



Geisinger

The Research process:
From idea to approval

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Compliance

October 7, 2016

Objectives

1. Describe the research process at Geisinger (Geisinger Research Flow)
2. Describe what types of projects require IRB review
3. Explain the types/levels of IRB review

Research > HRPP > Human Research Protection Program

Human Research Protection Program



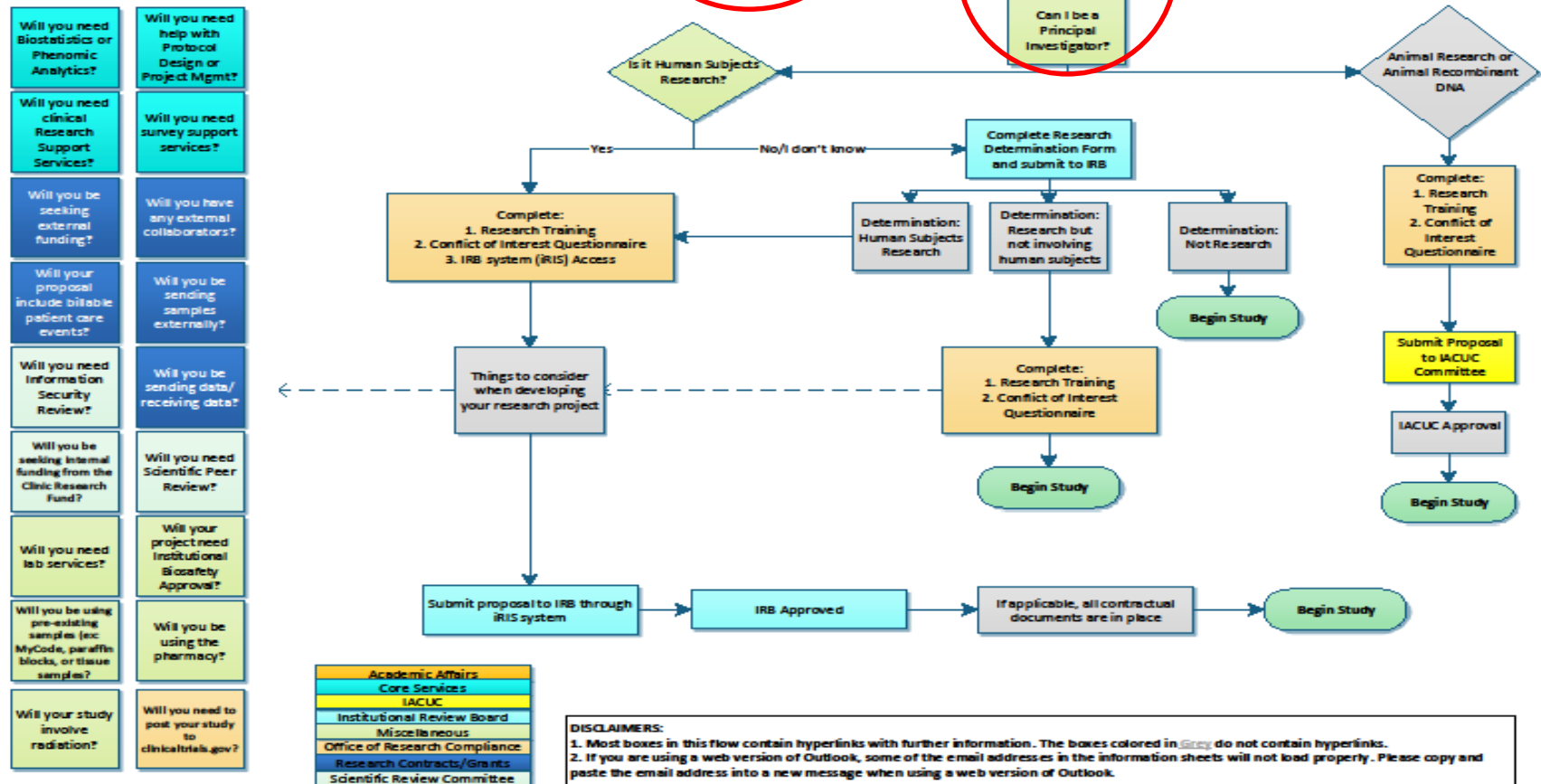
Geisinger's Human Research Protection Program (HRPP), integrates the activities and functions of Geisinger Institutional Review Board (IRB), Office of Research Compliance (ORC), Office of Sponsored Projects (OSP), and other review units through oversight, education and quality assurance activities, including 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 Submission Deadlines and Meeting 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
Forms / Templates	The Consent Process
<ul style="list-style-type: none"> Forms/Templates/Miscellaneous Patient IRS W-9 Inform Sheet Memo-IRB Letters No Signature 	<ul style="list-style-type: none"> Consent Authorization Temple Consent for Continued Participation in COG Research Consent for Patients Unable to Sign
Compliance Information	Manual / Policies / Guidance
<ul style="list-style-type: none"> FWA - IRB Membership Institutional Official Federal Policies and Guidance GHS HRPP GCP Compliance Information 	<ul style="list-style-type: none"> HRPP Handbook HRPP Guidance Documents HRPP SOPs Research Policy Manual
FAQs / Presentations / Updates	HRPP Components
<ul style="list-style-type: none"> FAQs Helpful Presentations HRPP Update Archives 	<ul style="list-style-type: none"> Ancillary Research Committees Office of Research Compliance Office of Sponsored Projects

Geisinger Research Process

Geisinger Research Process Flow
https://spresearch/grant/resident/Visio%20Drawings/Flow_FINAL.pdf



Preparatory to Research (PTR)

Sometimes access to protected health information is needed to before the research begins ...

- to design the project
- identify eligibility criteria
- determine whether there is a sufficient number or type of patients to conduct the research
- aid in recruitment



"Can I do this study?"

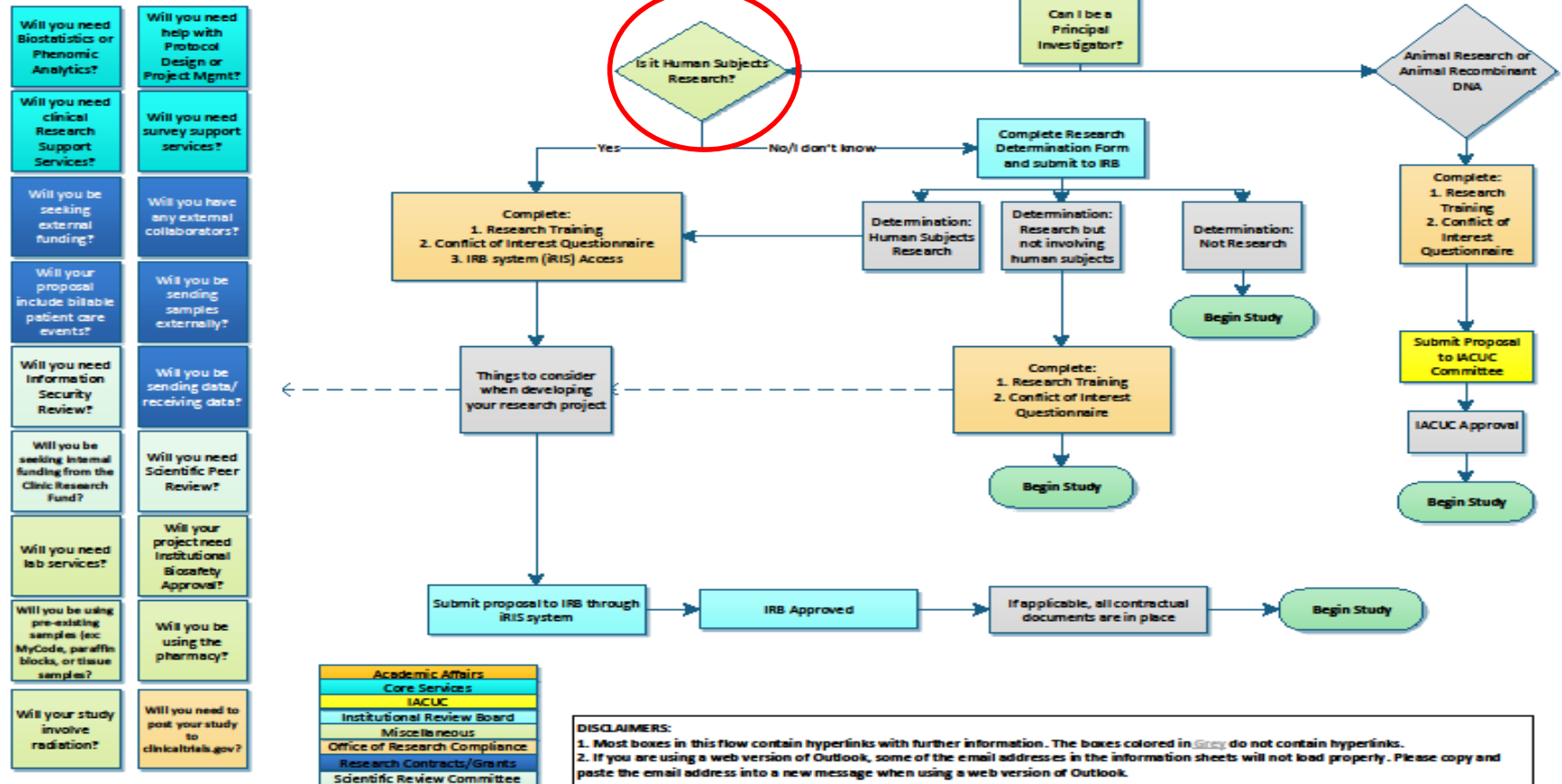
Preparatory to Research (PTR)

HIPAA Privacy Rule allows use or disclosure of PHI to prepare a research application or proposal

1. The activity must fit the PTR definition
2. Complete the Preparatory to Research (PTR) Form
 - directly in Geisinger Clinical Decision Intelligence System (CDIS), or
 - via email to Geisinger Office of Research Compliance (ORC)
3. Comply with the certification on the PTR form

Geisinger research process

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Research Determination

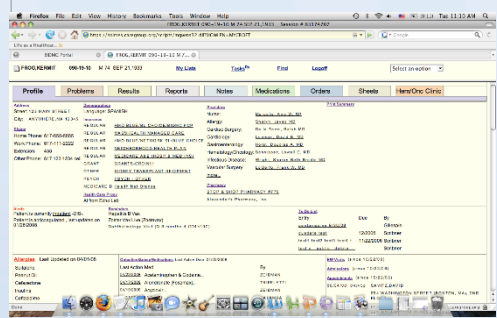
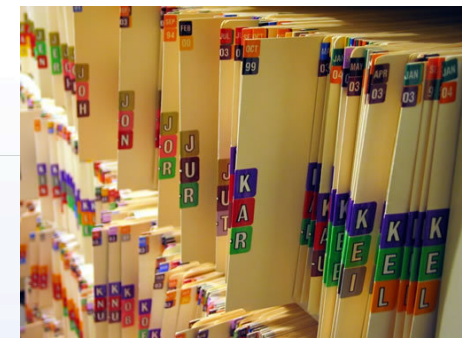
Is It Human Subjects Research ?

Research

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

“Systematic Investigation ... Designed To”

- Attempts to answer research questions (in some research, this would be a hypothesis)
- Is methodologically driven - it collects data or information in an organized and consistent way
- Data or information is analyzed in some way, be it quantitative or qualitative data analysis
- Conclusions are drawn from the results



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Research

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

“Contribute to Generalizable Knowledge”

Knowledge contributes to a theoretical framework of an established body of knowledge



Results are expected to be generalized to a larger population beyond the site of data collection or population studied



Activities Not Typically Generalizable

NOT the intention to share the results beyond Geisinger or any agency supporting the project

- Case reports; case studies ≤ 3 patients
- Clinical program evaluations, unless they can be generalized to other individuals
- QI activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond Geisinger

Human Subject

“Living individual about whom an investigator conducting research obtains either data/samples through intervention or interaction with individual; or obtains identifiable private information (coded information may or may not be identifiable)”

“Living Individual About Whom”

- About living individuals or their data/samples

Why “about whom” is key ...

- Consider if the project focuses on the person or if the focus is on policies, practices or procedures about which the person is knowledgeable.
- Some interactions with people for the purpose of collecting information do not collect any information about that person.
- Projects which collect information about policies, practices or procedures – even if the person who provided that information is identified – do not constitute human subject research.

Example of the difference ...

- Ask provider to describe their departments’ asthma treatment regimes = NOT “about individual”
- Ask provider to rank his/her preferences of asthma treatment regimes = “About the individual”

Human Subject

*“Living individual about whom an investigator conducting research obtains either data/samples through **intervention** or interaction with individual; or obtains identifiable private information (coded information may or may not be identifiable)”*

“Intervention”

- Intervention may be physical procedures (e.g. venipuncture) or manipulations of living individuals or the living individuals' environments
- Examples
 - Compare behavioral interventions
 - Compare surgical interventions
 - Effectiveness of drugs or devices



Human Subject

*“Living individual about whom an investigator conducting research obtains either data/samples through intervention or **interaction** with individual; or obtains identifiable private information (coded information may or may not be identifiable)”*

“Interaction”

- Interaction may be communication or interpersonal contact between the investigator (or research team) and the living individual.
- Interacting with people in order to gather data about them
- Examples
 - Interviews
 - Questionnaires
 - Surveys
 - Focus groups
 - Participant observations



Human Subject

“Living individual about whom an investigator conducting research obtains either data/samples through intervention or interaction with individual; or obtains identifiable private information (coded information may or may not be identifiable)”

“Identifiable”

The identity of the individual from whom the information was obtained...

- is learned or may be readily learned by the investigator; or
- is associated or may be readily associated with the information.



“Private”

- information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place, or
- information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g. medical record, employee or student records).

Identifiable, Private Information

Examples:

- Name, address, phone number
- Social security number
- Medical record number
- Student or employee identification number
- Combination of data that allows one to identify a single individual through deductive reasoning.
 - EXAMPLE - data about employer, job title, age and gender may not individually identify a subject, but when combined, could in certain cases, identify a specific individual.



HIPAA 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

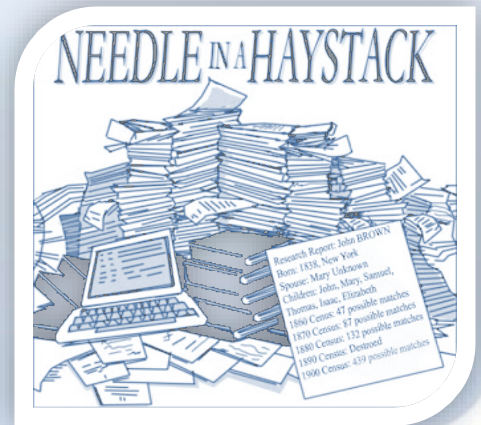
“NOT” identifiable, private information

Data is considered public information

- Is given with the expectation that it will be made public and that it will be linked to the individual (e.g. biography or news story)

Cannot be linked to a living individual

- Specimens/cells/material/data collected and not linked to any identifiers that would make it reasonably possible to identify an individual is not considered research with human subjects.
- Examples:
 - Use of a publicly available data set that does not contain identifiers or codes linked to individuals
 - Use of Geisinger Data Broker to provide a de-identified data set



Human Subjects Research

RESEARCH

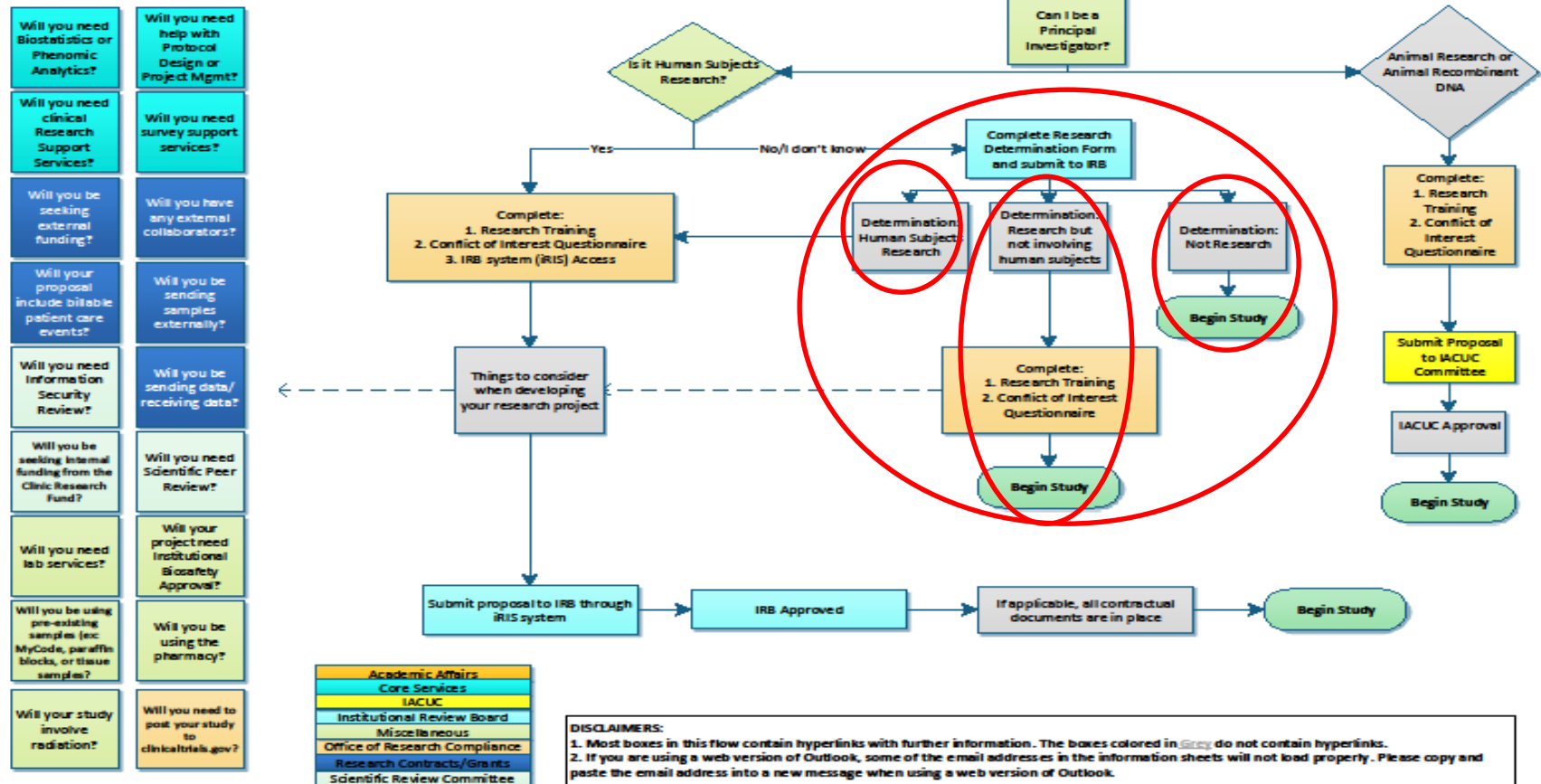
“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”


HUMAN SUBJECT

“Living individual about whom an investigator conducting research obtains either data/samples through intervention or interaction with individual; or obtains identifiable private information”

Research determination worksheet

Geisinger Research Process Flow
https://spresearch/grant/resident/Visio%20Drawings/Flow_FINAL.pdf

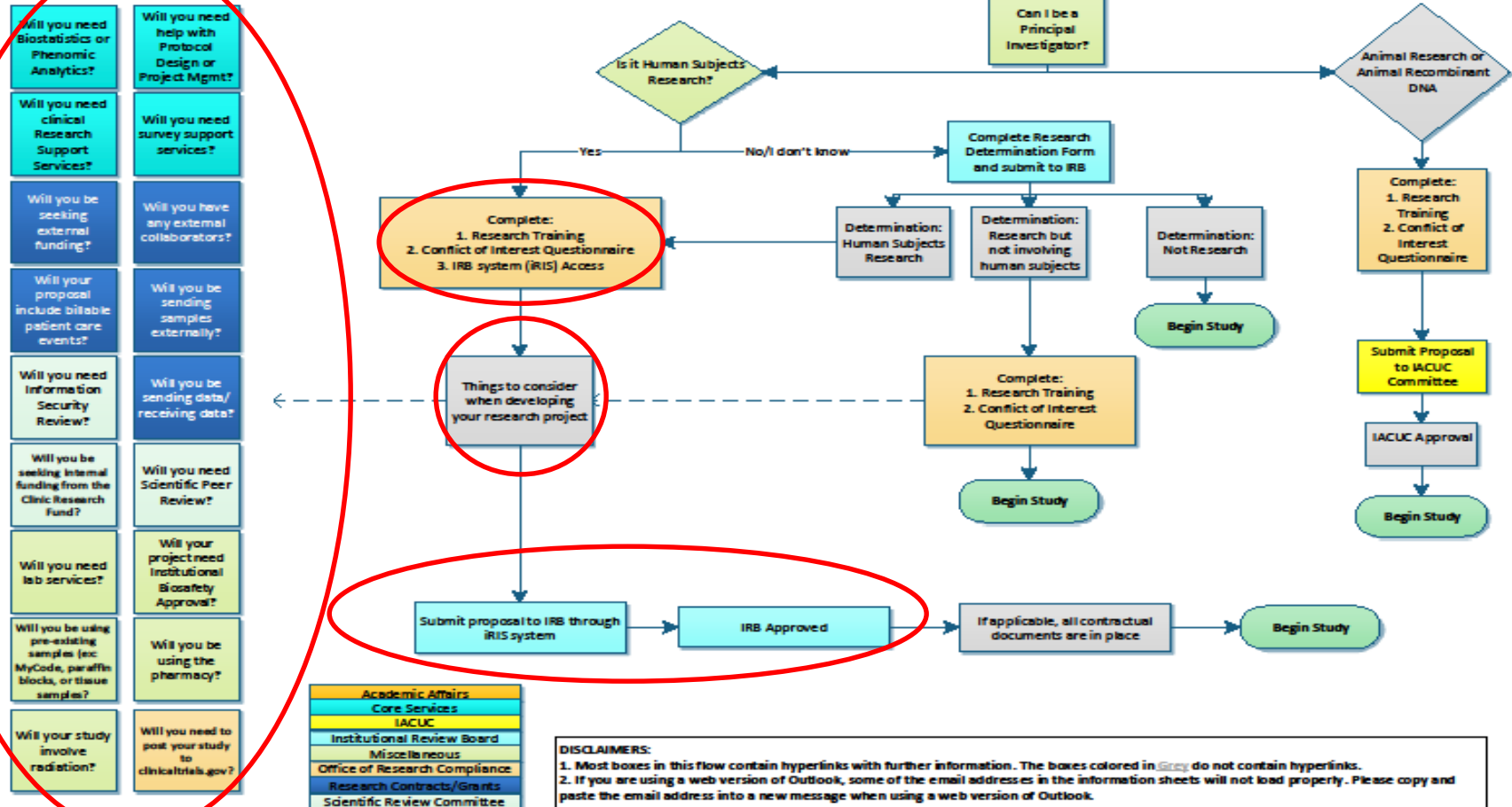




research + human subjects = IRB review

Research determination worksheet

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EXEMPT REVIEW

IRB Determines if the Research Qualifies for Exempt Review

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



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EXPEDITE REVIEW

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 is not required. (§ 21 CFR Part 312)

(b) Research on medical devices for which:

(i) an investigational device exemption application 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. (§ 21 CFR Part 812)

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 ≥ 110 pounds)
 - i. Draw ≤ 550 ml / 8 week period and
 - ii. Draw ≤ 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.
 - i. Draw ≤ 50 ml or 3 ml per kg in an 8 week period and
 - ii. Draw ≤ 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
 - i. 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



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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



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

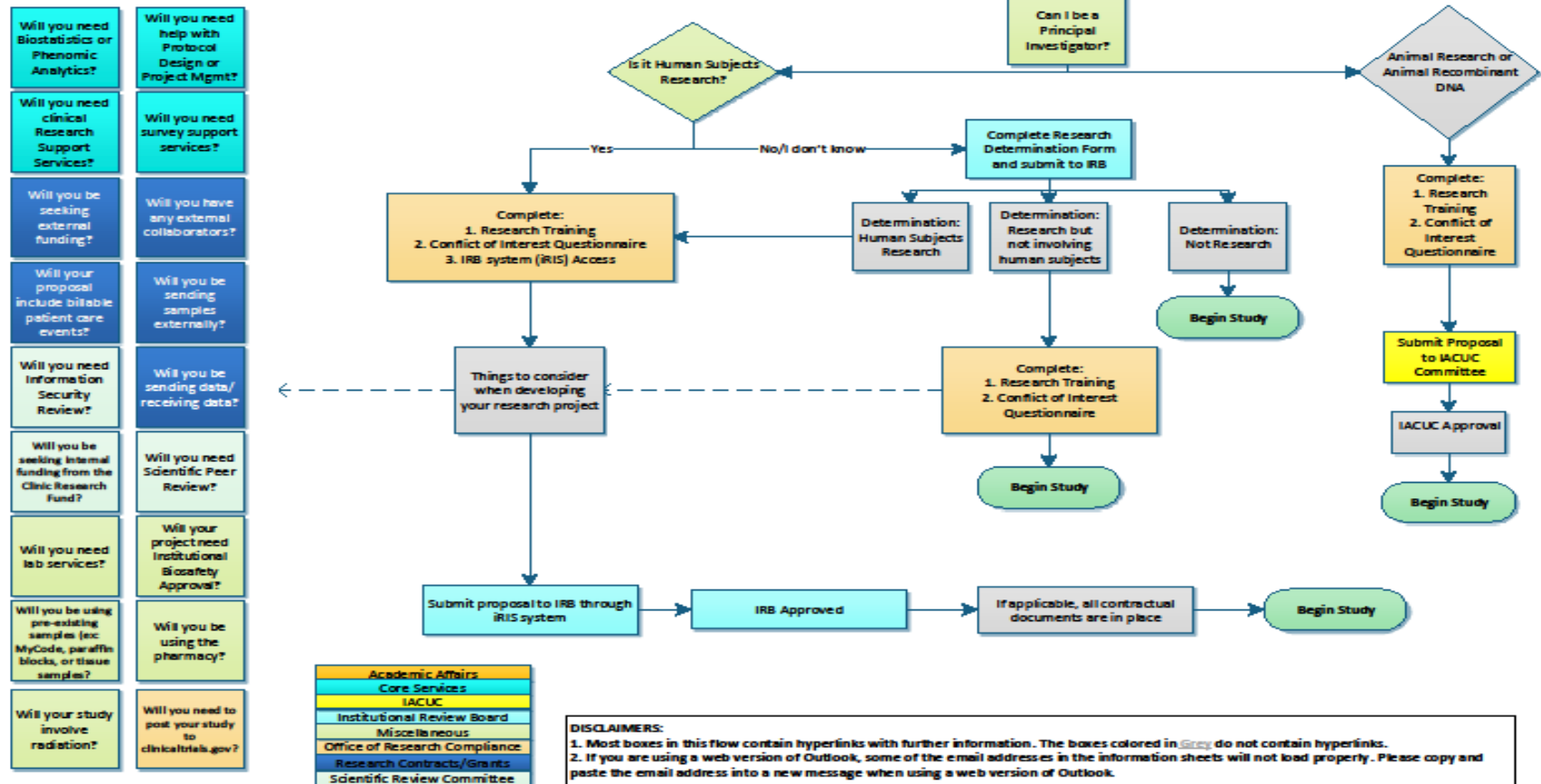


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TIPS FOR SUCCESSFUL IRB SUBMISSION

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

Geisinger Research Process Flow
https://spresearch/grant/resident/Visio%20Drawings/Flow_FINAL.pdf



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



Geisinger IRB

IRB Co-Chairs

- Tom Challman, MD
- Les Kirchner, PhD

HRPP Staff (570-271-8663)

- Barb Kent, Administrative Assistant
- Chuck Brightbill, MS, IRB Specialist
- Gissel Martinez, BS, IRB Specialist
- Rosa Sober, BS, CIP, IRB Manager
- Deb Henninger, MHSA RN CCRC, Associate Director



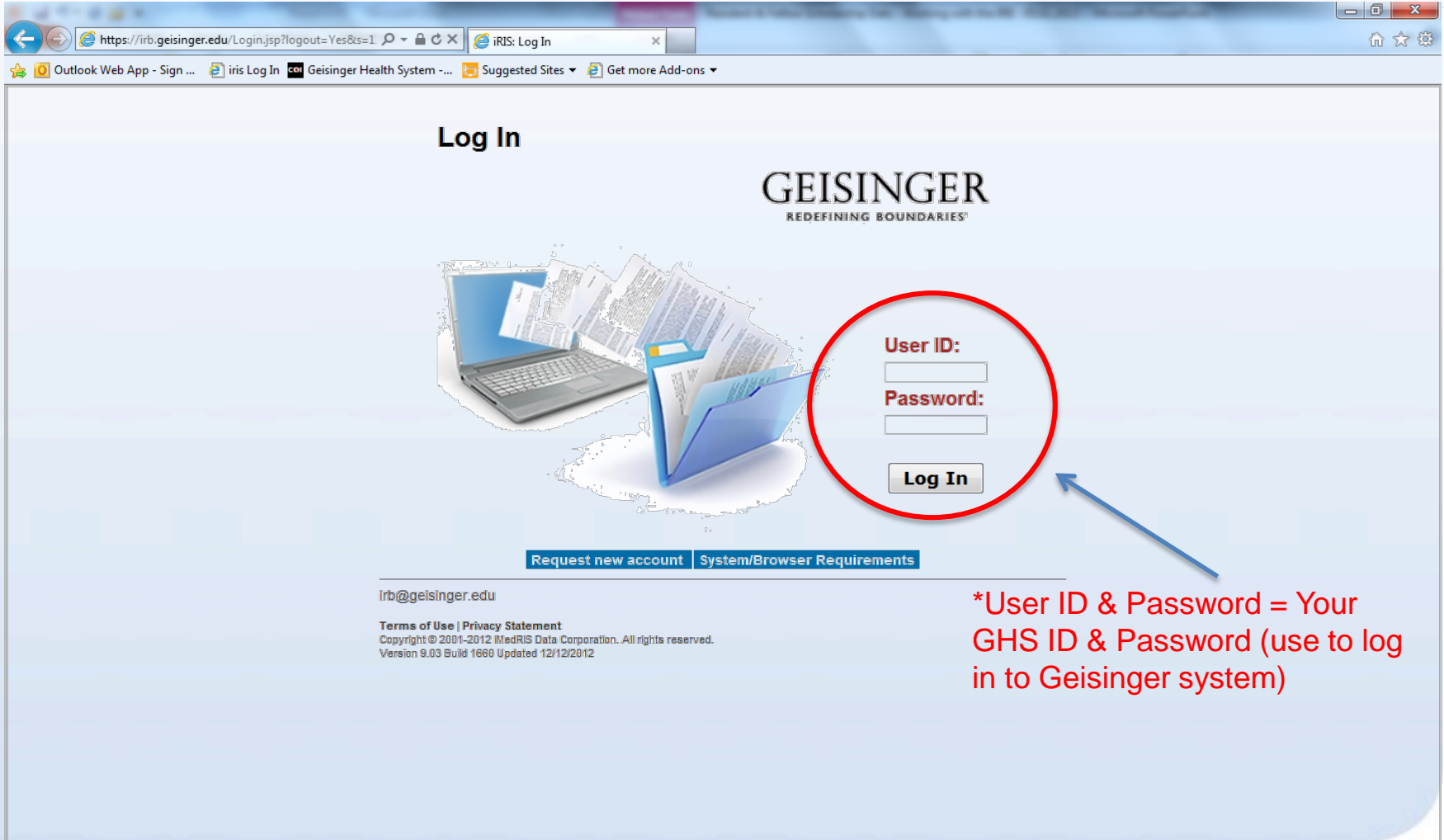
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IRIS

Integrated Research Information System

Electronic IRB Submission & Review

iRIS log-In <https://irb.geisinger.edu>



The screenshot shows a web browser window with the URL <https://irb.geisinger.edu/Login.jsp?logout=Yes&ts=1>. The page title is "iRIS: Log In". The main content area has a light blue background with the "Log In" heading and the "GEISINGER" logo with the tagline "REDEFINING BOUNDARIES". Below the logo is an illustration of a laptop and a folder. To the right of the illustration is a red circle containing the login fields: "User ID:" with a text input box, "Password:" with a password input box, and a "Log In" button. A blue arrow points from the bottom right towards the "Log In" button. Below the login fields are two links: "Request new account" and "System/Browser Requirements". At the bottom left, there is an email address "irb@geisinger.edu" and a "Terms of Use | Privacy Statement" link. Copyright information is also present: "Copyright © 2001-2012 iMedRIS Data Corporation. All rights reserved. Version 9.03 Build 1660 Updated 12/12/2012".

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

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

iRIS™ – My Assistant™

The screenshot shows the iRIS My Assistant web application. The browser address bar displays https://irb.geisinger.edu/Application_Main.jsp?tab=i. The page header includes the Geisinger logo with the tagline "REDEFINING BOUNDARIES", the user account "Debra L Henninger, RN, BSN, CCRC", and the department "GHS - Geisinger". Navigation links for Home, Logout, and Help are present. A left sidebar contains a menu with "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 shows the user's current department as "GHS - Geisinger" and their current review board as the "Institutional Review Board (IRB)". A "Worklist Filter" dropdown is set to "Internal Board Routing Signoff". Below this are four tabs: "Incomplete Tasks", "Complete Tasks", "Not Opened Correspondence", and "Previously Opened Correspondence". The "Incomplete Tasks" tab is active, displaying "No tasks found". The Geisinger logo and tagline are repeated in the background of the main content area, along with an illustration of a laptop and a folder.

iRIS™ – My Assistant™

IRIS - My Account - Windows Internet Explorer

File Edit View Favorites Tools Help

Account: Cathy A Betz
Department: GHS - 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:

Degree:

Gender:

Employee ID:

Specialty:

Relationship to the Institution: ☐ Affiliated ☐ Non-Affiliated

Affiliation:

Representational capacity: ☐ Scholar ☐ Non-Scholar

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:

Geisinger-Geisinger Department(s):

Geisinger

iRIS – My Assistant

Geisinger
REDEFINING BOUNDARIES®

Account: Debra L Henninger, RN, BSN, CCRC
Navigation: Home

Home Logout Help

Operating Procedures and Templates

[Back](#)

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 iRIS 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

iRIS™ – Study Assistant™ - Add a New Study

The screenshot displays the iRIS Study Assistant web application. The browser address bar shows the URL: https://irb.geisinger.edu/Application_Main.jsp?tab=i. The page header includes the GEISINGER logo and the tagline "REDEFINING BOUNDARIES". The user account information is displayed as: Account: Debra L Henninger, RN, BSN, CCRC; Department: GHS - Geisinger. The navigation sidebar on the left contains the following items: My Assistant, Study Assistant, Add a New Study (highlighted with a red circle and a red arrow), My Studies, Find a Study, My Appointments, Department Schedule, IRB Assistant, and System Administration. The main content area shows 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. Below this, there is a "Worklist Filter" dropdown menu set to "Internal Board Routing Signoff". A table with four tabs is visible: Incomplete Tasks, Complete Tasks, Not Opened Correspondence, and Previously Opened Correspondence. The "Incomplete Tasks" tab is selected, and the message "No tasks found" is displayed. The GEISINGER logo and tagline "REDEFINING BOUNDARIES" are also present in the main content area. At the bottom of the main content area, there is an illustration of a laptop and a folder with documents.

iRIS™ – Study Assistant™ - Study Application

Geisinger
REDEFINING BOUNDARIES®

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

Home Logout Help

Study Application

Back

Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information

* Please enter the full title of your study:

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* Please enter a short descriptor that you would like to use to reference the study:

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* 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?

-none--		
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