HUMAN SUBJECTS RESEARCH …

REVIEW & APPLICATION

IRB Training

October 22, 2015

RESEARCH DETERMINATION

IS IT RESEARCH?

Research Determination

Determination of whether the activity involves Research

- Is it clinical care?
- Is it quality improvement?
- Is it program evaluation?
- Is it research?

Submission of a Research Determination Worksheet (RDW) to IRB

- Administratively review and make final determination

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"?

Living individual about whom an investigator conducting research obtains:

- **Data/samples** through intervention or interaction with individual;
- **Identifiable private information**

EXEMPT REVIEW

WHAT IS “EXEMPT”?

- **IRB**
  - Initial review
  - No ongoing oversight

- **Proposed Research**
  - Minimal Risk

    And
  - Fit one or more of the exempt categories

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

WHAT QUALIFIES AS “EXPEDITED”?

- **IRB**
  - Initial review
  - Ongoing oversight with annual review

- **Proposed Research**
  - Minimal Risk

    And
  - Fit one or more of the expedited categories

CATEGORIES OF RESEARCH THAT MAY QUALIFY FOR EXPEDITED REVIEW:

(1) Clinical studies of drugs and medical devices only when (a) **or** (b) is met.

(1) 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

CONVENED REVIEW

REVIEW AT CONVENED MEETING?

- Greater than minimal risk
- Minimal risk but does not qualify under categories of exempt or expedited
- IRB reviewer defers to full committee review

CEDING REVIEW

CEDE IRB OVERSIGHT TO ANOTHER IRB?

- Administrative review
- IRB Authorization Agreement (IAA)
- IRB responsible for HIPAA – Auth or Waiver
- Geisinger responsible for investigator compliance
- New Ceded Application in iRIS

IRB APPROVAL CRITERIA

1) Risks to subjects are minimized

2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3) Selection of subjects is equitable

4) Informed consent will be sought

5) Informed consent will be appropriately documented

APPROVAL CRITERIA

1) Adequate provision for monitoring the data collected to ensure the safety of subjects

2) Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

3) Additional safeguards are included in the study to protect the rights and welfare of vulnerable subjects

ADDITIONAL CRITERIA (WHEN APPLICABLE)

INFORMATION TO REVIEW

- Purpose
- Background
- Setting
- Resources available
- Recruitment
- Risks to subjects
- Potential benefits to subjects
- Provisions to protect privacy interests of subjects
- Provisions to maintain confidentiality of data
- Inclusion/exclusion criteria
- Procedures
- Provisions to monitor data to ensure the safety of subjects
- Consent process
- Process to document consent
- Additional protections for vulnerable populations

- IRB Submission … Minimize requirements
  - Protocol
  - Study Application

GROUP EXERCISE