What is your Acronym IQ?

- ASC
- DOC
- DOS
- FYS
- SACS
- NEH
- NIH
- OSHA
- IRB
- TGIF

The Institutional Review Board at ASC

What is the IRB?

- An Institutional Review Board (IRB) is charged with protecting the rights and welfare of people participating in research.
- The IRB is comprised of faculty, students, and staff at Agnes Scott College. In addition, one local community person serves on the board.
- The IRB reviews proposals for research involving human subjects.

Goals of the IRB

- Protect the welfare and dignity of human subjects.
- Assist investigators in conducting ethical research that complies with the U.S. Code of Federal Regulations, DHHS (CFR), Title 45 Part 46 (45 CFR 46).

Origins of Federal Requirement for Human Subjects Research Reviews

1. **Nazi Medical Experiments (WW II): people infected with disease, forced to take poison, etc.**

2. **Tuskegee Syphilis Study (1932-1972): African-American men with syphilis studied but not treated.**

3. **Willowbrook study (1963-66): children with mental disabilities were intentionally infected with hepatitis.**

When the Tuskegee and Willowbrook cases became publicly known in the 1970s, the federal government decided to put in place legal requirements for review and approval of human subjects research conducted using federal funds.

How is Human Subjects Research Defined?

- An institution becomes “engaged” in human subjects research when its members intervene or interact with living individuals for research purposes.

- An institution becomes “engaged” in human subjects research when an institution receives a direct federal award to support such research.

Federal Assurance Number

- In order for faculty members to support their research with human subjects using federal funding, ASC must have a federal assurance number.

How is the Federal Assurance number and the Agnes Scott IRB connected?

The Agnes Scott IRB must show that all human subjects research conducted by Agnes Scott faculty, students, and staff as well as external researchers (who use any Agnes Scott College individuals in their research) complies with the mandated federal guidelines for protecting human subjects.

Examples of Human Subjects Research Needing IRB Approval

- All human subjects research which involves studies conducted in the lab as well as in the field. These may include surveys, interviews, focus groups and some observational studies often associated with the social sciences and medical studies.

- Human subjects research that is part of a class assignment or project.

Examples from the Humanities

- An interview study of Hurricane Katrina victims who are writers.
- An oral history of Agnes Scott lesbians.
- Videotaping dance students to determine the relationship between body movement and emotional problems.

Examples from the Social Sciences

- Study of political attitudes of middle school children (vulnerable subject population).
- Sex Drive Survey of Agnes Scott students.
- Economic decisions in mildly segmented asset markets.

Examples from the Sciences

- Class project on what types of medications Agnes Scott students take.
- Collection of EEG readings during visual perceptions of colors.
- Examination of stereotypes using mild deception.

When does an Observational Study need IRB Review?

- IRB approval is NOT needed if people are in public places and the behavior they are engaging in is public.

- However, IRB approval is needed when there is any interaction or intervention or when children (minors) or any other sensitive groups (e.g., institutionalized) are involved.

Types of IRB Review*

- Exempt from further review
- Expedited
- Full Board Review
- *Category types determined by the IRB depend on level of risk, type of intervention, and type of subject population.

When Planning A Course Project A Professor Should Consider the Following Questions:

- Does the activity or project involve *minimal risk*—"probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in daily life or doing the performance of routine physical or psychological examination or tests?"

How much intervention is involved?

- Intervention means manipulations of subjects or subjects' environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator or subjects. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and …..*privacy*

Privacy

- Private information is information which has been provided for specific purposes by an individual and which the individual can reasonably expect will **not** be made public (e.g., academic record). Private information must be *individually* identifiable in order for it to constitute "research" involving human subjects.

Does the research involve a vulnerable population?

- Vulnerable populations include:

- Children (all minors younger than 18 years of age must also have parental consent)
- Pregnant women
- Institutionalized individuals (e.g., prisoners, individuals in mental institutions)
- Cognitively impaired individuals

If you think you or your students need IRB approval for a human subjects research project,

- Go to the new IRB website http://irb.agnesscott.edu/index.html for the information or email the IRB at irb@agnesscott.edu .

Time Frame

- Please allow 7-10 days for Exempt or Expedited Reviews.
- Up to 1 month for Full Board Reviews.

AAUP Concerns about IRB Oversight

- There are some concerns about IRB oversight and these are discussed at the following websites: www.aaup.org/AAUP/pubsrres/academe/2006/SO/Rep/ResearchonHumanSubjects.htm.

- And of course rebuttal and discussion: http://www.aaup.org/AAUP/pubsres/academe/2007/JF/LTE/IRB.htm

Questions About:

- Faculty Research
- Independent Student Research
- Classroom Assignments
- Staff Research
- Researchers External to ASC?

- Go to: http://irb.agnesscott.edu/index.html or email irb@agnescott.edu.

If in doubt about a project, *please*:

- Email irb@agnesscott.edu. Questions and potential research scenarios are always welcome.