 PROTECTION OF HUMAN SUBJECTS

PRINCIPLES	APPLICATIONS	
Respect for persons	Informed consent • Information • Comprehension • Voluntariness	46.116 General requirements for informed consent 46.117 Documentation of informed consent
Beneficence	Risk/benefit assessment • Nature and scope of risks and benefits	46.111 (a) (1) Risks are minimized 46.111(a) (2) Risks are reasonable in relation to benefits 46.111(a)(6) safety monitoring 46.111(a)(7) Privacy & confidentiality protections
Justice	Selection of subjects	46.111 (a) (3) Equitable selection of subjects 46.111 (b) additional safeguards for vulnerable **Subpart B:** Pregnant Women, Fetuses, Neonates **Subpart C:** Prisoners **Subpart D:** Children

IRB Membership §45CFR46.107

Must have at least five voting members

- Varying backgrounds
- Review type of research conducted at institution

Must be sufficiently qualified

- Experience and expertise
- Diversity of the members – gender, profession

Must be able to determine if proposed research is approvable

- Applicable laws & regulations
- Institutional requirements
- Standards of professional conduct and practice

IRB Membership §45CFR46.107

Include individuals with knowledge and experience working with vulnerable populations

- Children
- Pregnant women
- Handicapped or mentally disabled persons
- Prisoners*

Consultant (ad hoc)

- Invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB
- Non-voting

IRB Membership §45CFR46.107

Must include:

- At least one scientific member, and
- At least one non-scientific member

Must include at least one community member:

- Not affiliated with the institution or immediate family of a person who is affiliated with the institution

Conflict of interest

- If an IRB member has a conflicting interest in a research project, s/he cannot review or participate in vote

Geisinger IRB Review

Preparatory to Research (PTR)

- Email submission to IRB (bkent@geisinger.edu)
- IRB Office review – rolling review

Research Determination (RDW)

- Email submission to IRB (bkent@geisinger.edu)
- IRB Office review – rolling review

Geisinger IRB Review

Initial IRB Review

Exempt Review

- iRIS submission
- IRB Member review – rolling review

Expedite Review

- iRIS submission
- IRB Member review – rolling review

Convened Review

- iRIS submission
- IRB Committee review – meets 1st and 3rd Thursday each month

Ongoing IRB Review of Research

Reporting Requirements

- ✓ Continuing Review
- ✓ Amendments/Modifications
- ✓ Prompt Report – UPs, Significant Protocol Deviations, HIPAA Disclosures)
- ✓ Final Report
- ✓ Emergency Use

Types of IRB Review

EXEMPT	EXPEDITED	CONVENED
IRB determination	IRB approval	IRB approval
Minimal risk	Minimal risk	More than minimal risk
Fit Exempt categories	Fit Expedite categories	Not fit categories
Typically no PHI	PHI	PHI
Surveys, focus groups	Retrospective, identifiable data; minimal risk procedure; observational	Clinical trial; interventional; investigational drug, device, biologic
No annual review	Annual review	Annual review
No amendments	Submit amendments	Submit amendments
1-2 IRB reviewers	1-2 IRB reviewers	Full board review
Rolling submission	Rolling submission	Meeting deadline

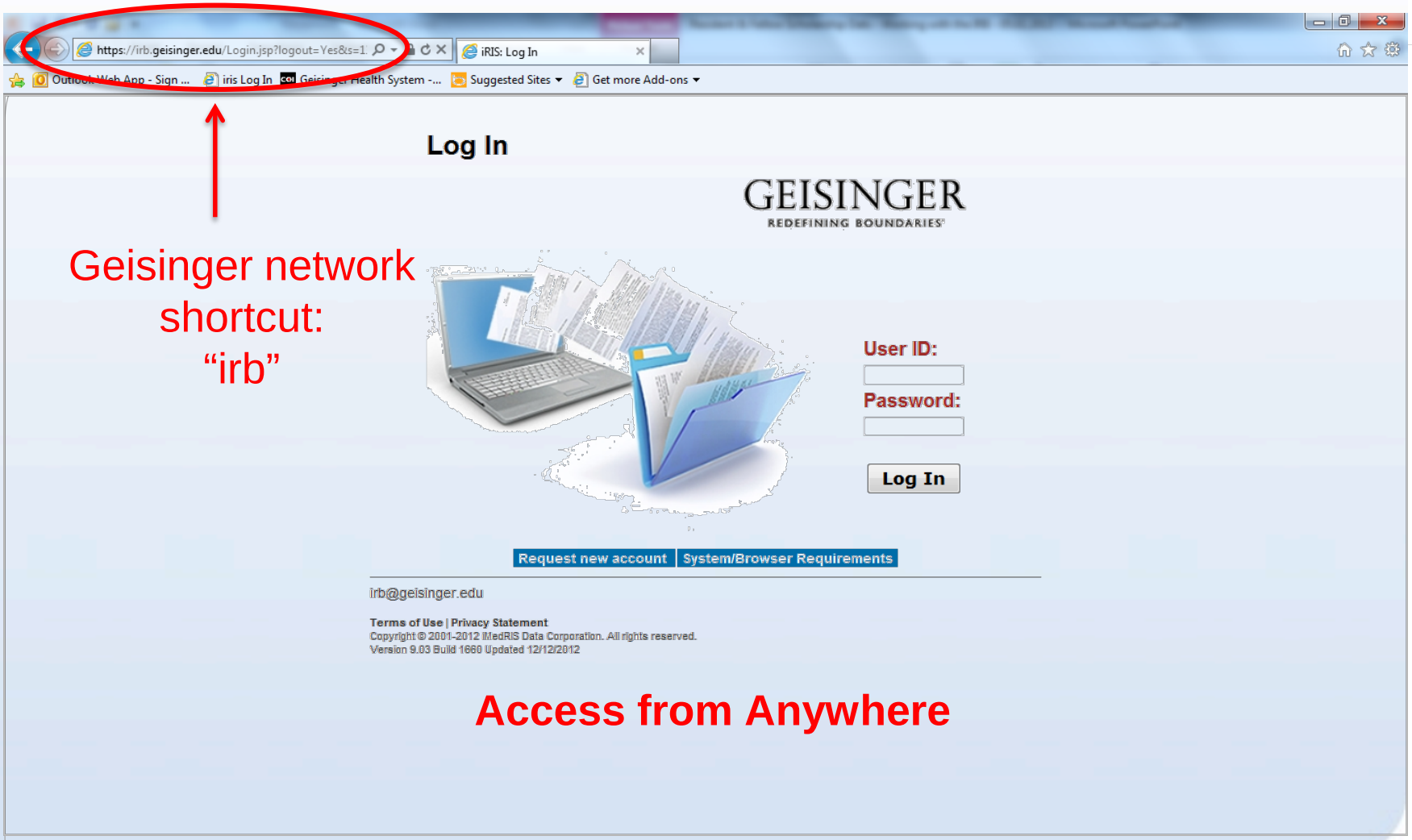
Caring

Geisinger

iRIS

(Electronic IRB System)

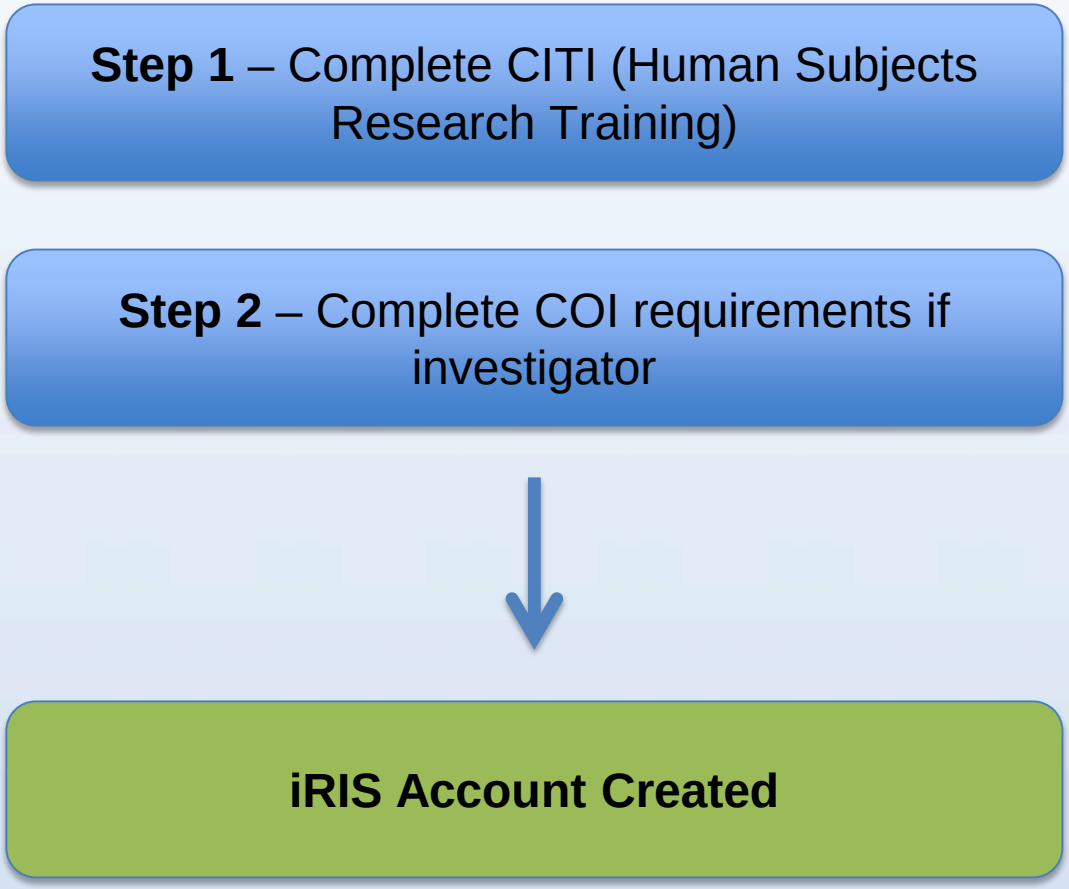
iRIS IRB System https://irb.geisinger.edu (web-based system)



Geisinger network shortcut: "irb"

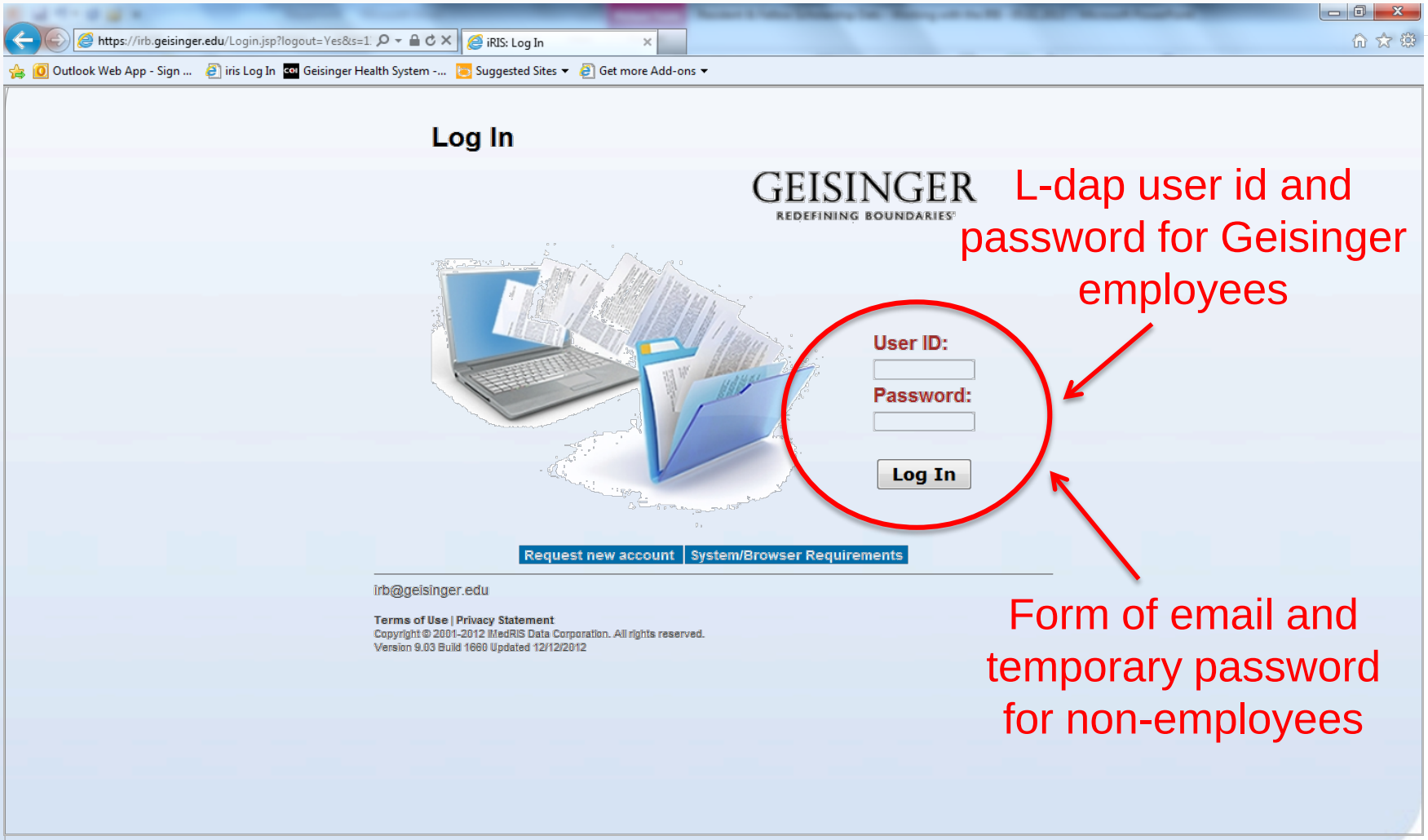
Access from Anywhere

iRIS – Obtaining an Account



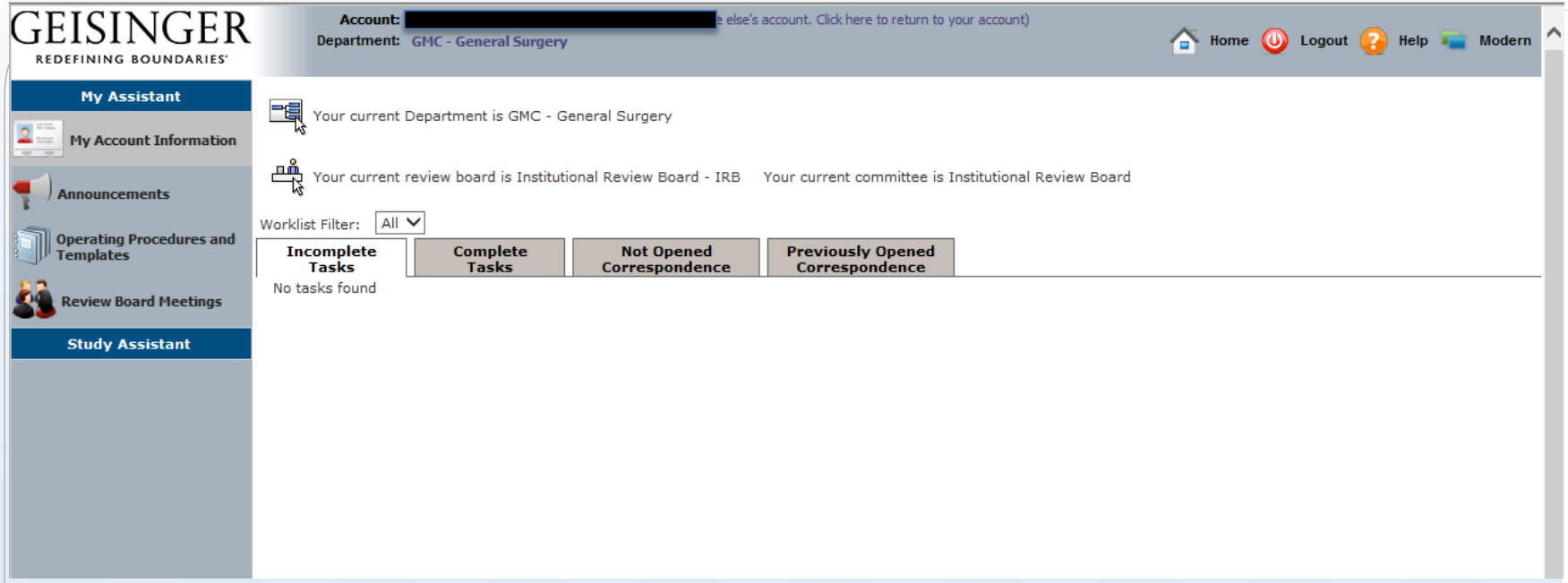
Geisinger

iRIS IRB System https://irb.geisinger.edu (web-based system)



Geisinger

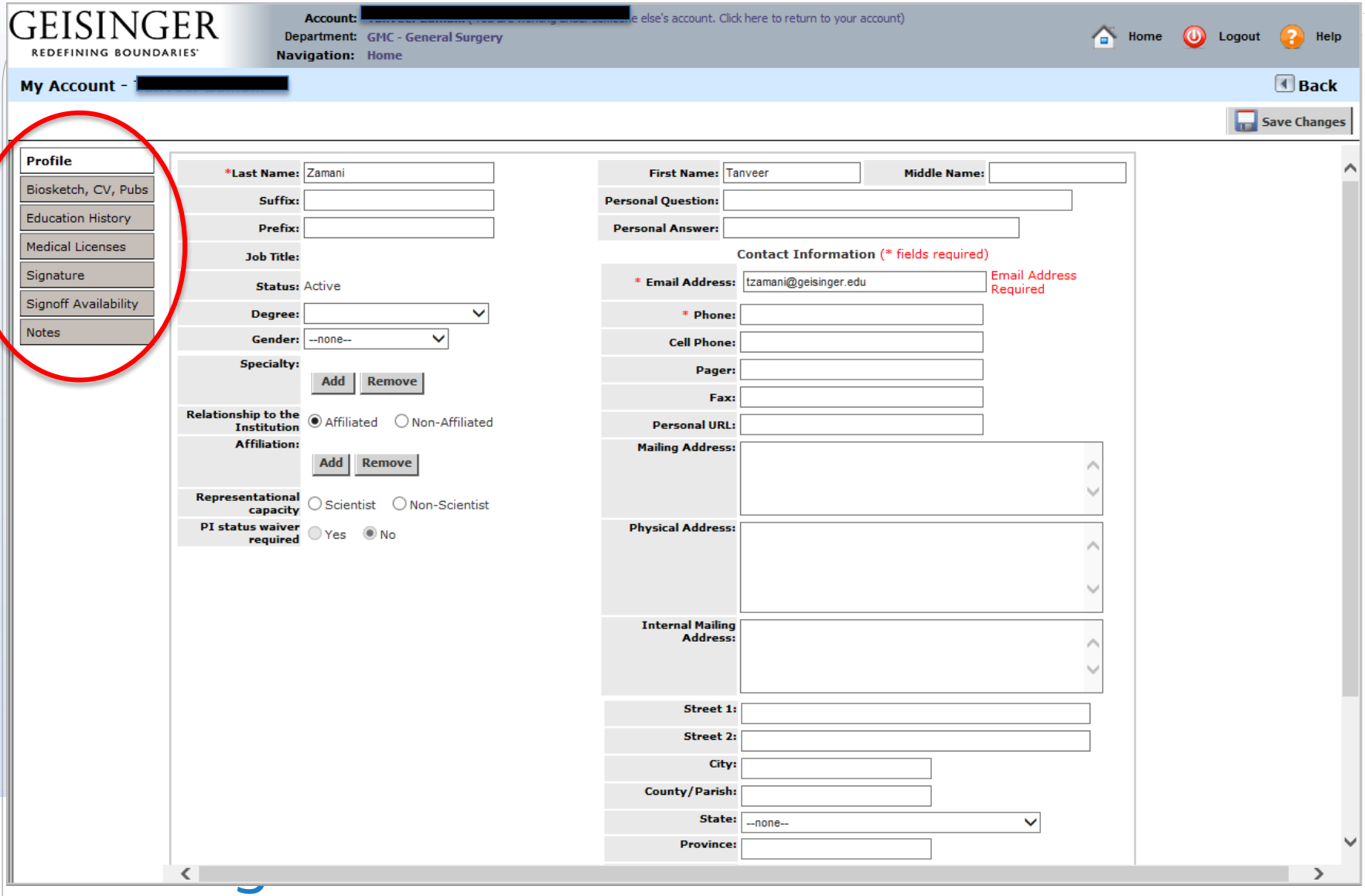
iRIS IRB System



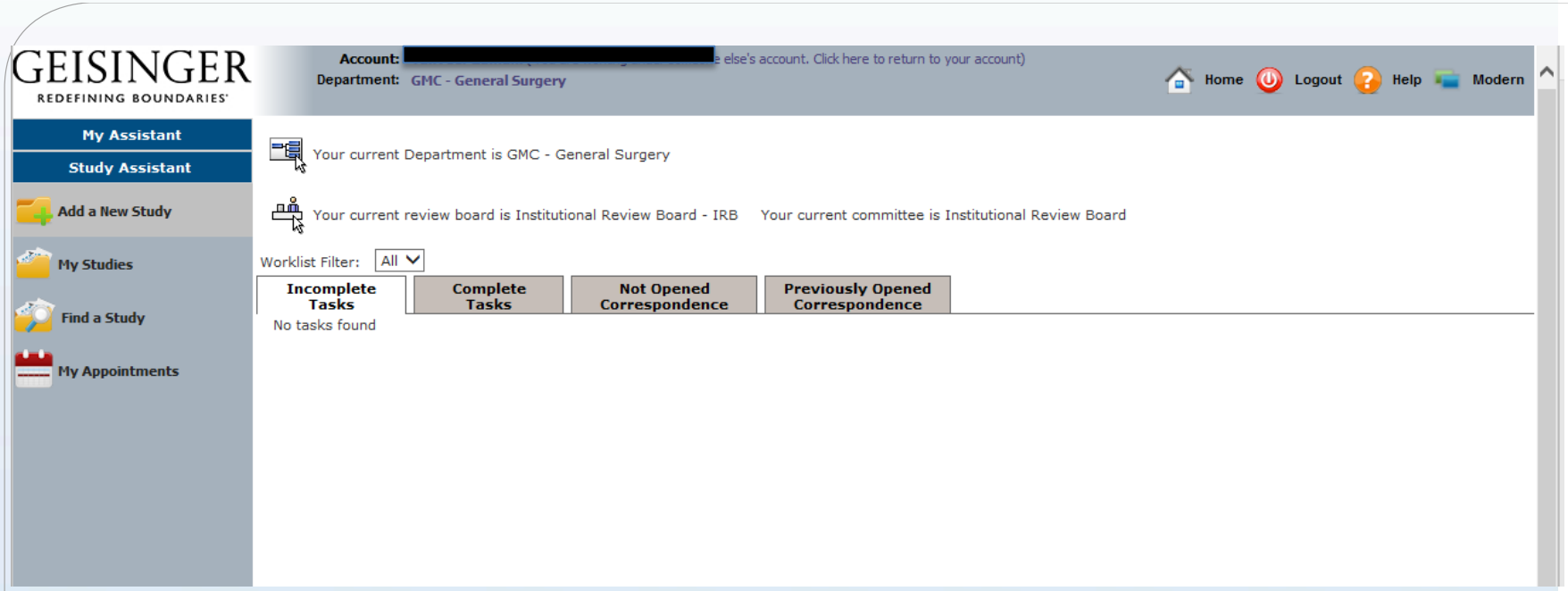
My Assistant: Your account information, resources, IRB Meeting dates

Geisinger

iRIS IRB System



iRIS IRB System

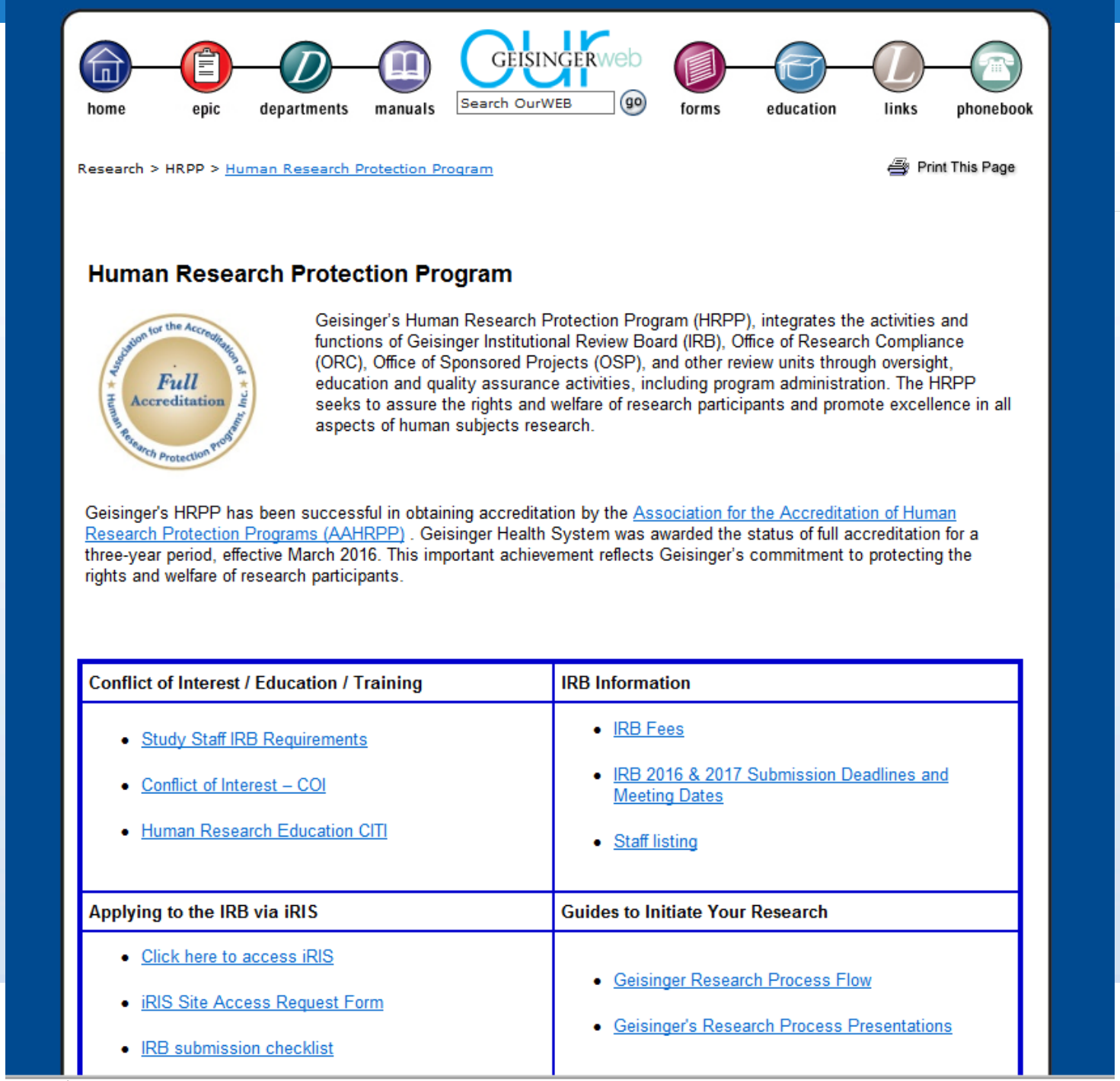


Study Assistant: Working area where new studies are added and past opened studies can be accessed

Caring

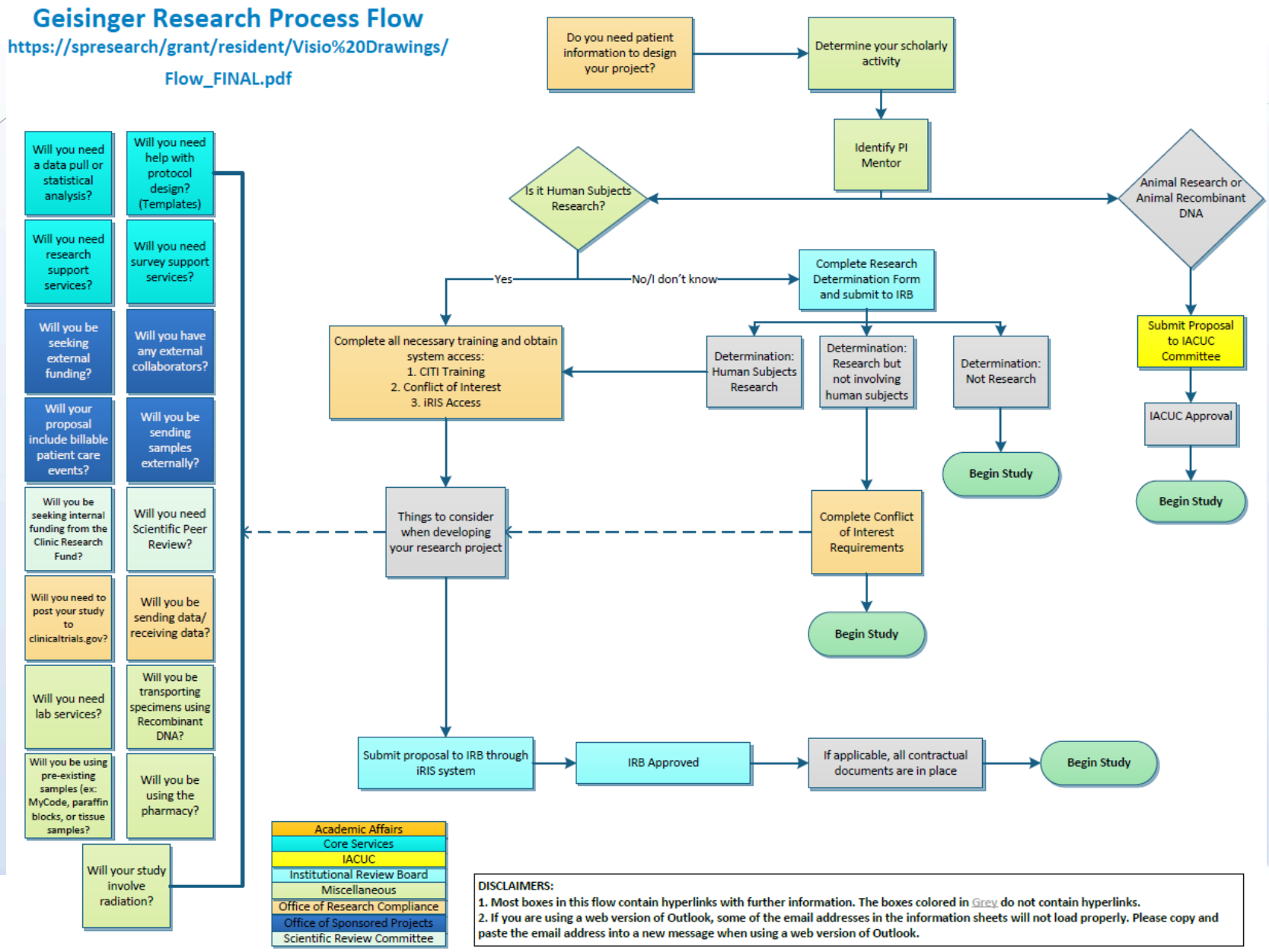
Geisinger

HRPP Webpage
&
IRB Resources



HRPP Webpage

Geisinger Research Process Flow



Geisinger Research Process Flow

- Created with several departments
- Walks through steps of starting Research Project
- Accessible on Geisinger Network (https://spresearch/grant/resident/Visio%20Drawings/Flow_FINAL.pdf)
- InfoWeb (OurWeb) > Departments > Research > Research - HRPP/IRB
- Interactive flow including information sheets
- Departments/ reviews needed before IRB review and contact information

Geisinger IRB Information

NAME:	Geisinger Institutional Review Board
IRB REGISTRATION #:	00008345
INSTITUTION:	Geisinger Clinic
FWA ASSURANCE:	FWA00000063
ACCREDITATION:	Geisinger Health System is accredited by the Association for the Accreditation of Human Protection Programs, Inc. (AAHRPP)
ADDRESS:	Geisinger Institutional Review Board 100 North Academy Avenue Danville, PA 17822-3069
TELEPHONE:	570-271-8663 or 844-542-3299

Geisinger

Contacts

- Barb Kent, Administrative Assistant - **(570) 271-8663**
  - (bkent@geisinger.edu)
- Chuck Brightbill, MS, IRB Specialist
  - (cebright@geisinger.edu)
- Gissel Martinez, BS, IRB Specialist
  - (gnmartinez@geisinger.edu)
- Rosa Sober, BS, CIP, IRB Manager
  - (rmsober@geisinger.edu)
- Jeanie Wesner CCRC CHRC, IRB Project Manager
  - (jwesner@geisinger.edu)
- Deb Henninger, MHSA RN CCRC, Associate Director
  - (dhenninger@geisinger.edu)
- Dorothy Sellers, BS, Director
  - (dcsellers@geisinger.edu)
- Les Kirchner, PhD, IRB Chair
- Tom Challman, MD, IRB Chair

QUESTIONS??