



Introduction to Geisinger's Research Process

Rosa Jarvis, BS

IRB Specialist

Human Research Protection Program

Deb Henninger MHA RN CCRC

Associate Director

Office of Research Compliance & Training

WHAT IS THE IRB?

What is the IRB?

- An IRB is a committee that performs ethical review of proposed research ensuring the **protection of the rights, welfare and safety of human subjects**
- Health & Human Services (HHS) mandates Institutional Review Board (IRB) oversight of research involving human subjects (§ 45CFR46)
- GHS Research Privacy Board

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



KEY IRB CONCEPTS

Protocol Design / Data / Specimens

Understand the difference between prospective and retrospective protocol design.

- **Retrospective** - Research using specimens/data **previously collected** (“already existing”, “on the shelf” **before** the date of IRB submission).
- **Prospective**: Research that includes specimens/data that **will be collected in the future** (**after** date of submission to the IRB).

PHI (Protected Health Information) – Identifiers

•Name	•Account Numbers
•Street address, city, county, precinct, zipcode	•Certificate/license numbers
•Dates	•Vehicle identifiers and serial numbers
•Telephone Number	•Device identifiers and serial numbers
•Fax Number	•Web addresses (URL)
•Electronic mail address	•Internet addresses (IP)
•Social Security Number	•Biometric identifiers including fingerprints and voiceprints
•Medical record number	•Full face photographic images and comparable images
•Health plan identification numbers	•Any other unique identifying number, characteristic or code

Define 'Use' and 'Disclosure'

'Use' = sharing of PHI within Geisinger (GC, GCMC, GWV)
– single entity

'Disclosure' = sharing PHI outside of Geisinger

- GHP
- Another institution
- Mentors or students from another institution

Use and Disclosure Requirements

Required to access identifiable data for research:

<i>Written HIPAA Authorization</i>	IRB-approved Consent/Authorization
<i>Waiver of HIPAA Authorization</i>	IRB approves
<i>Partial waiver of HIPAA Authorization</i>	IRB approves

Use and Disclosure Requirements

Agreements required to **disclose** identifiable data:

<i>Data Use Agreement</i>	Dates City, state, zip codes
<i>Agreement for Disclosure of PHI</i>	Any of the 19 identifiers
<i>Clinical Trial or Sponsored Research Agreement with HIPAA language</i>	Any of the 19 identifiers

What is Research?

Research is defined as ...

“a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**”.

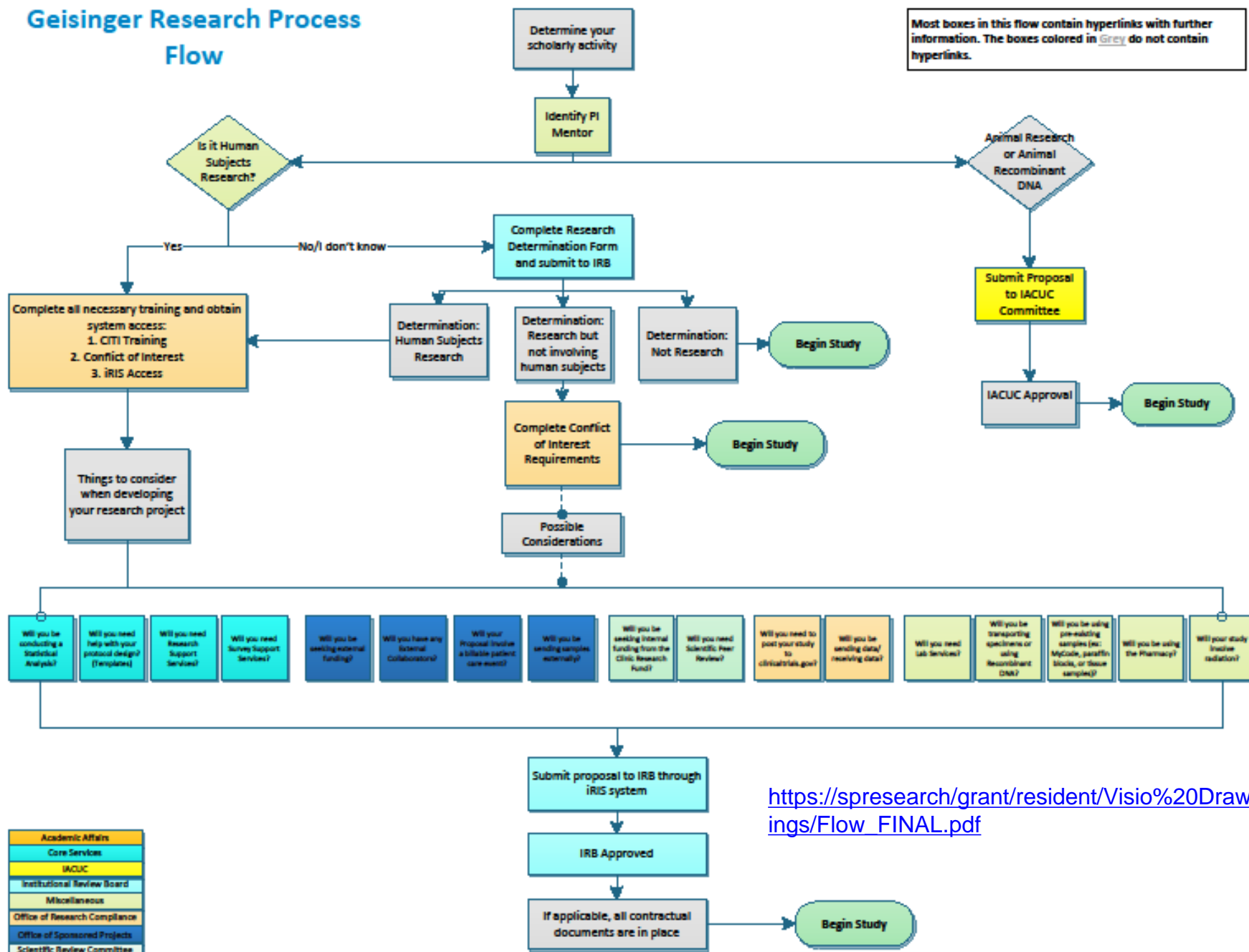
What is a Human Subject?

Human Subject is ...

- **Living individual** about whom an investigator conducting research obtains:
 - **Data/samples** through intervention or interaction with individual;
 - **Intervention**
 - physical procedures by which data are gathered (e.g., venipuncture)
 - manipulations of the subject or their environment that are performed for research purposes.
 - **Interaction** includes communication or interpersonal contact between investigator and subject.
 - **Identifiable private information** (coded information may or may not be identifiable)

Geisinger Research Process Flow

Most boxes in this flow contain hyperlinks with further information. The boxes colored in Grey do not contain hyperlinks.



https://spresearch/grant/resident/Visio%20Drawings/Flow_FINAL.pdf

Academic Affairs
Core Services
IACUC
Institutional Review Board
Miscellaneous
Office of Research Compliance
Office of Sponsored Projects
Scientific Review Committee

iRIS Log-In

<https://irb.geisinger.edu>

Log In

GEISINGER
REDEFINING BOUNDARIES™

User ID:

Password:

Log In

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

irb@geisinger.edu

[Terms of Use](#) | [Privacy Statement](#)
Copyright © 2001-2012 iMedRIS Data Corporation. All rights reserved.
Version 9.03 Build 1660 Updated 12/12/2012

***User ID & Password =
Your GHS ID & Password
(use to log in to Geisinger
system)**

iRIS™ – My Assistant™

The screenshot shows a web browser window displaying the iRIS My Assistant application. The browser's address bar shows the URL https://irb.geisinger.edu/Application_Main.jsp?tab=i. The application header includes the Geisinger logo with the tagline "REDEFINING BOUNDARIES" and the user's account information: "Account: Debra L Henninger, RN, BSN, CCRC" and "Department: GHS - Geisinger". Navigation links for "Home", "Logout", and "Help" are present in the top right.

The left sidebar contains a menu with the following items: "My Assistant" (highlighted with a red circle and a red arrow), "Study Assistant", "Add a New Study", "My Studies", "Find a Study", "My Appointments", "Department Schedule", "IRB Assistant", and "System Administration".

The main content area displays the following information:

- Your current Department is GHS - Geisinger
- Your current review board is Institutional Review Board (IRB) Your current committee is Institutional Review Board
- Worklist Filter: Internal Board Routing Signoff
- Task filters: Incomplete Tasks, Complete Tasks, Not Opened Correspondence, Previously Opened Correspondence
- No tasks found

The bottom of the page features a large graphic of a laptop and a blue folder with papers, and the Geisinger logo with the tagline "REDEFINING BOUNDARIES". The Windows taskbar at the bottom shows the system clock as 1:34 AM on 4/30/2013.

iRIS™ – My Assistant™

IRIS - My Account - Windows Internet Explorer

http://medrptest/My_Account.jsp?tab=demo&id=1354894657480

File Edit View Favorites Tools Help

IRIS - My Account

GEISINGER
REDEFINING BOUNDARIES™

Account: Cathy A Betz
Department: GITS - Geisinger
Navigation: Home

Home Logout Help

My Account - Cathy A Betz

Back Save Changes

Profile

- Biosketch, CV, Pubs
- Education History
- Medical Licenses
- Signature
- Disclosures
- Signoff Availability
- Notes

*Last Name:

Suffix:

Prefix:

Job Title:

Status: Active

Degree:

Gender:

Employee ID:

Specialty:

Relationship to the Institution
 Affiliated Non-Affiliated

Affiliation:

Representational capacity
 Scientist Non-Scientist

PI status waiver required
 Yes No

First Name: Middle Name:

Personnel Question:

Personnel Answer:

Contact Information (* fields required)

* Email Address: Email Address Required

* Phone:

Cell Phone:

Pager:

Fax:

Personal URL:

Mailing Address:

Physical Address:

Internal Mailing Address:

Department(s)
• Geisinger-Geisinger

Local intranet 100%

iRIS – My Assistant

The screenshot displays the iRIS web application interface. At the top, the browser address bar shows the URL https://irb.geisinger.edu/System_SOP.jsp?Init=Yes&:. The page header features the **GEISINGER** logo with the tagline "REDEFINING BOUNDARIES". To the right of the logo, the user's account information is displayed: "Account: Debra L Henninger, RN, BSN, CCRC" and "Navigation: Home". Further right, there are navigation links for "Home", "Logout", and "Help" (the latter is circled in red). Below the header, the main content area is titled "Operating Procedures and Templates" (also circled in red). This section is organized into several categories:

- Checklists**
 - IRB Submission Checklist
 - Definitions - Glossary of Terms
- Forms**
 - Research Determination Worksheet
 - Preparatory to Resarch - Processed by Office of Research Compliance
- iRIS User Training**
 - iRIS Basic User Training - Researchers and Study Staff
 - Steps to Modify Approved Study Documents in iRIS - Converting PDF to Word
 - Steps to Send an Amendment to the Application and/or Protocol
 - Steps to Respond to an IRB Letter of Outcome
- Policies**
 - PI/Program Director Policy
 - PI/Program Director - Sample Letter
 - PHI Elements - Permitted Uses and Disclosures of PHI
- Submission Tips**
 - iRIS Submission Tips for Studies Approved Before 1-2-13
- Templates**
 - Protocol Template - Prospective Study
 - Protocol Template - Retrospective Study
 - Consent/Authorization Template

The bottom of the screenshot shows a Windows taskbar with various application icons and a system tray displaying the time as 1:21 AM on 4/30/2013.

iRIS™ – Study Assistant™ - Add a New Study

Account: Debra L Henninger, RN, BSN, CCRC
Department: GHS - Geisinger

Home Logout Help

My Assistant
Study Assistant
Add a New Study
My Studies
Find a Study
My Appointments
Department Schedule
IRB Assistant
System Administration

Your current Department is GHS - Geisinger

Your current review board is Institutional Review Board (IRB) Your current committee is Institutional Review Board

Worklist Filter: Internal Board Routing Signoff

Incomplete Tasks **Complete Tasks** **Not Opened Correspondence** **Previously Opened Correspondence**

No tasks found

GEISINGER
REDEFINING BOUNDARIES™

1:34 AM
4/30/2013

iRIS™ – Study Assistant™ - Study Application

The screenshot shows a web browser window with the URL https://irb.geisinger.edu/Study_App.jsp?FORM_MOD. The browser's address bar shows the page title "iRIS: Study Application".

The application header features the Geisinger logo with the tagline "REDEFINING BOUNDARIES". To the right of the logo, the user's account information is displayed: "Account: Debra L Henninger, RN, BSN, CCRC", "Department: GHS - Geisinger", and "Navigation: Home". Further right are navigation links for "Home", "Logout", and "Help".

The main content area is titled "Study Application" and includes a "Back" button. A "Save and Continue to Next Section" button is also present. Below the title, there are two tabs: "Section view of Application" and "Entire view of the Application". The "Section view of Application" tab is active, showing a sidebar with "1.0 General Information" selected.

The "1.0 General Information" section contains the following fields:

- 1.0 General Information**
- * Please enter the full title of your study:** A large text input field.
- * Please enter a short descriptor that you would like to use to reference the study:** A text input field. Below it, a note states: "This descriptor allows you and other study team members to quickly identify the study. This would be the acronym/ sponsor protocol and/or abbreviated study title."
- Please identify the Research Type?** A dropdown menu currently showing "--none--".

The Windows taskbar at the bottom of the screen shows the time as 3:53 AM on 4/30/2013, along with various system icons and application shortcuts.

EXEMPT REVIEW

THE IRB DETERMINES IF THE RESEARCH MEETS
EXEMPTION CRITERIA

EXEMPT from Ongoing IRB Oversight

- Must meet the definition of **MINIMAL RISK**
 - “the probability and magnitude of harm or discomfort anticipated in the research are not greater than those **ordinarily encountered in daily life** or during the performance of routine physical or psychological examinations or tests”

And

- Meet the criteria of one or more of the Exempt categories (§ 45CFR46.101.b.)

Exempt Categories- (§ 45 CFR 46.101.b.)

1. Educational Strategies, Curricula or Classroom Management in Educational Settings
2. Tests, Surveys, Interviews, Public Behavior Observation
3. Tests, Surveys, Interviews, Public Behavior Observation of Public Officials
4. Existing Data, Documents, Records and Specimens
5. Public Benefit or Service Programs
6. Taste and Food Evaluation and Acceptance Study

EXPEDITE REVIEW

**THE IRB DETERMINES IF THE RESEARCH QUALIFIES FOR
EXPEDITE REVIEW**

Qualify for EXPEDITE Review

- Must meet the definition of **MINIMAL RISK**
 - “the probability and magnitude of harm or discomfort anticipated in the research are not greater than those **ordinarily encountered in daily life** or during the performance of routine physical or psychological examinations or tests”

And

- Meet the criteria of one or more of the Expedite categories (§ 45 CFR 46.110 and § 21 CFR 56.110)

Categories of Research that may qualify for Expedited Review:

- (1) Clinical studies of drugs and medical devices only when
 - (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application (§ 21 CFR Part 312) is not required.
 - (b) Research on medical devices for which:
 - (i) an investigational device exemption application (§ 21 CFR Part 812) is not required; or
 - (ii) the medical device is cleared/approved for marketing and the medical device is being used according to its approved labeling.

Categories of Research that may qualify for Expedited Review (cont.):

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) Healthy, nonpregnant adults (wt \geq 110 pounds)

(a) Draw \leq 550 ml / 8 week period and

(b) Draw \leq 2 times / week; or

(b) Other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.

a) Draw \leq 50 ml or 3 ml per kg in an 8 week period and

b) Draw \leq 2 times / week

Categories of Research that may qualify for Expedited Review (cont.):

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

a) Examples - urine specimen, buccal swab

(4) Collection of data through noninvasive procedures routinely part of clinical practice

a) Excludes procedures requiring sedation or general anesthesia

b) Excludes procedures involving x-rays or microwaves

c) Medical devices must be cleared/approved for marketing

a) Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for **new** indications.

Categories of Research that may qualify for Expedited Review (cont.):

(5) Research involving data, documents, records, or specimens that have been collected, or will be collected solely for **non-research purposes** (such as medical treatment or diagnosis)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes

(7) Research on individual or group characteristics or behavior

- a) Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior)
- b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

FULL BOARD (CONVENED) REVIEW

Require IRB Review at a Convened Meeting

- Research is greater than minimal risk, or
- Does not fit into any Exempt or Expedited category, or
- The IRB reviewer defers approval, sending the study to a convened meeting for full committee review.



Tips for Successful IRB Submission

- 1) Review Research Flow info sheets
 - Complete all steps required before IRB (ISO, IBC, SRC, BD if applicable)
- 2) Use protocol templates as a guide
 - Protocol templates in iRIS, HRPP website, flow
 - Not required, yet help guide correct information
- 3) Determine idea of risk level
 - If > than minimal risk, investigator-initiated and has NOT undergone previous peer review - SRC review prior to IRB
- 4) Determine if you will need funding

Tips for Successful IRB Submission

- 5) Assure all study personnel have completed human research requirements:
 - CITI Human Research Protections Training
 - Financial Conflict of Interest Training*
 - Annual Conflict of Interest Questionnaire*
- 6) Submit early (1-2 months), if possible
- 7) Contact us early in the process

We are here and willing to help!



Geisinger IRB

IRB Chairs

- Tom Challman, MD
- Les Kirchner, PhD

HRPP Staff (570-271-8663)

- Barb Kent, Administrative Assistant
- Chuck Brightbill, MS, IRB Analyst
- Gissel Martinez, BS, IRB Analyst
- Rosa Jarvis, BS, IRB Specialist
- Cathy Betz, HRPP Project Manager
- Deb Henninger, MHSA RN CCRC, Associate Director, ORC

Discussion / Questions