Caring

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Geisinger IRB Membership -Session #1

Introduction to IRB & IRB Membership

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Associate Director, Research Compliance

Objectives

Human Research Protection Program

Institutional Review Board

Geisinger

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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.

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

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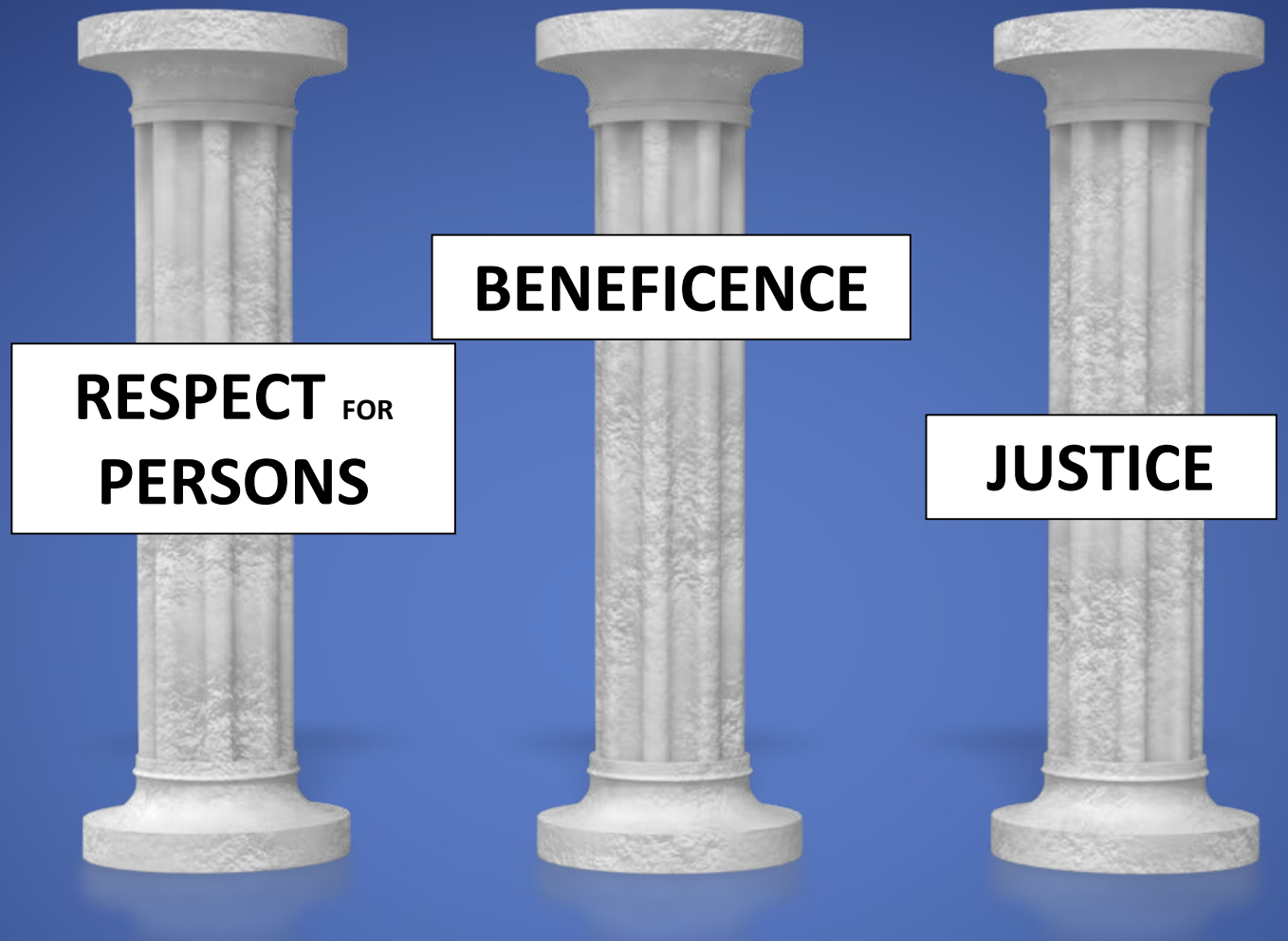
IRB Role §45CFR46

- 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

Objectives

- GIRB Demographics
- GIRB Member Responsibilities
- Submission Processing

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Objectives

- **GIRB Demographics**
- GIRB Member Responsibilities
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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

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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

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IRB Membership §45CFR46.107

Must include:

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

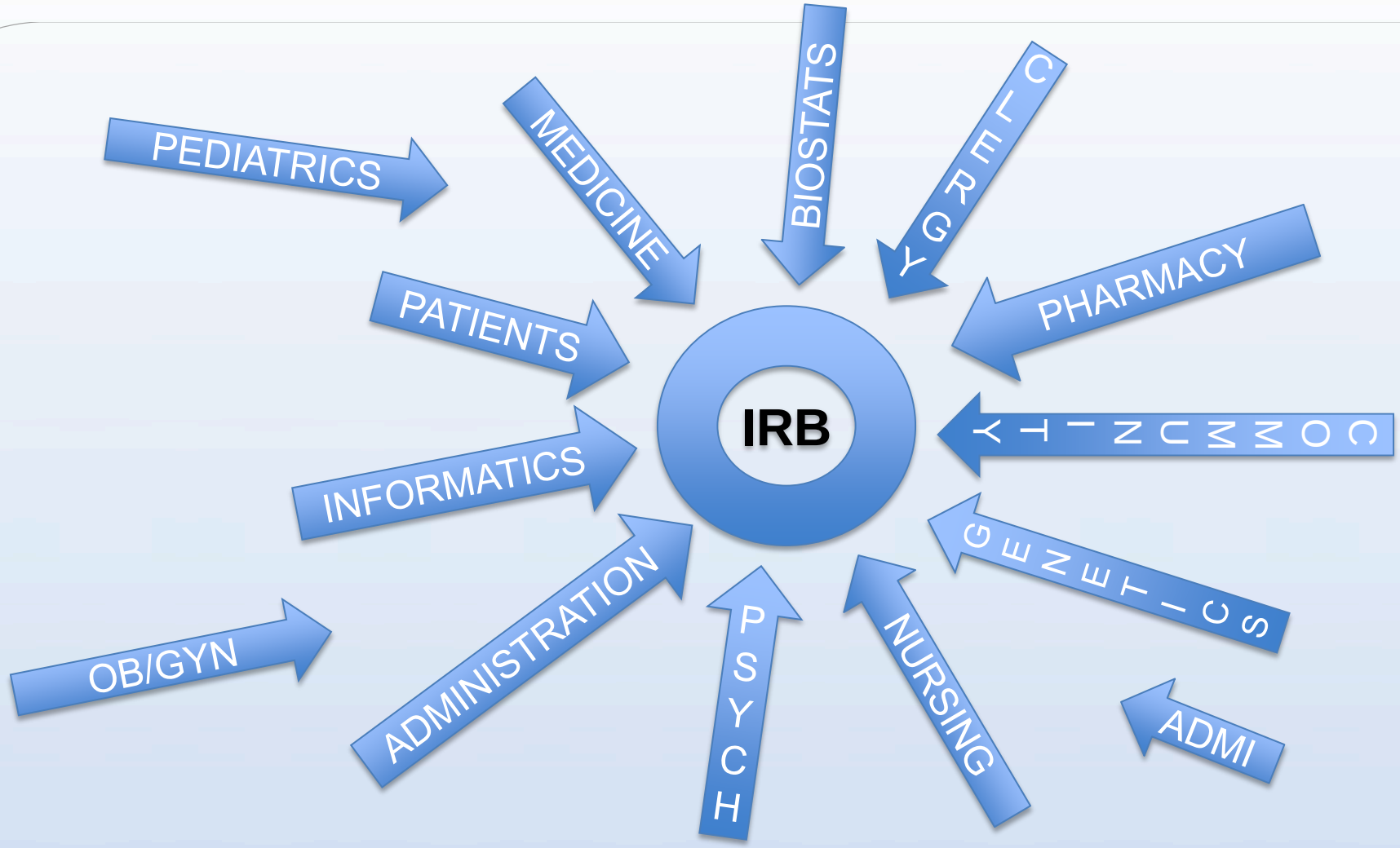
Must include at least one community member:

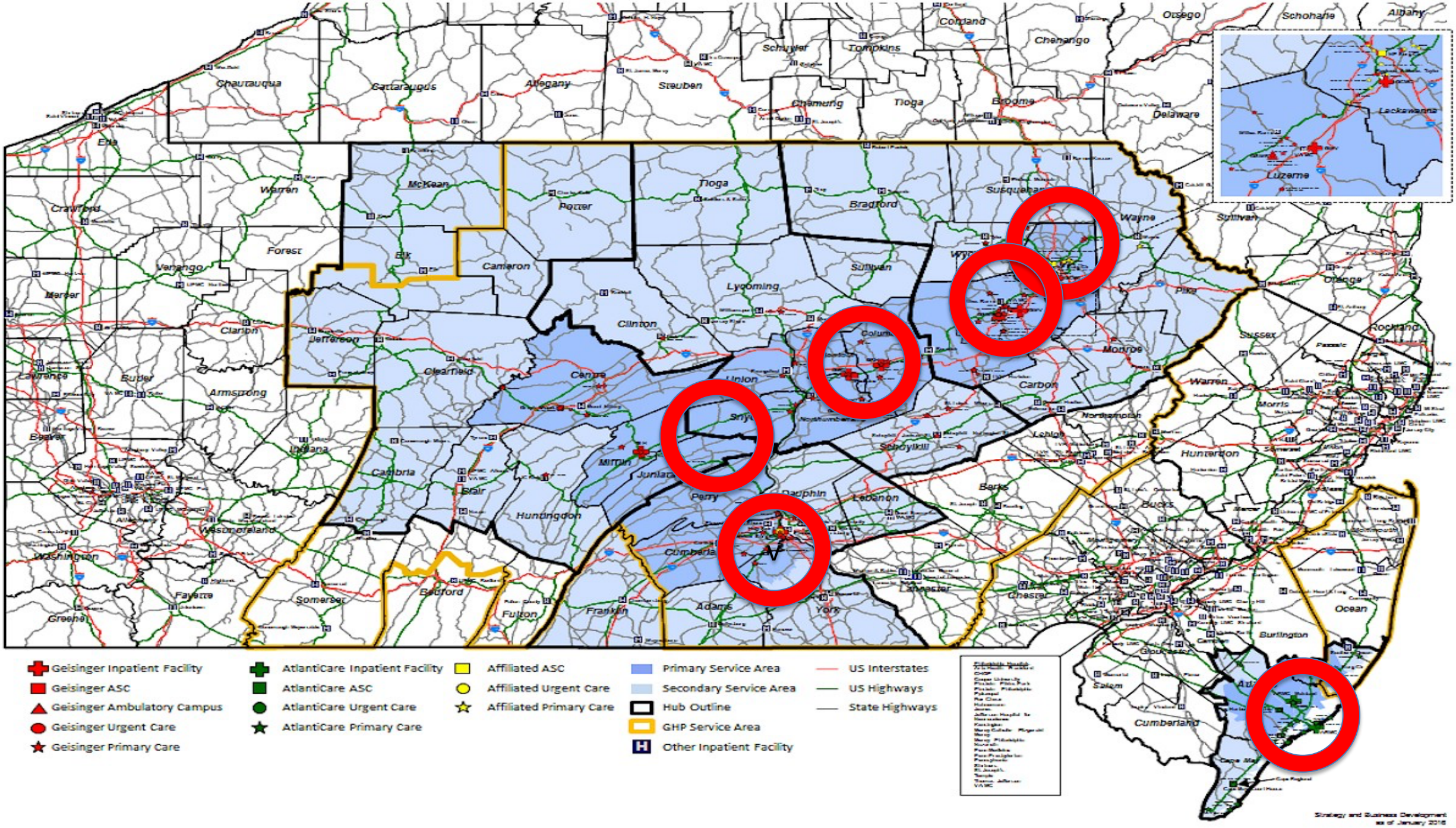
- Not affiliated with the institution or immediate family of a person who is affiliated with the institution

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 Demographics




Geisinger Inpatient Facility
Geisinger ASC
Geisinger Ambulatory Campus
Geisinger Urgent Care
Geisinger Primary Care
AtlantiCare Inpatient Facility
AtlantiCare ASC
AtlantiCare Urgent Care
AtlantiCare Primary Care
Affiliated ASC
Affiliated Urgent Care
Affiliated Primary Care
Primary Service Area
Secondary Service Area
Hub Outline
GHP Service Area
Other Inpatient Facility
US Interstates
US Highways
State Highways
Strategy and Business Development
as of January 2016

Objectives

GIRB Demographics

GIRB Member Responsibilities

Submission Processing

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Member Responsibilities

Meeting attendance – 1st & 3rd Thursday of each month @ 2:30

- ✓ Quorum
- ✓ Alternates

Submission reviews

- ✓ Primary review - meeting
- ✓ Secondary review – meeting
- ✓ Expedite review – 3-5 business days

Communication with IRB staff

- ✓ Conflicts of interest
- ✓ Availability – expedite & meeting
- ✓ Questions for investigator – before meeting

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Member Responsibilities

Confidentiality

Conflict of Interest

✓ Annual disclosure

Research Education – CITI – every 3 years

✓ Human Subjects Protection

✓ Responsible Conduct of Research

✓ Good Clinical Practice

IRB Training

✓ Quarterly

✓ IRB meetings

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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 & HIPAA Determination

Exempt Review

- iRIS submission
- IRB Member review – rolling review

Expedite Review

- iRIS submission
- IRB Member review – rolling review

Convened Review

- iRIS submission
- Primary & Secondary Member Review
- IRB Committee review – meets 1st and 3rd Thursday each month

Ongoing IRB Review of Research

Reporting Requirements

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

Institutional Requirements

Must be completed & submitted to IRB with study application (as applicable):

- ✓ Research Education requirements
- ✓ Research Financial Conflict of Interest requirements
- ✓ Principal Investigator requirements
- ✓ MCA & Billing Determination
- ✓ Investigational Pharmacy
- ✓ Radiation Safety Committee
- ✓ Information Security Office (ISO)
- ✓ Nurse Research Council (nurse researchers)
- ✓ MyCode Governing Board (use of MyCode data/samples)
- ✓ Geisinger Health Plan Proposal (use of GHP data)

Geisinger IRB Review Process

1. Submission Triage – IRB Office
   - ✓ Research Education
   - ✓ Conflict of Interest
   - ✓ Completeness
2. Submission Pre-Review – IRB Office
3. Assignment / member notification – IRB Office
4. Submission Review – IRB Member
5. Communication with researchers/staff – IRB Office
6. Outcome letter – IRB Office
7. Documentation of review outcome in iRIS – IRB Office

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&
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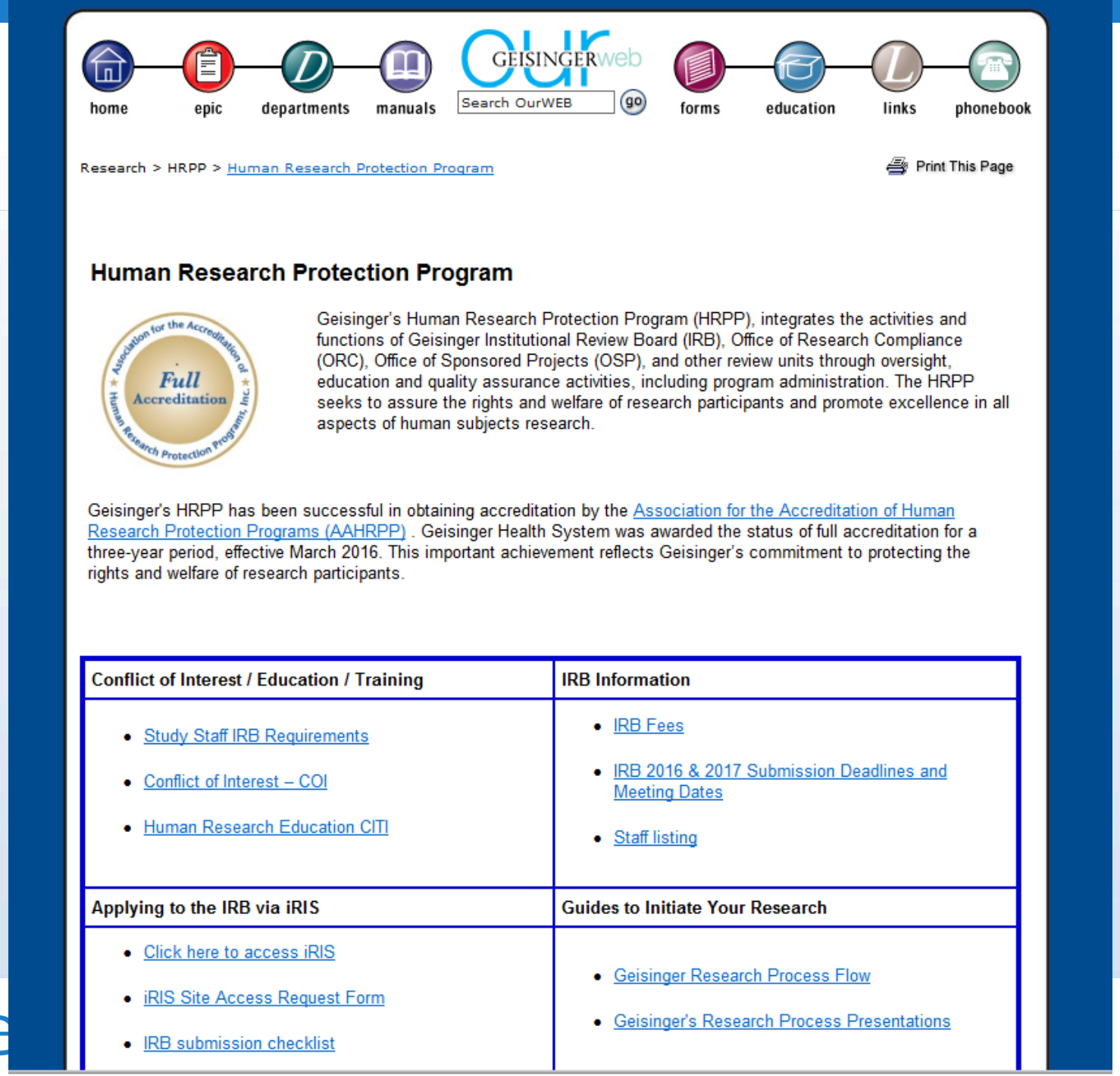
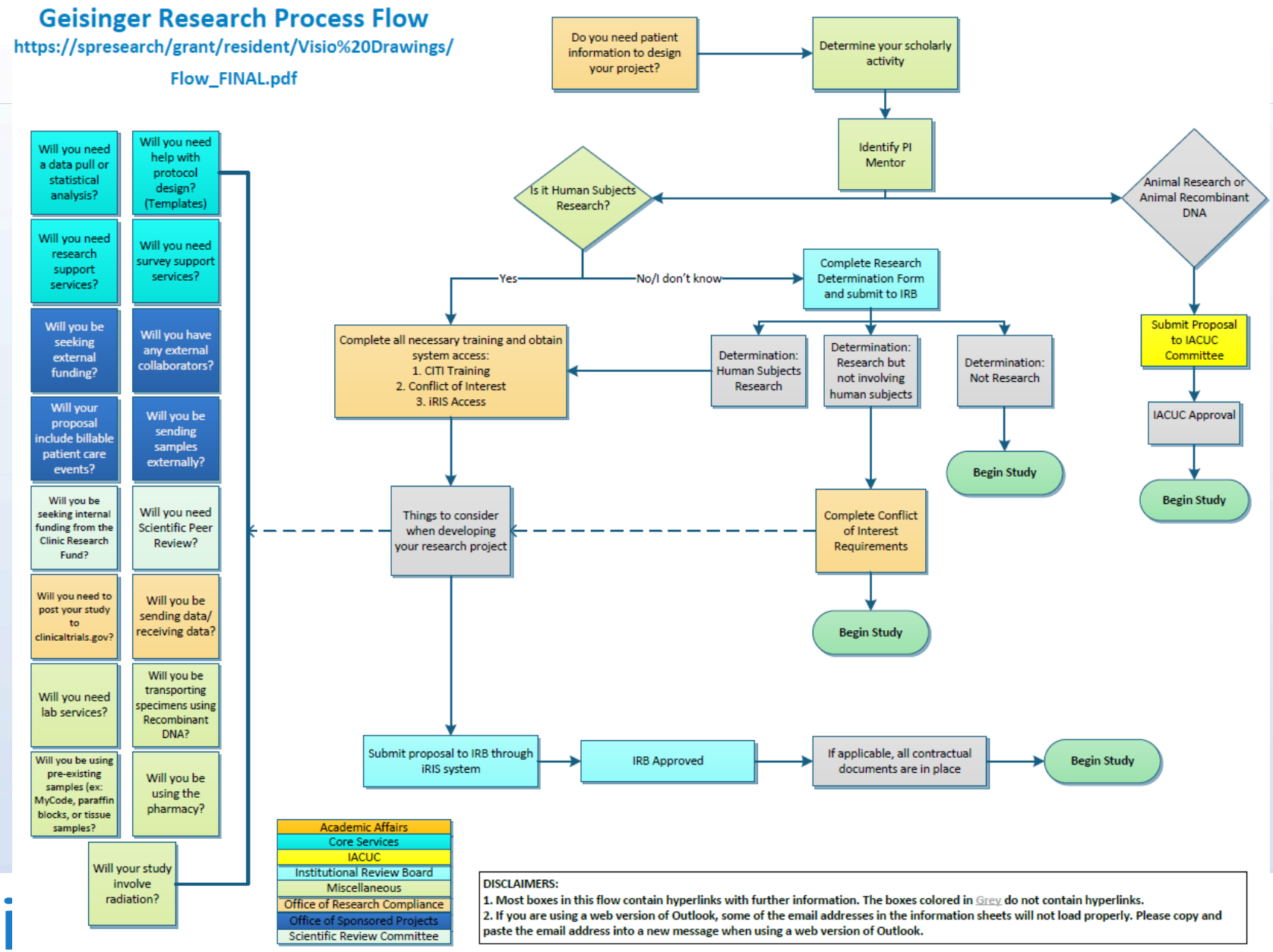


HRPP Webpage

Geisinger Research Process Flow



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

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Contacts

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- Les Kirchner, PhD, IRB Chair
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- Tom Challman, MD, IRB Chair
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QUESTIONS??