INITIAL REVIEW

RESEARCH INVOLVING HUMAN

DEFINITION OF RESEARCH

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

DEFINITION OF HUMAN

- a living individual about whom an investigator conducting research obtains
- Data through intervention or interaction with the individual, or
- Identifiable private information.

DEFINITION OF INTERVENTION

- includes both physical procedures by which data are gathered (for example, venipuncture) and
- manipulations of the subject or the subject's environment that are performed for research purposes.

DEFINITION OF INTERACTION

- includes communication or
- interpersonal contact between investigator and subject.

PRIVATE INFORMATION

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

IRB REVIEW

- IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities.
- IRB shall require that information given to subjects would meaningfully add to the protection of the rights and welfare of subjects.

IRB REVIEW (CONT.)

- IRB shall require documentation of informed consent or may waive documentation.
- IRB shall notify investigators and the institution in writing of its decision.
- If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

INITIAL REVIEW

- New protocol submission
- Materials

TYPE OF INITIAL REVIEW

- Exemption - Insignificant risk
- Expedited – Minimal risk
- Full Board – More than minimal risk

EXEMPTION

EDUCATIONAL RESEARCH

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
  - (i) research on regular and special education instructional strategies, or
  - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

SURVEY, INTERVIEW, OBSERVATION

- Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures**, **interview procedures** or **observation of public behavior**, unless:

- No identified, directly or through identifiers linked to the subjects; and
- Not place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

EXISTING MATERIAL

- Data, documents, records, pathological specimens, or diagnostic specimens, if:
  - publicly available or
  - if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

SERVICE PROGRAM

- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - (i) Public benefit or service programs;
  - (ii) procedures for obtaining benefits or services;
  - (iii) possible changes in or alternatives to those programs or procedures; or
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs.

FOOD

- Taste and food quality evaluation and consumer acceptance studies,
  - (i) without additives or
  - (ii) contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXEMPTION CANNOT APPLY

- prisoner
- children involving survey or interview procedures or observation of public behavior, except
  - observations of public behavior when the investigator(s) do not participate in the activities being observed.

EXPEDITED REVIEW

EXPEDITED REVIEW*

- (1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
- (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

**45 CFR 46.110*

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.

EXAMPLE

- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a) from healthy, nonpregnant adults who weigh at least 110 pounds - ≯ 550 ml in an 8 week period and collection ≯ 2 times per week; or
  - b) from other adults and children ≯50 ml or 3 ml per kg in an 8 week period and collection ≯ 2 times per week.

EXAMPLE

- Prospective collection of biological specimens by noninvasive means
  - (a) hair and nail clippings in a non-disfiguring manner;
  - (b) deciduous teeth at time of exfoliation or routine patient care
  - (c) permanent teeth indicates a need for extraction;
  - (d) excreta and external secretions (including sweat);
  - (e) uncannulated saliva (either unstimulated or stimulated) nebulization.

EXAMPLE

- Prospective collection of biological specimens by noninvasive means
- (f) placenta removed at delivery;
- (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- (h) supra- and subgingival dental plaque and calculus;
- (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- (j) sputum collected after saline mist nebulization.

EXAMPLE

- Collection of data through noninvasive procedures (not involving general anesthesia or sedation)

routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

- a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’ s privacy;
- (b) weighing or testing sensory acuity;

EXAMPLE

- (c) magnetic resonance imaging;
- (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

EXAMPLE

- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Collection of data from voice, video, digital, or image recordings made for research purposes

CRITERIA FOR IRB APPROVAL

(1) Risks to subjects are minimized.

(2) Risks to subjects are reasonable in relation to anticipated benefits.

(3) Selection of subjects is equitable.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

FULL BOARD REVIEW

- Quorum was made.
  - ≥5 members
    - diversity of race, gender, culture
    - at least one physician, one non-scientific, one non-affiliated member
- No COI member participate in voting

DECISION MAKING

- By majority vote or consensus
  - approve/approvable
  - require modification before approve
  - reconsideration/table
  - disapprove

EXERCISE

- โครงการวิจัยหนึ่งเป็นการศึกษาปัจจัยที่มีผลต่อระดับของไอโอดีนในปัสสาวะของหญิงตั้งครรภ์ ผู้วิจัยจะขอเก็บปัสสาวะจำนวน 50 ml 1 ครั้ง และให้อาสาสมัครตอบแบบสอบถามเกี่ยวกับการรับประทานอาหารระหว่างการตั้งครรภ์ จำนวนอาสาสมัครทั้งหมด 200 คนจาก รพ. มหาวิทยาลัยและ รพ. ศูนย์ แห่งละเท่าๆกัน