



Geisinger

Overview - HRPP, IRB & iRIS

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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



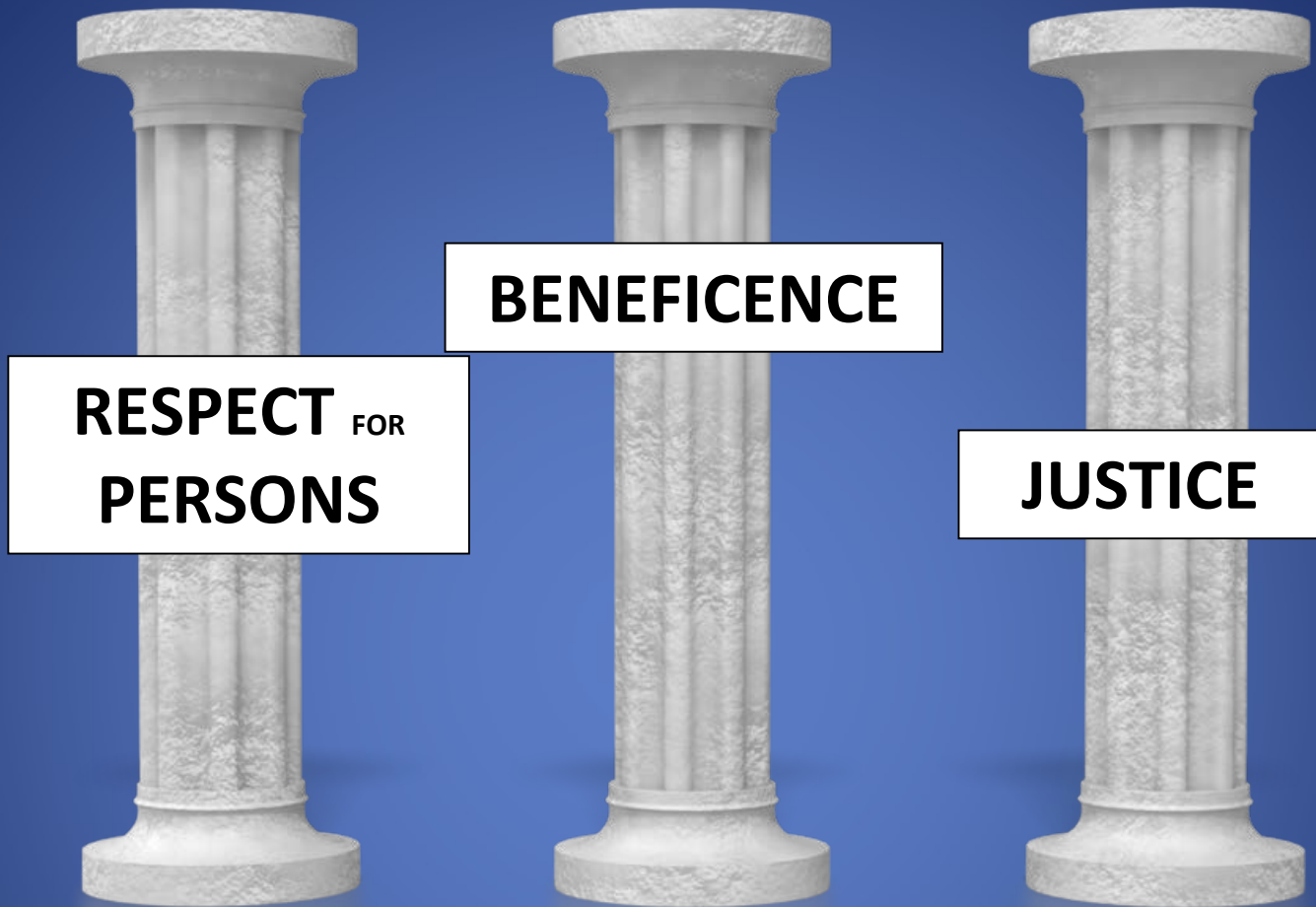
Caring

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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*


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

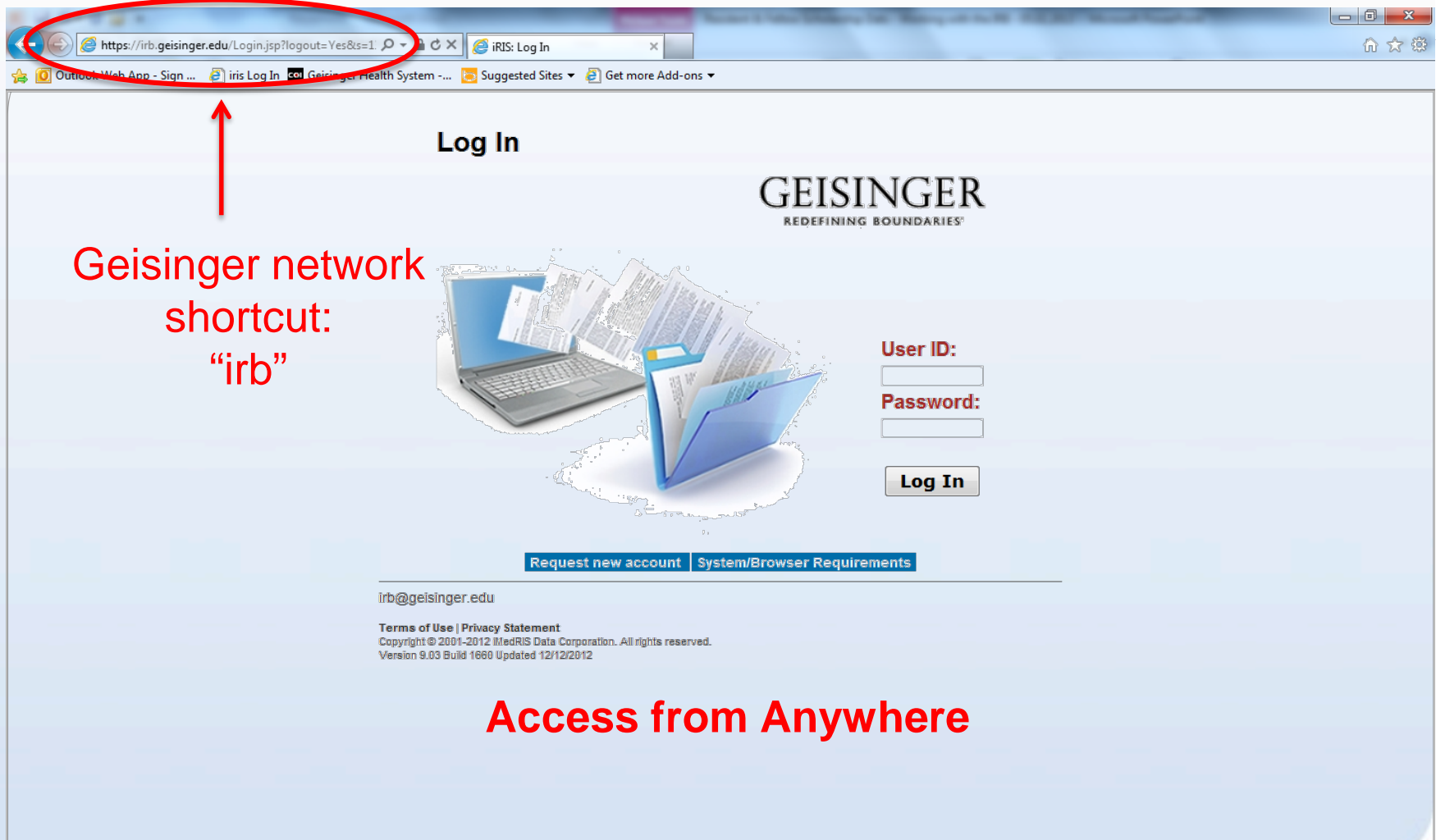


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iRIS (Electronic IRB System)

iRIS IRB System

<https://irb.geisinger.edu> (web-based system)



Log In

GEISINGER
REDEFINING BOUNDARIES®

User ID:

Password:

Log In

[Request new account](#) | [System/Browser Requirements](#)

irb@geisinger.edu

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Version 9.03 Build 1660 Updated 12/12/2012

Access from Anywhere

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iRIS – Obtaining an Account

Step 1 – Complete CITI (Human Subjects Research Training)

Step 2 – Complete COI requirements if investigator



iRIS Account Created

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

The screenshot shows the iRIS Log In page in a web browser. The browser's address bar displays the URL <https://irb.geisinger.edu/Login.jsp?logout=Yes&ts=1>. The page features the Geisinger logo with the tagline "REDEFINING BOUNDARIES". To the left of the login form is an illustration of a laptop and a folder with documents. The login form itself is enclosed in a red circle and contains the following fields and buttons:

- User ID:** A text input field.
- Password:** A password input field.
- Log In**: A button.

Two red arrows point from the right side of the page to the login form, with accompanying text:

- The top arrow points to the User ID field and is labeled "L-dap user id and password for Geisinger employees".
- The bottom arrow points to the Password field and is labeled "Form of email and temporary password for non-employees".

Below the login form, there are two links: "Request new account" and "System/Browser Requirements". At the bottom of the page, the email address irb@geisinger.edu is listed, followed by the "Terms of Use | Privacy Statement" link and copyright information: "Copyright © 2001-2012 iMedRIS Data Corporation. All rights reserved. Version 9.03 Build 1660 Updated 12/12/2012".

iRIS IRB System

The screenshot shows the 'My Assistant' dashboard of the iRIS IRB System. The top navigation bar includes the Geisinger logo, account information (Account: [redacted], Department: GMC - General Surgery), and links for Home, Logout, Help, and Modern. The left sidebar contains links for My Assistant, My Account Information, Announcements, Operating Procedures and Templates, and Review Board Meetings. The main content area displays a 'Worklist Filter' set to 'All' and a table of tasks. The table has four columns: Incomplete Tasks, Complete Tasks, Not Opened Correspondence, and Previously Opened Correspondence. The 'Incomplete Tasks' column shows 'No tasks found'.

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REDEFINING BOUNDARIES®

Account: [redacted] [If you're not logged in, click here to return to your account](#)
Department: GMC - General Surgery

Home Logout Help Modern

My Assistant

My Account Information

Announcements

Operating Procedures and Templates

Review Board Meetings

Study Assistant

Your current Department is GMC - General Surgery

Your current review board is Institutional Review Board - IRB Your current committee is Institutional Review Board

Worklist Filter: All

Incomplete Tasks	Complete Tasks	Not Opened Correspondence	Previously Opened Correspondence
No tasks found			

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

iRIS IRB System

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REDEFINING BOUNDARIES™

Account: [REDACTED]

Department: GMC - General Surgery

Navigation: Home

Home

Logout

Help

My Account - [REDACTED]

Back

Save Changes

Profile

Biosketch, CV, Pubs

Education History

Medical Licenses

Signature

Signoff Availability

Notes

*Last Name:

Zamani

Suffix:

Prefix:

Job Title:

Status:

Active

Degree:

Gender:

--none--

Specialty:

Add

Remove

Relationship to the Institution

☒ Affiliated

☐ Non-Affiliated

Affiliation:

Add

Remove

Representational capacity

☐ Scientist

☐ Non-Scientist

PI status waiver required

☐ Yes

☒ No

First Name:

Tanveer

Middle Name:

Personal Question:

Personal Answer:

Contact Information (* fields required)

* Email Address:

tzamani@geisinger.edu

Email Address Required

* Phone:

Cell Phone:

Pager:

Fax:

Personal URL:

Mailing Address:

Physical Address:

Internal Mailing Address:

Street 1:

Street 2:

City:

County/Parish:

State:

--none--

Province:

iRIS IRB System

The screenshot displays the iRIS IRB System interface. At the top left is the Geisinger logo with the tagline "REDEFINING BOUNDARIES". The top navigation bar includes the user's account information (Account: [redacted], Department: GMC - General Surgery) and links for Home, Logout, Help, and Modern. The left sidebar contains navigation options: My Assistant, Study Assistant (selected), Add a New Study, My Studies, Find a Study, and My Appointments. The main content area shows the Study Assistant interface, which includes a message about the current department (GMC - General Surgery) and the current review board (Institutional Review Board - IRB). Below this is a Worklist Filter dropdown set to "All", and four task status buttons: Incomplete Tasks (showing "No tasks found"), Complete Tasks, Not Opened Correspondence, and Previously Opened Correspondence.

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



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HRPP Webpage
&
IRB Resources

[home](#)[epic](#)[departments](#)[manuals](#)[forms](#)[education](#)[links](#)[phonebook](#)[Research > HRPP > Human Research Protection Program](#) [Print This Page](#)

Human Research Protection Program



Geisinger's Human Research Protection Program (HRPP), integrates the activities and functions of Geisinger Institutional Review Board (IRB), Office of Research Compliance (ORC), Office of Sponsored Projects (OSP), and other review units through oversight, education and quality assurance activities, including program administration. The HRPP seeks to assure the rights and welfare of research participants and promote excellence in all aspects of human subjects research.

Geisinger's HRPP has been successful in obtaining accreditation by the [Association for the Accreditation of Human Research Protection Programs \(AAHRPP\)](#). Geisinger Health System was awarded the status of full accreditation for a three-year period, effective March 2016. This important achievement reflects Geisinger's commitment to protecting the rights and welfare of research participants.

Conflict of Interest / Education / Training	IRB Information
<ul style="list-style-type: none"> • Study Staff IRB Requirements • Conflict of Interest – COI • Human Research Education CITI 	<ul style="list-style-type: none"> • IRB Fees • IRB 2016 & 2017 Submission Deadlines and Meeting Dates • Staff listing
Applying to the IRB via iRIS	Guides to Initiate Your Research
<ul style="list-style-type: none"> • Click here to access iRIS • iRIS Site Access Request Form • IRB submission checklist 	<ul style="list-style-type: none"> • Geisinger Research Process Flow • Geisinger's Research Process Presentations

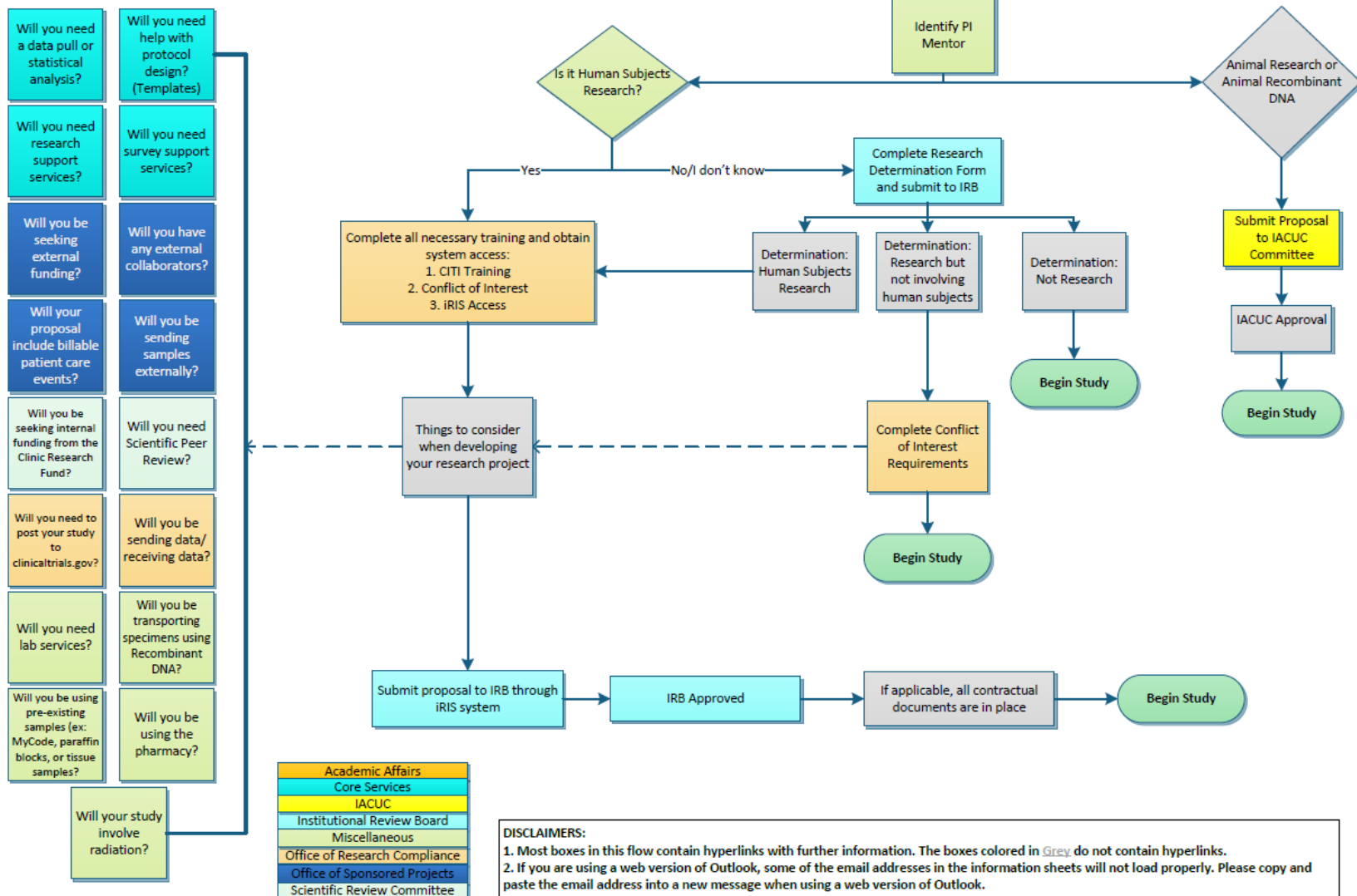
HRPP Webpage

Geisinger Research Process Flow

Geisinger Research Process Flow

<https://spresearch/grant/resident/Visio%20Drawings/>

Flow_FINAL.pdf



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

Contacts

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 - (bkent@geisinger.edu)
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- Dorothy Sellers, BS, Director
 - (dc sellers@geisinger.edu)
- Les Kirchner, PhD, IRB Chair
- Tom Challman, MD, IRB Chair

QUESTIONS??