Introduction to Geisinger's Research Process

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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).**

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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 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

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:

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

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Use and Disclosure Requirements

Agreements required to **disclose** identifiable data:

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

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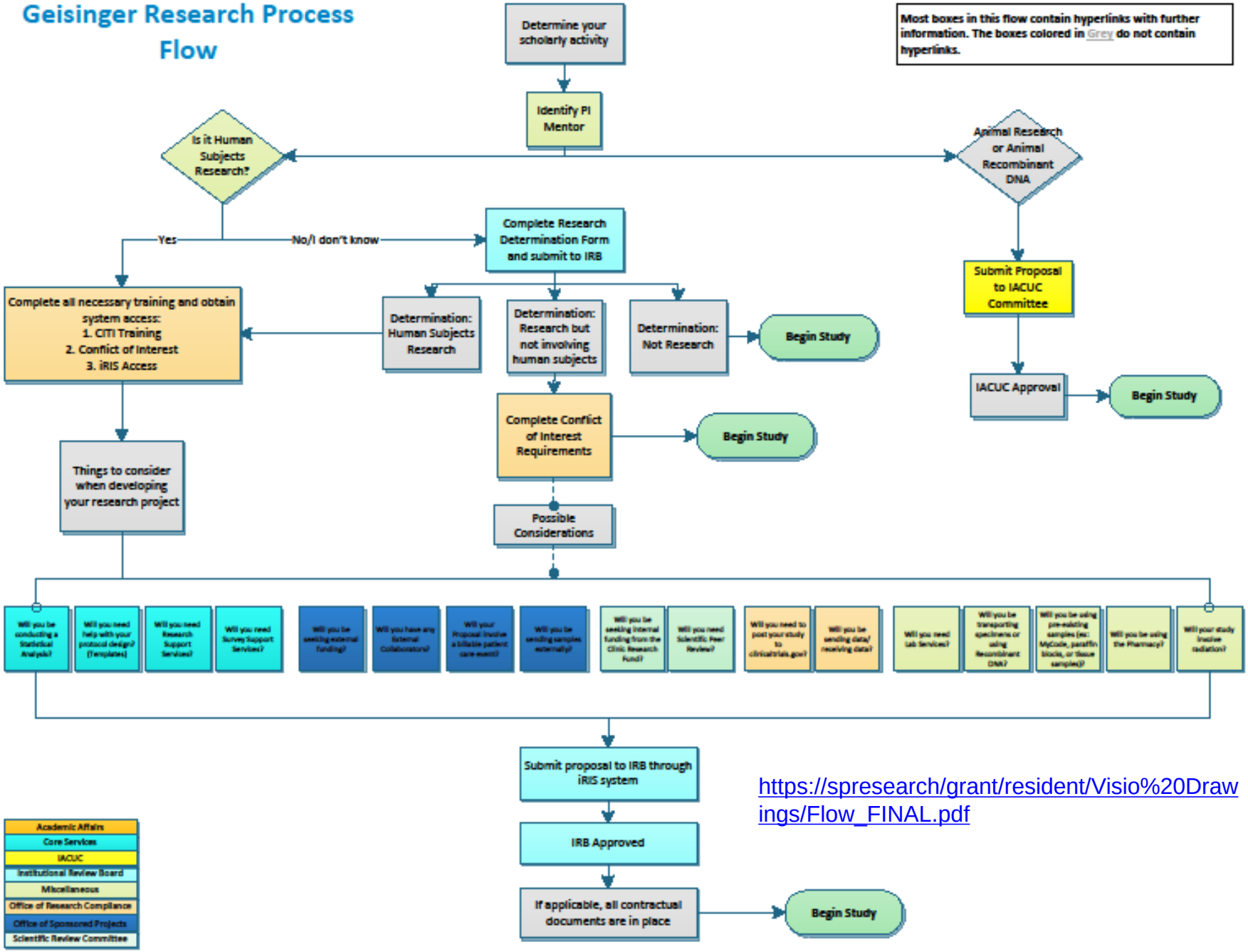
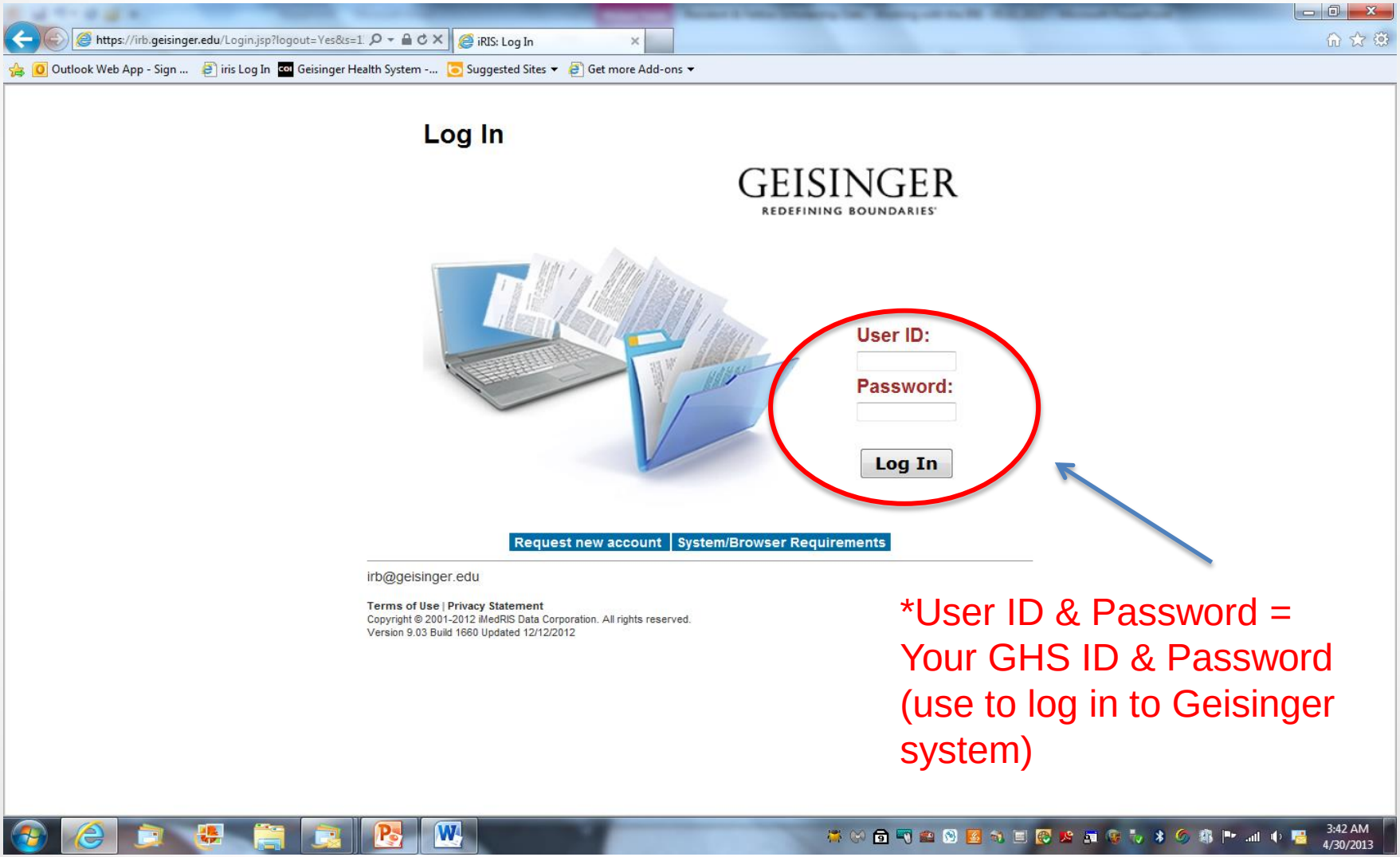
Geisinger Research Process Flow



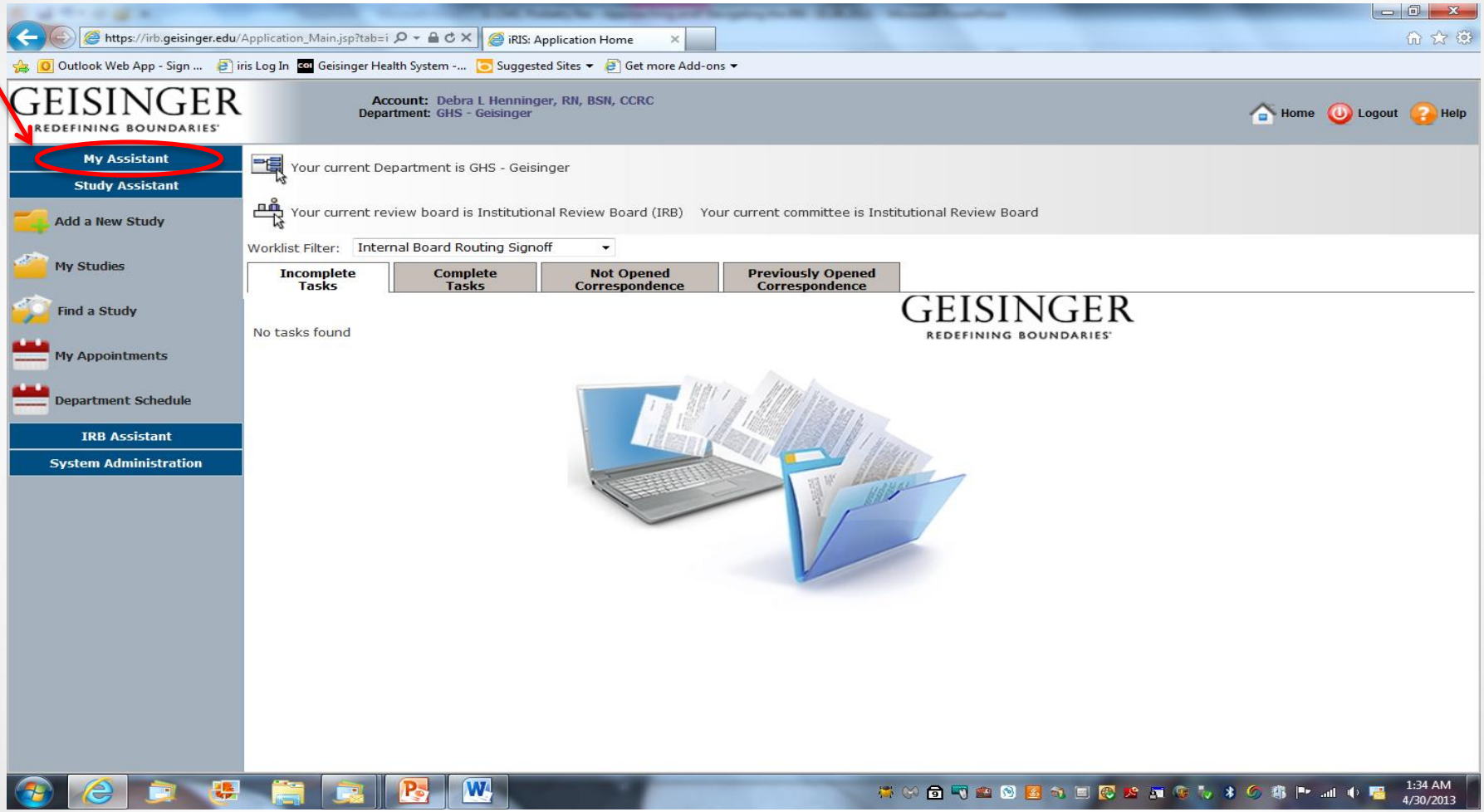
https://spresearch/grant/resident/Visio%20Drawings/Flow_FINAL.pdf

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

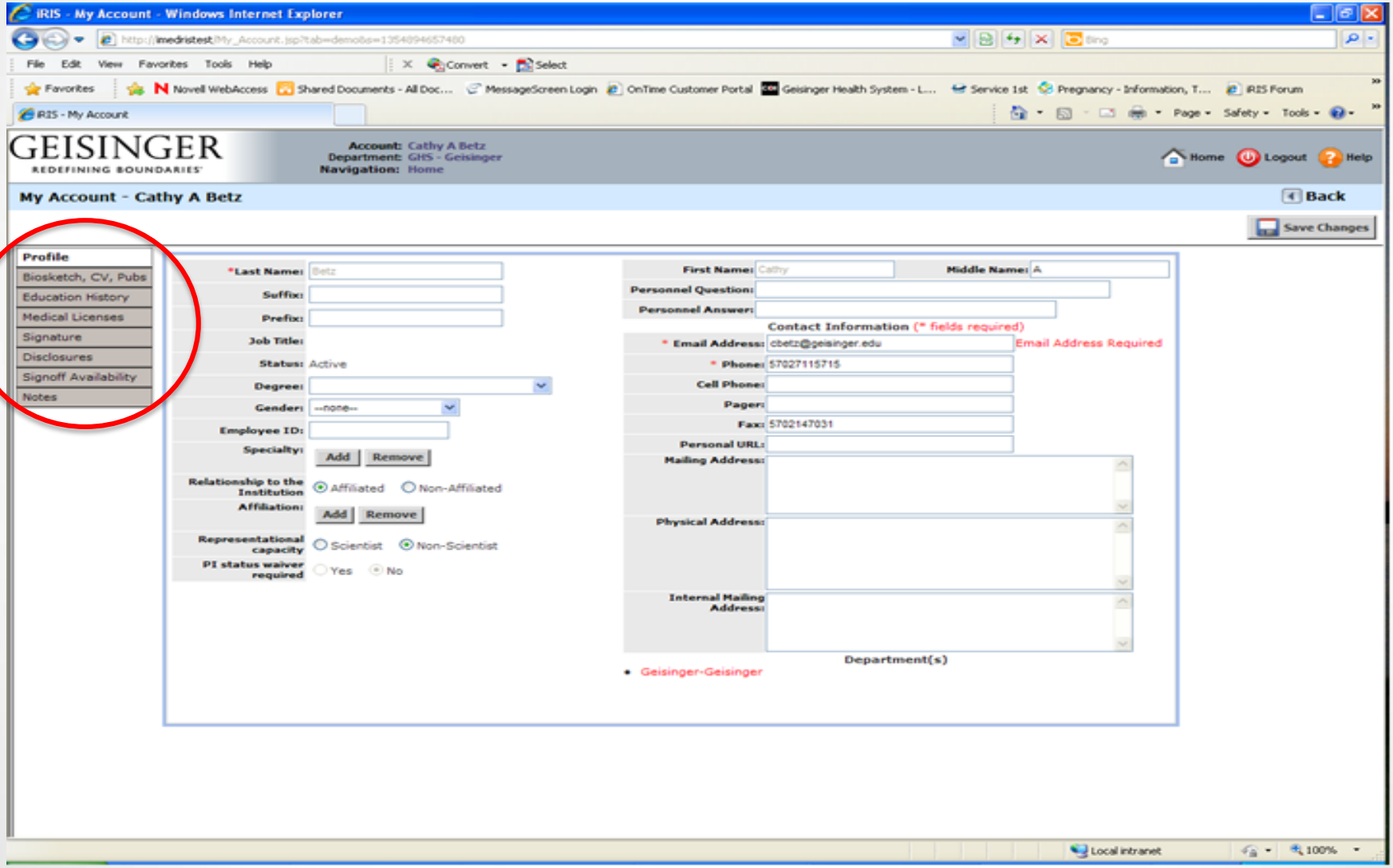


*User ID & Password = Your GHS ID & Password (use to log in to Geisinger system)

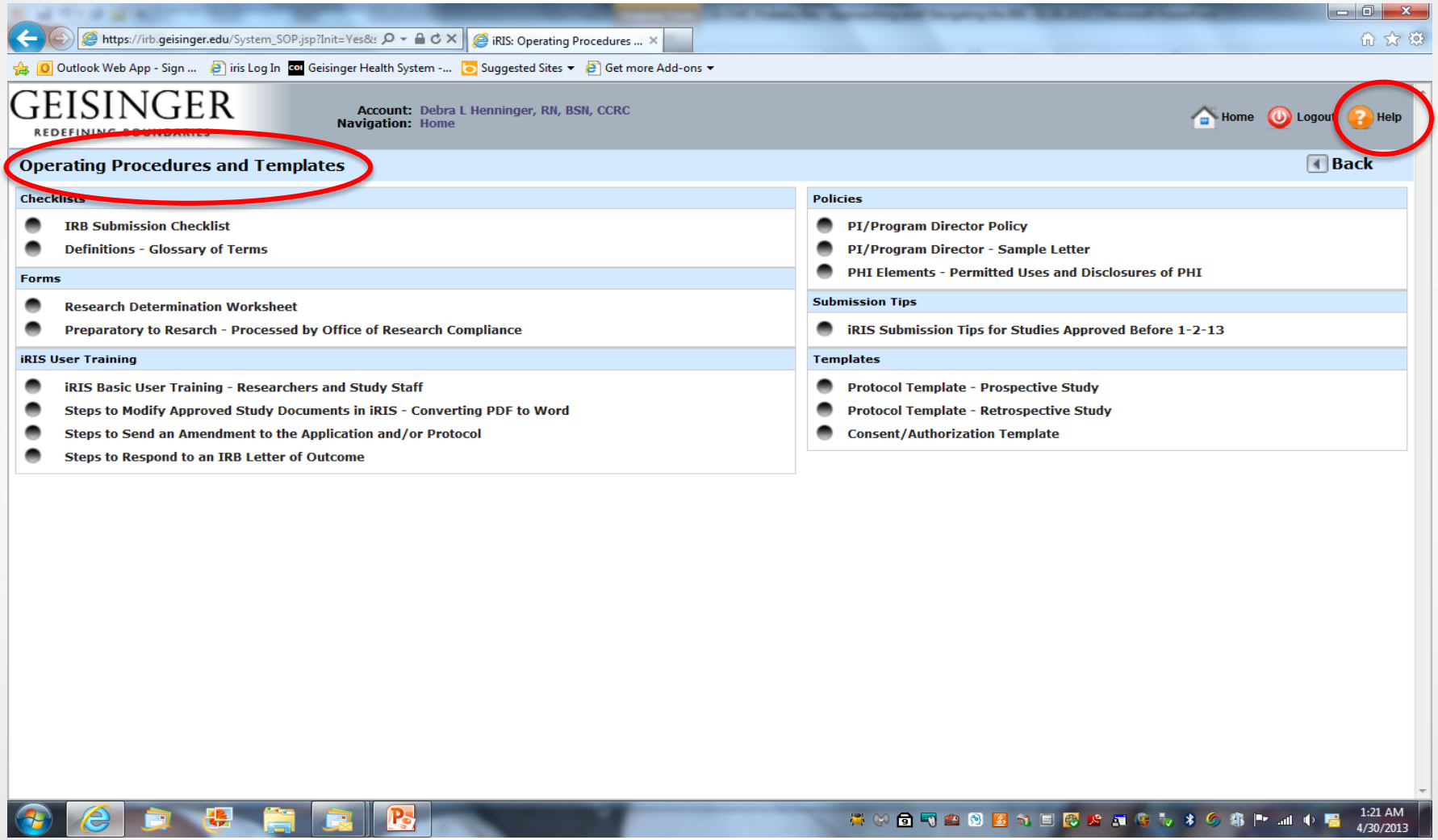
iRIS™ – My Assistant ™



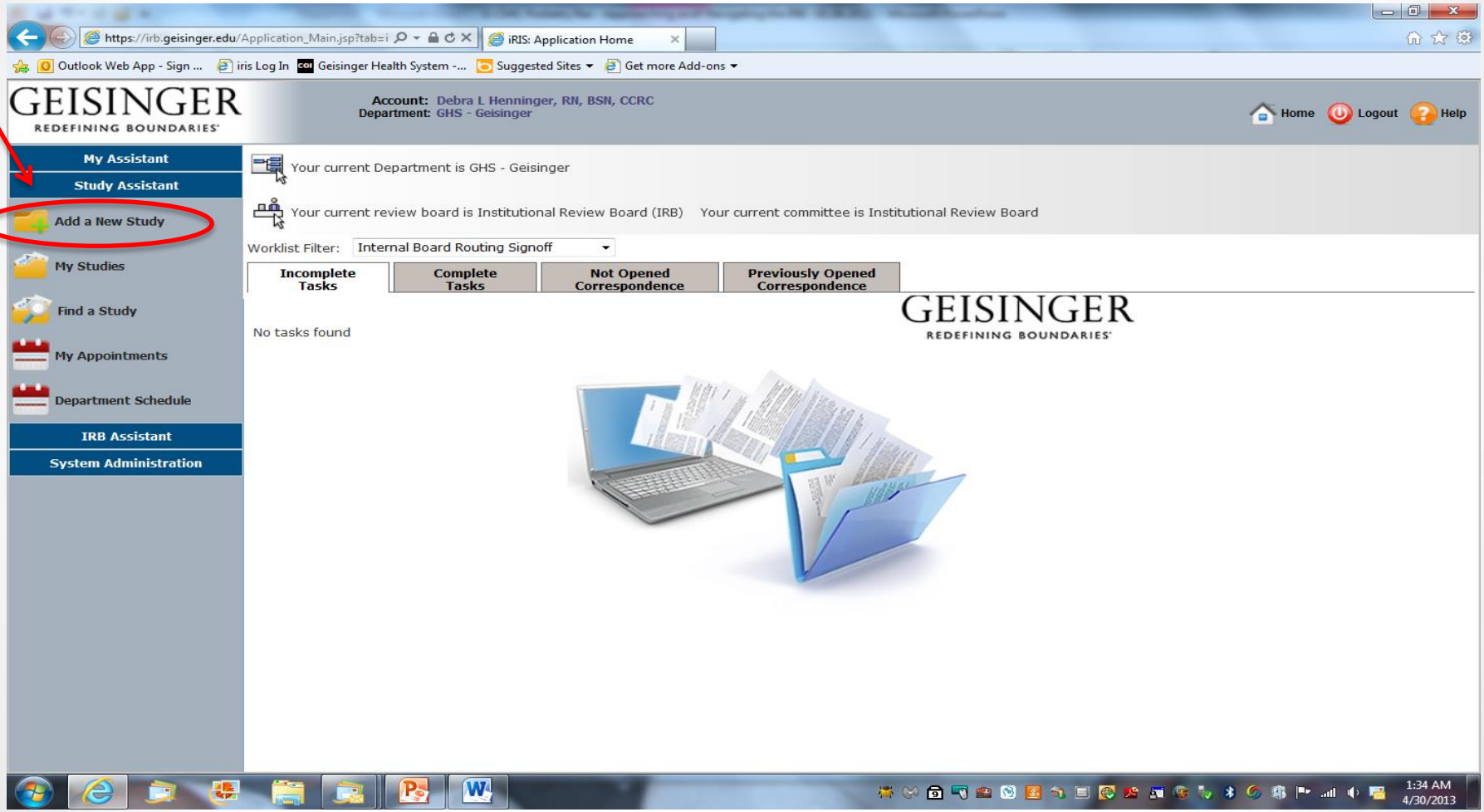
iRIS™ – My Assistant ™



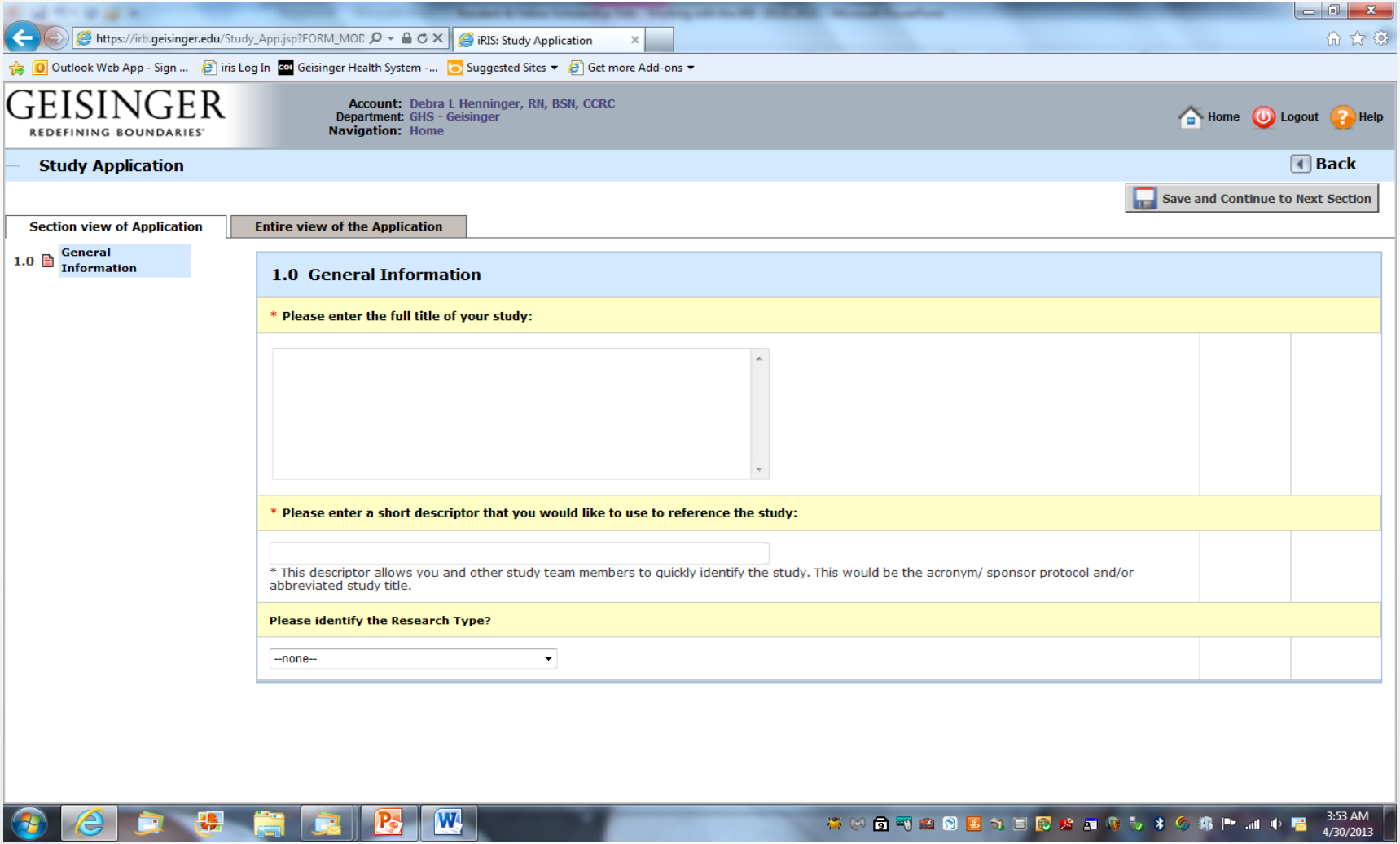
iRIS – My Assistant



iRIS™ – Study Assistant ™ - Add a New Study



iRIS™ – Study Assistant ™ - Study Application



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 ≥110 pounds)
   (a) Draw ≤ 550 ml / 8 week period and
   (b) 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.
   a) Draw ≤ 50 ml or 3 ml per kg in an 8 week period and
   b) 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
    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