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The Research process:

From idea to approval

Rosa Sober, BS, CIP
IRB Manager

Deb Henninger, MHSA RN CCRC
Associate Director, Office of Research 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
• Study Staff IRB Requirements • Conflict of Interest – COI • Human Research Education CITI	• IRB Fees • IRB 2016 Submission Deadlines and Meeting • Staff listing
Applying to the IRB via iRIS	**Guides to Initiate Your Research**
• Click here to access iRIS • iRIS Site Access Request Form • IRB submission checklist	• Geisinger Research Process Flow • Geisinger's Research Process Presentations
Forms / Templates	**The Consent Process**
• Forms/Templates/Miscellaneous • Patient IRS W-9 Inform Sheet • Memo-IRB Letters No Signature	• Consent Authorization Temple • Consent for Continued Participation in COG Research • Consent for Patients Unable to Sign
Compliance Information	**Manual / Policies / Guidance**
• FWA - IRB Membership • Institutional Official • Federal Policies and Guidance • GHS HRPP GCP Compliance Information	• HRPP Handbook • HRPP Guidance Documents • HRPP SOPs • Research Policy Manual
FAQs / Presentations / Updates	**HRPP Components**
• FAQs • Helpful Presentations • HRPP Update Archives	• Ancillary Research Committees • Office of Research Compliance • Office of Sponsored Projects

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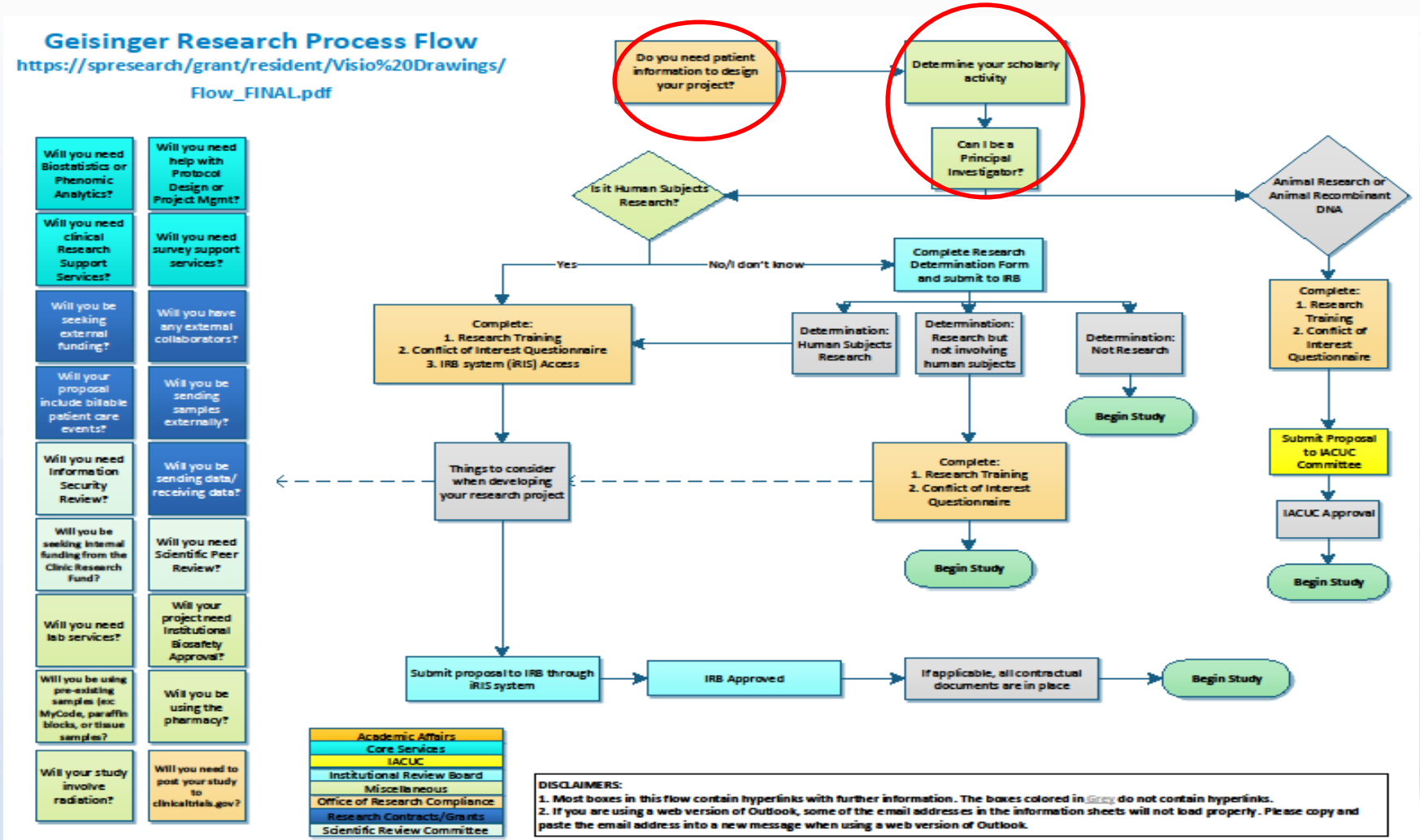
Geisinger Research Process



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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

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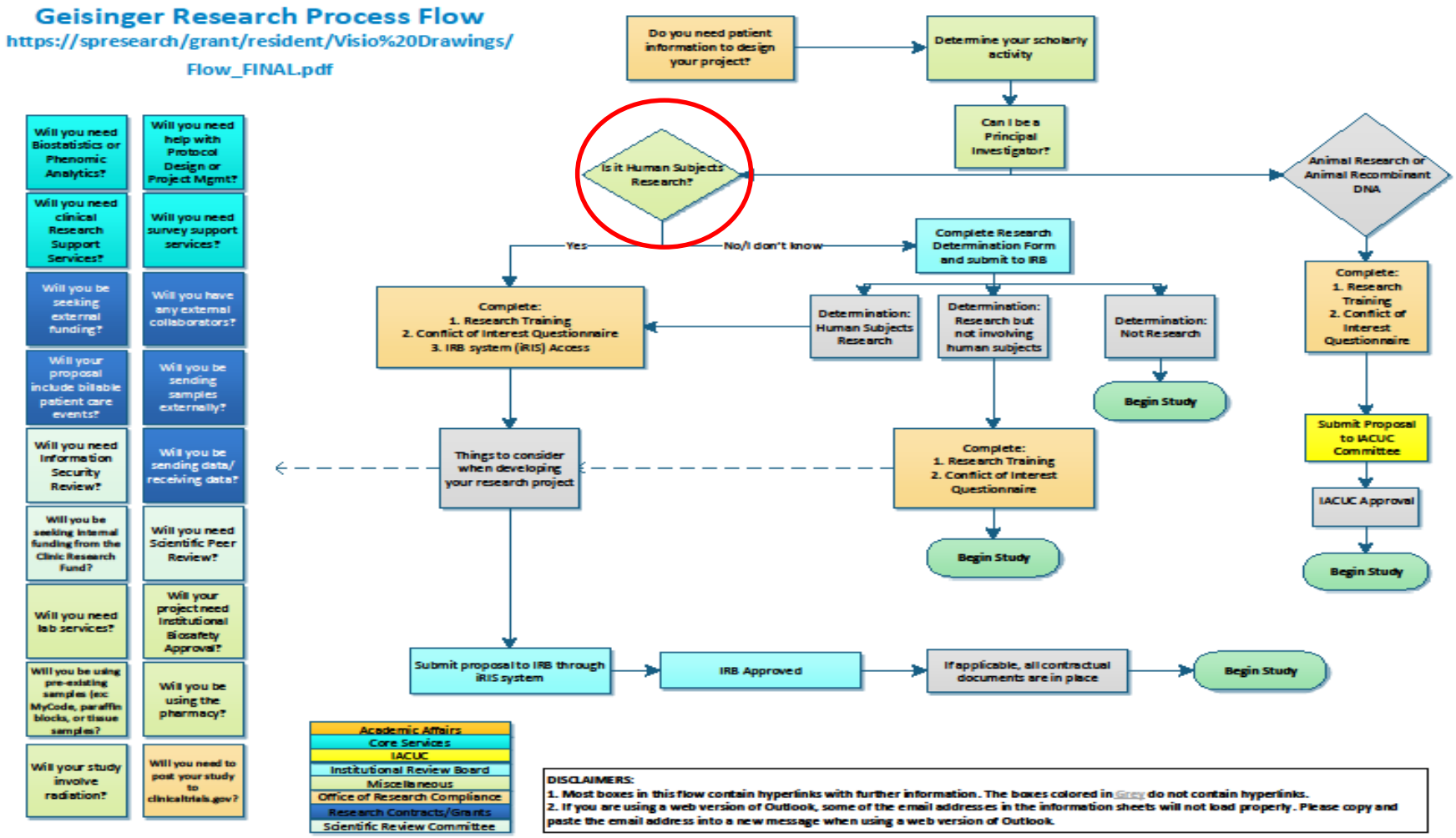
Preparatory to Research (PTR)

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 ?

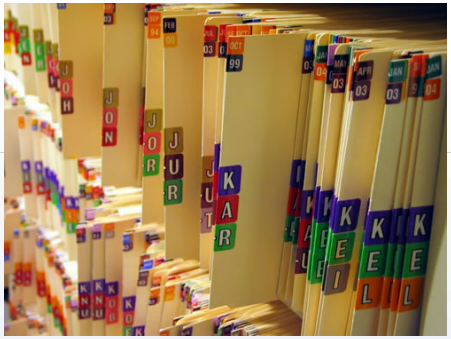
Research

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

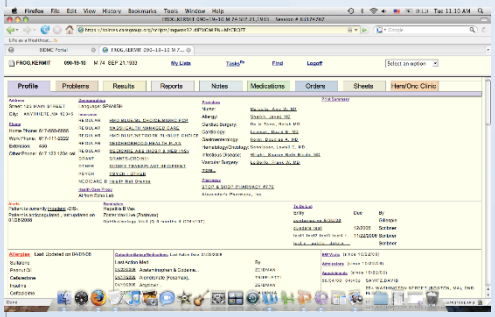
“Systematic Investigation … Designed To”

- 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


Survey
Very Satisfied
Satisfied
Neutral
Unsatisfied
Very Unsatisfied




QUESTIONNAIRE
Very often
Often
Sometimes
Rarely



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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

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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

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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

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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)"

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“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 numbes
•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

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“NOT” identifiable, private information

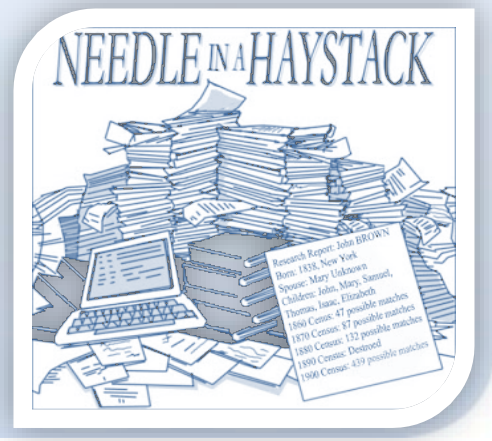
Data is considered public information

- 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



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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"

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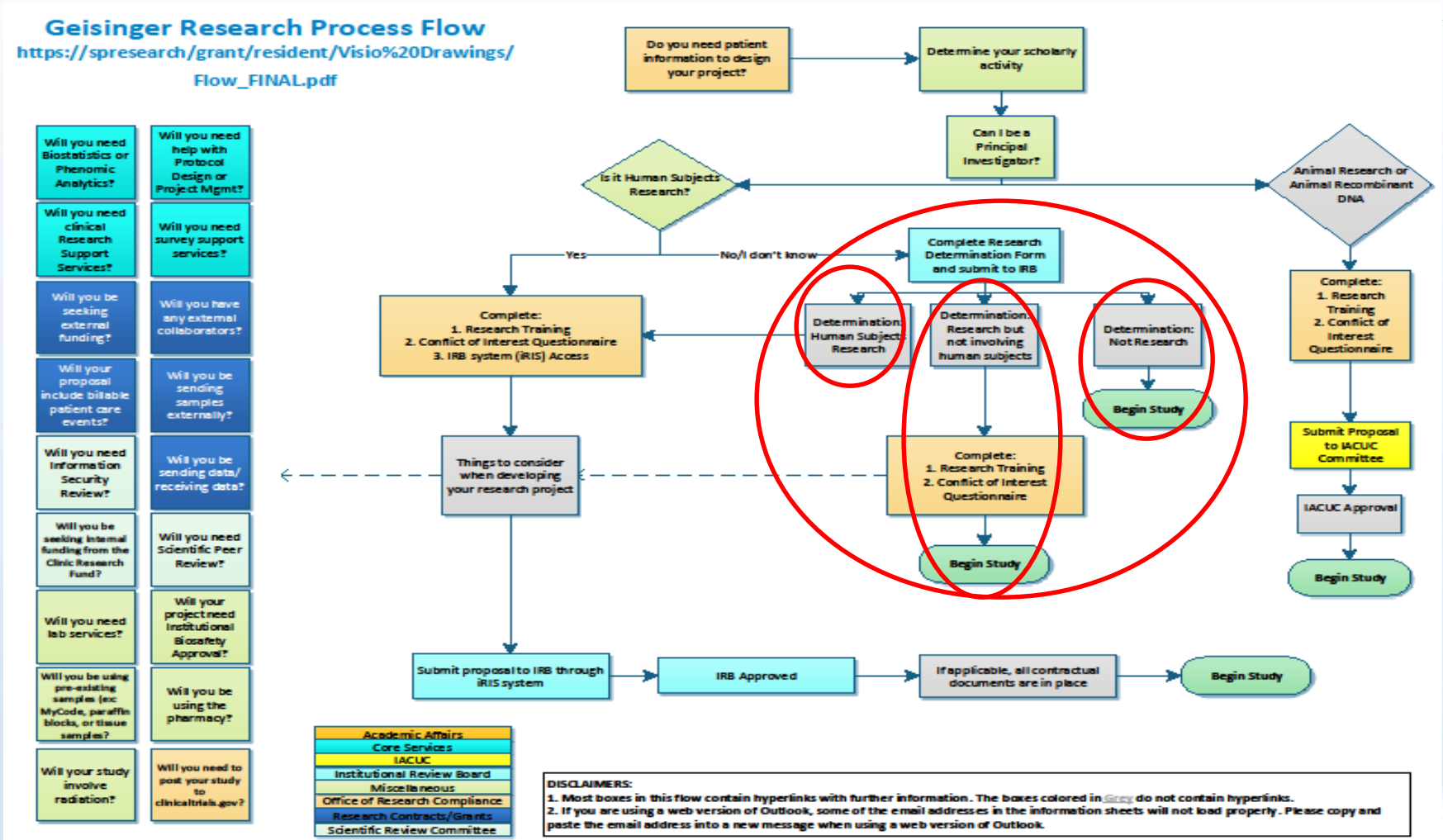
Research determination worksheet



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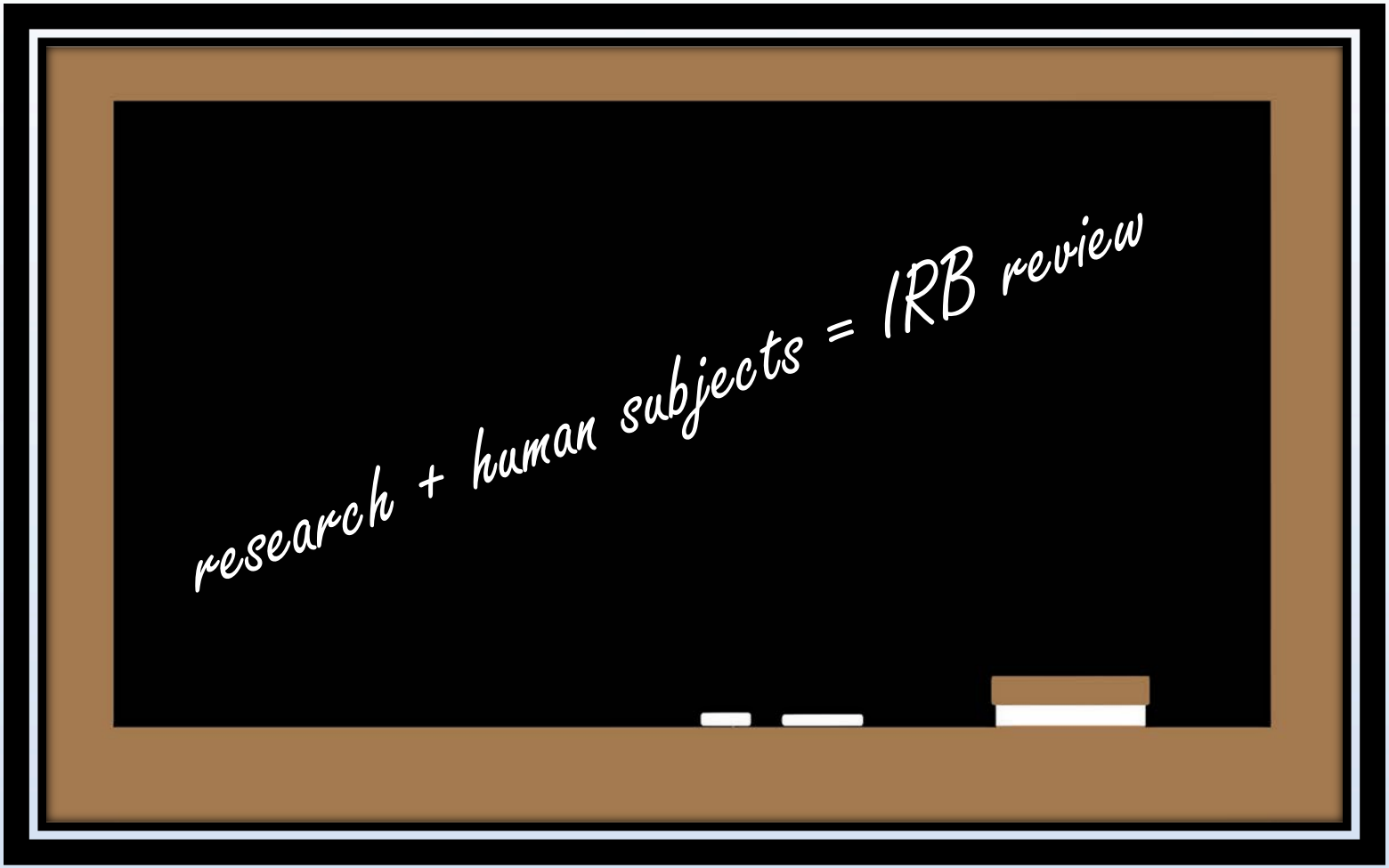

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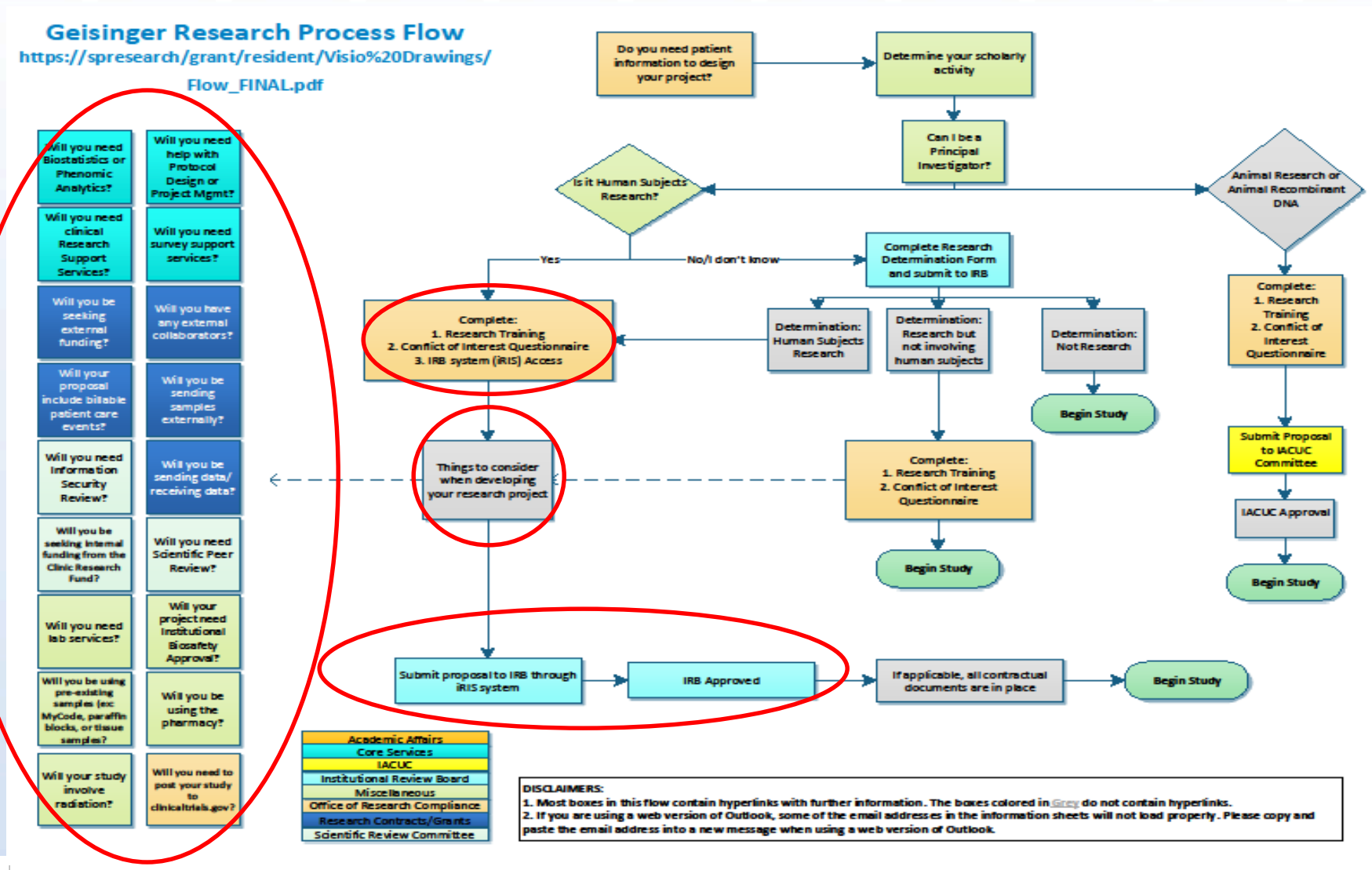
Research determination worksheet



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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.)

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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)

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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)

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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

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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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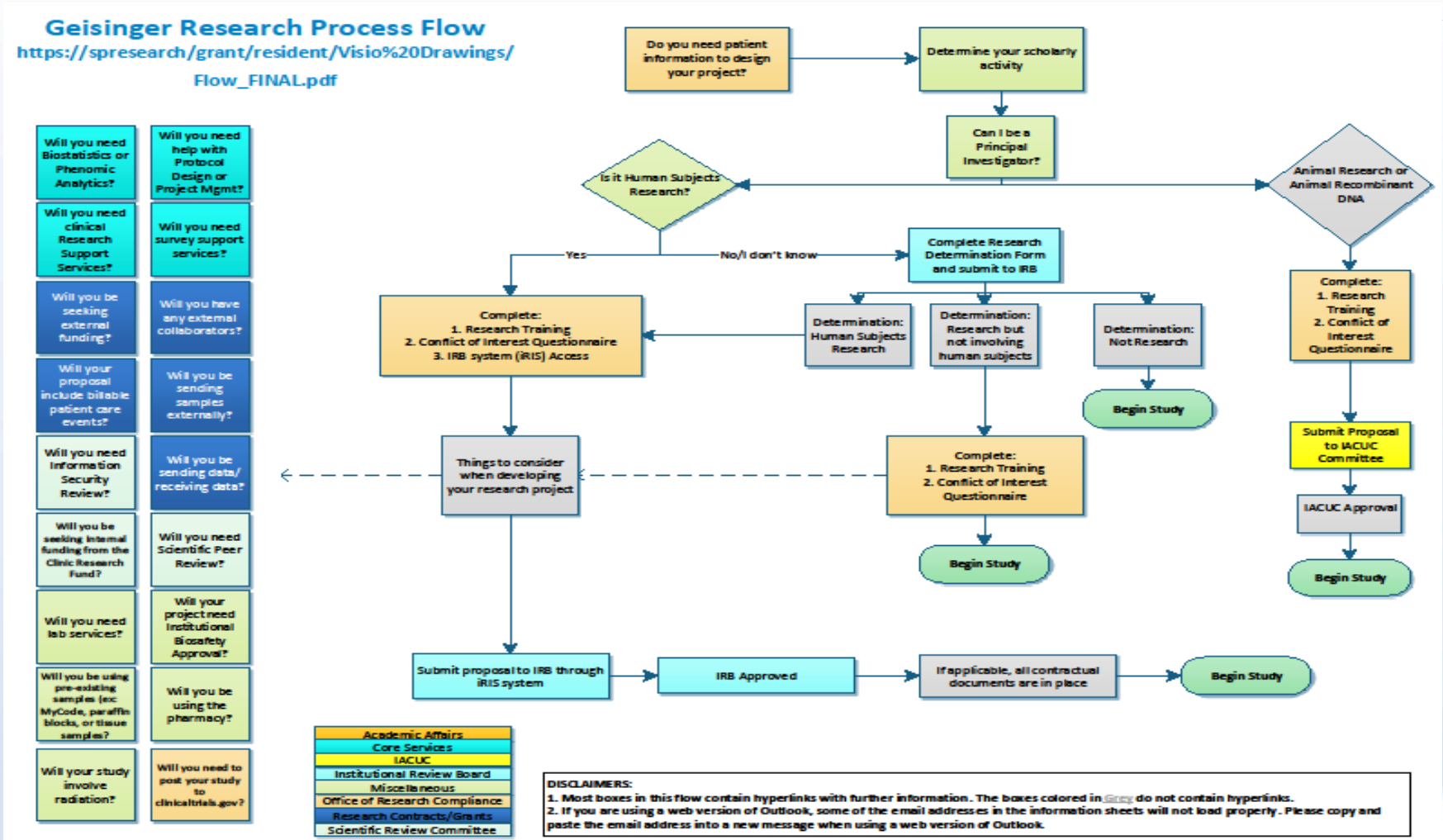
TIPS FOR SUCCESSFUL IRB SUBMISSION

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



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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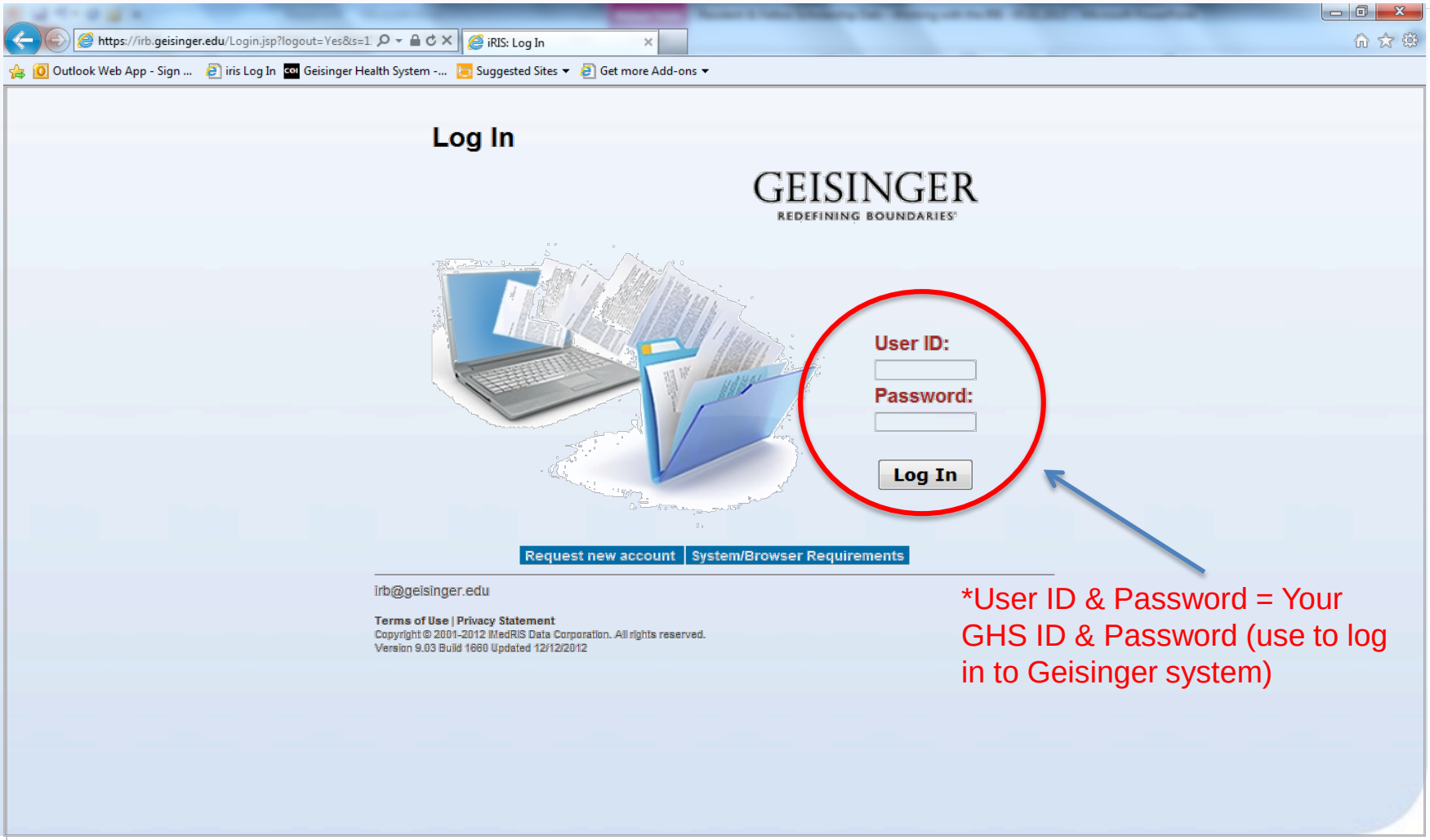
IRIS

Integrated Research Information System

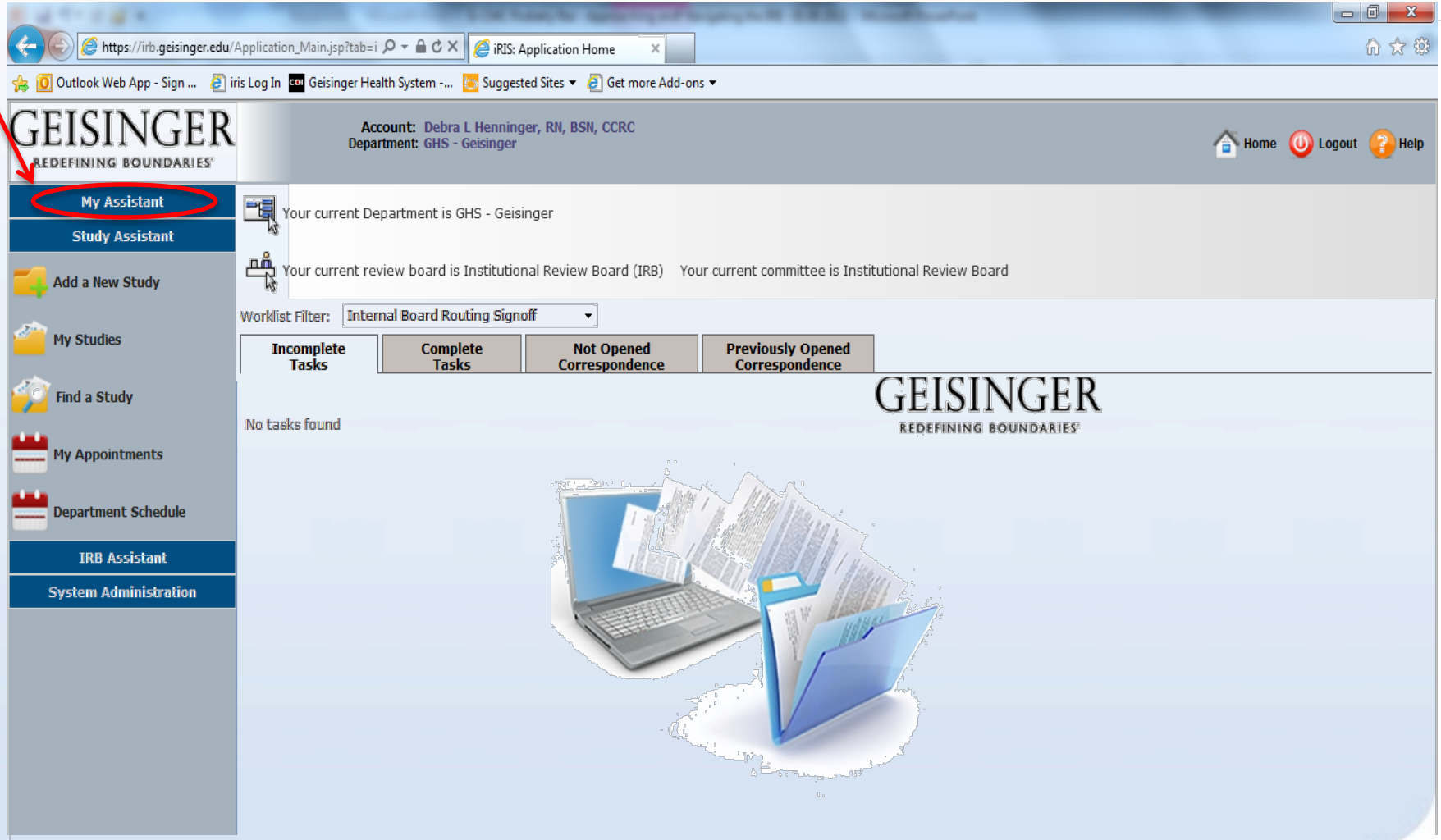
Electronic IRB Submission & Review

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



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

iRIS™ – My Assistant ™



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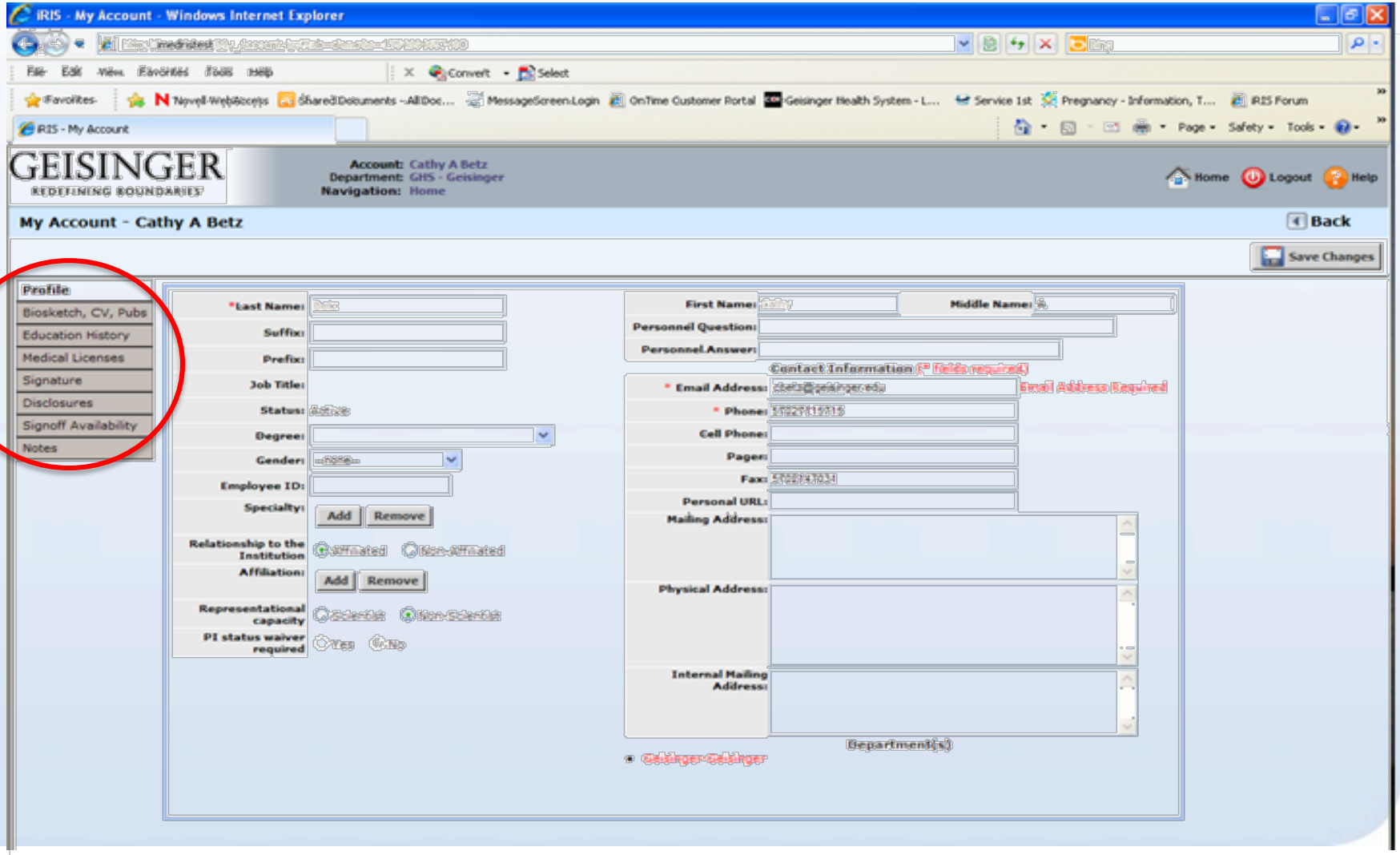
iRIS™ – My Assistant ™



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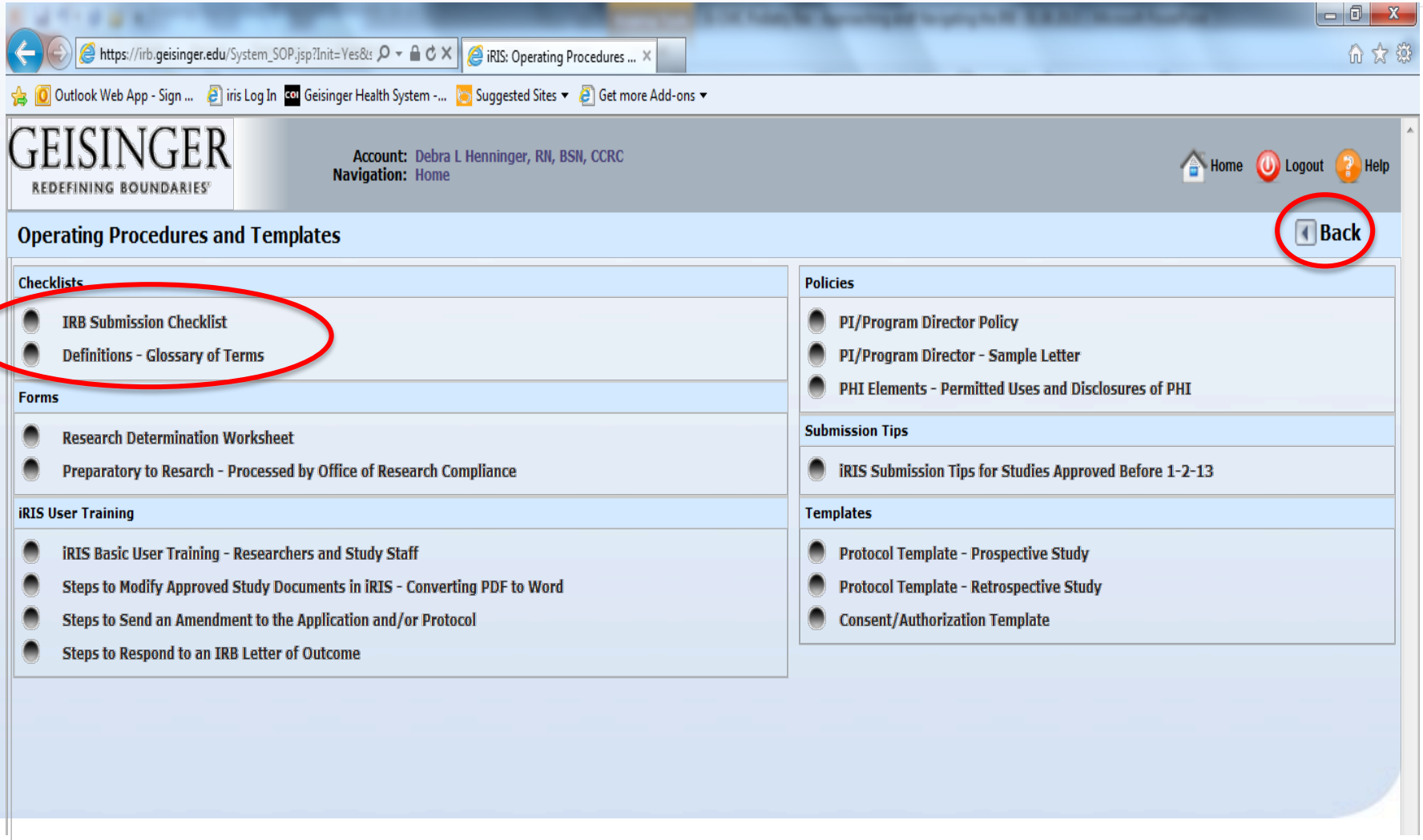
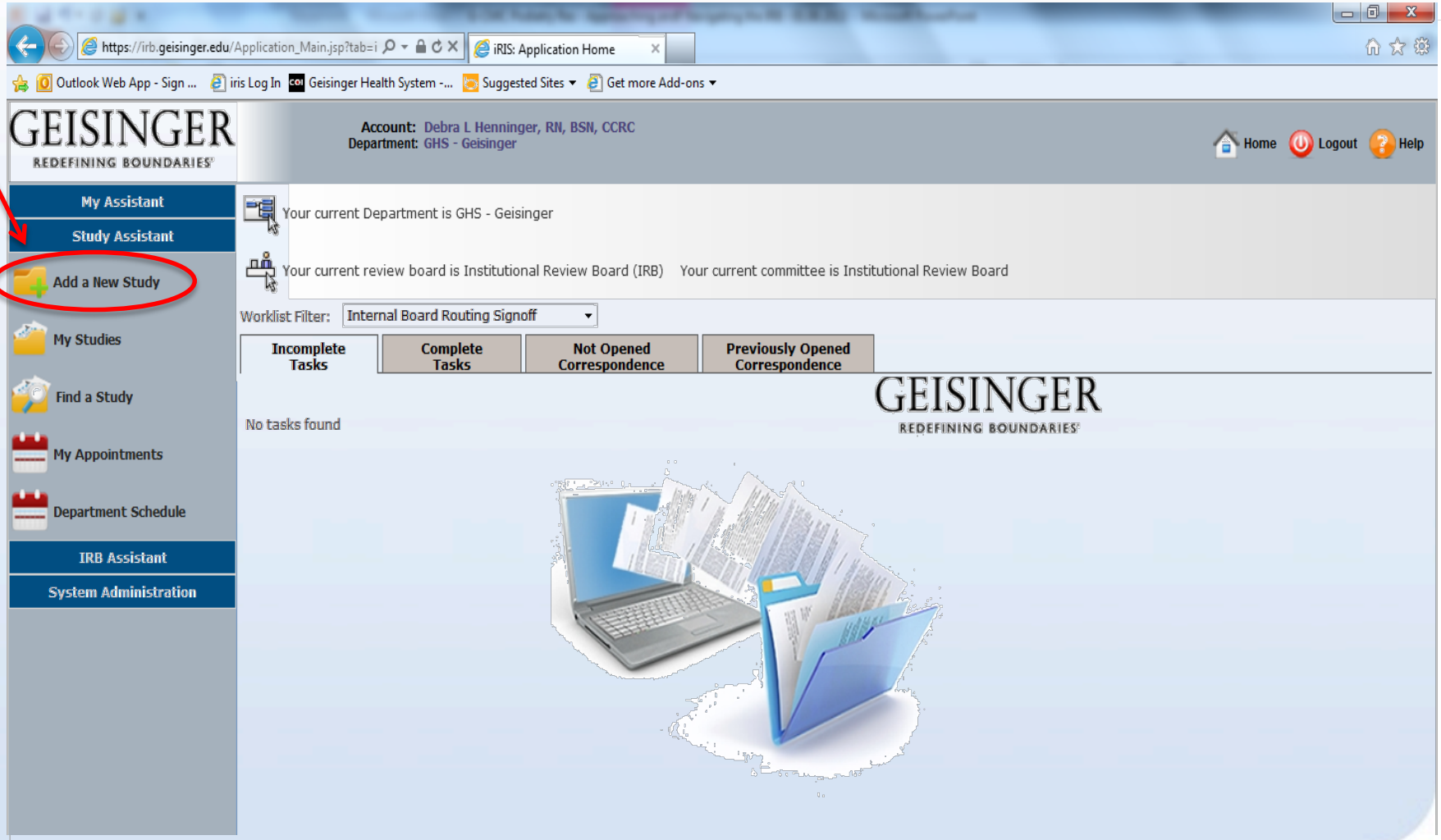
iRIS – My Assistant



iRIS™ – Study Assistant ™ - Add a New Study



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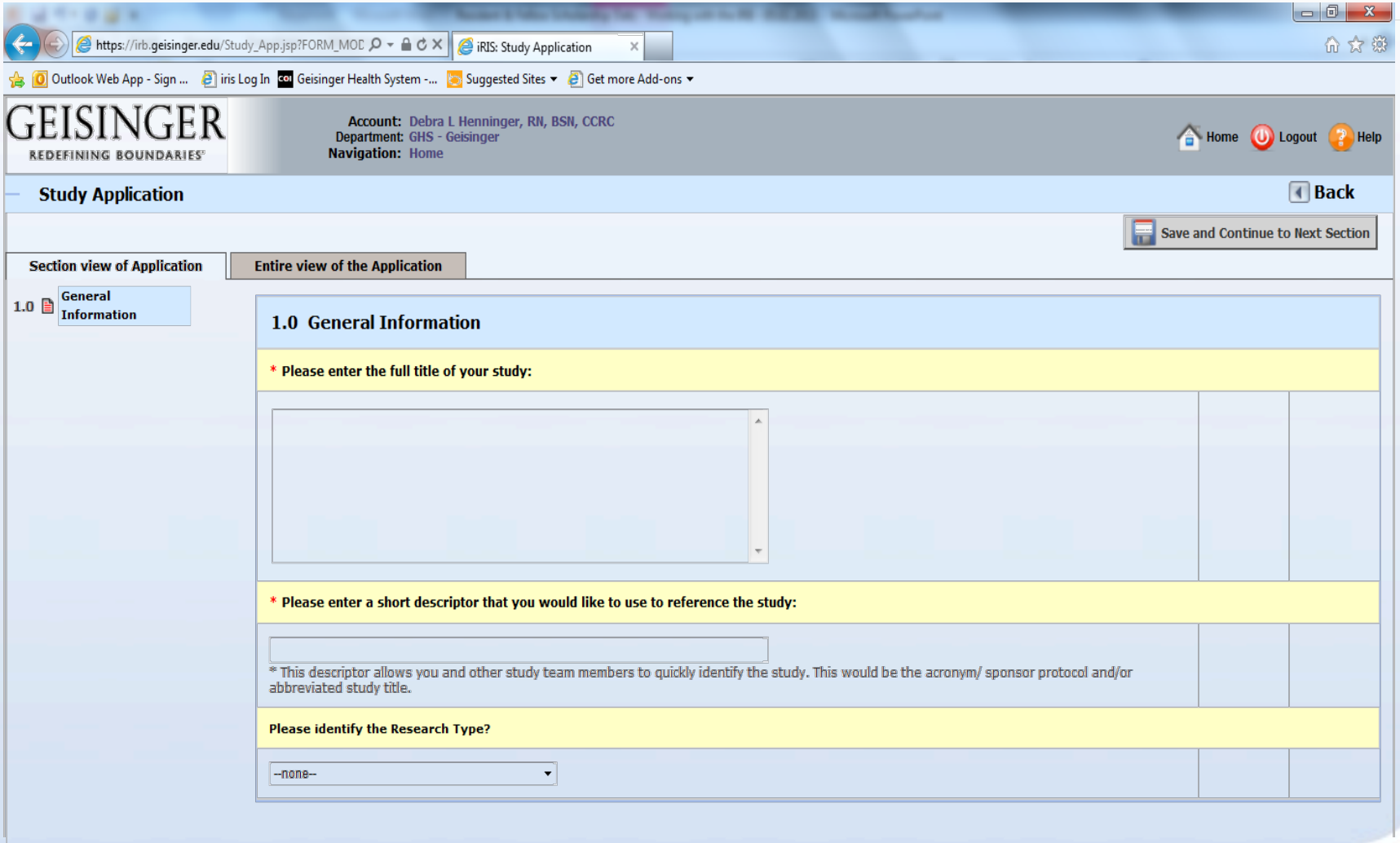
iRIS™ – Study Assistant ™ - Study Application



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