DOES MY PROJECT NEED IRB APPROVAL?

DEFINITION OF HUMAN SUBJECTS RESEARCH

- **Research**: a systematic investigation designed to develop or contribute to generalizable knowledge

- **Human subject**: a living individual about whom an investigator (whether professional or student) conducting research obtains
  - Data through intervention or interaction with the individual
  - Identifiable private information

(45 CFR 46)
**KEY QUESTIONS**

- Are you collecting information **from people**?
- Are you collecting information **about people** from existing sources?
- Are these existing sources **publicly available** (websites, federal data sets) or is access restricted (Loyola patient medical records)?
- Are you planning to publish your results in a journal?

**NOT ALL HSR IS CREATED EQUAL...**

- **Subject Population**
  - Patients
  - Community members
  - medical students/faculty/staff
- **Design**
  - Data collection or intervention?
  - Nature of information collected?
  - Researcher-subject interactions?
- **Risks**
  - Physical harm
  - Informational harm (breach of confidentiality)
  - Social harm
BUT IT ALL NEEDS SOME KIND OF IRB REVIEW

- Full Board Review
- Expedited Review
  - No greater than minimal risk
- Exempt Review

MINIMAL RISK (REGULATORY)

- Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i))
“EXEMPT” RESEARCH (45 CFR 46)

- **Minimal risk** research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior (with adults), **IF**

- Information obtained is **recorded** in such a manner that human subjects **can NOT be identified**, directly or through identifiers linked to the subjects; **AND**

- Any **disclosure** of the human subjects' responses outside the research **would NOT reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

WHAT DOES “EXEMPT” REALLY MEAN?

- Still needs to go to IRB for review
- Quicker review turnaround time
- Don’t need signed consent form
- Minor changes don’t need to go to the board for re-review
- No continuing review required
- IRB makes the determination that it’s exempt – NOT YOU
ETHICAL ISSUES TO CONSIDER

(REGARDLESS OF REVIEW CATEGORY)

THINGS TO CONSIDER: RECRUITMENT

- Where are you finding your subjects?
- Does it create any bias/unfairness?
- How will you be first approaching them?
- Is there any reason they might have a hard time saying no?
THINGS TO CONSIDER: INFORMED CONSENT

- You (almost) always have to tell people what you’re doing
  - exception: observation of public behavior

- But you do not always have to have them sign something

- Surveys/interviews/focus groups
  - Need to provide information, but usually don’t need a signature
  - Participation can imply consent

- Depends on subject population and risk
  - Kids and sensitive information

THINGS TO CONSIDER: PRIVACY AND CONFIDENTIALITY

- Who’s asking the questions?

- Where is the research taking place?

- Who is going to see the data?

- Where are data being stored?

- How are data being reported?

- Are you going to find out anything
  - you might need to tell someone else about
  - you might not want to know
PRIVACY ON THE INTERNET

- Cannot promise subjects complete confidentiality
- Survey monkey and other free survey software stores IP addresses
- Authentication/confirmation of identity
- LUC Survey Software Checklist
  - criteria which LUC would expect any survey software systems to have
  - [http://www.luc.edu/irb/irbonlinesurveysrequirements.shtml](http://www.luc.edu/irb/irbonlinesurveysrequirements.shtml)

EXAMPLES OF RESEARCH THAT NEEDS IRB REVIEW
YOU PLAN TO:

- **COLLECT DATA ANONYMously ONLINE:** conduct anonymous on-line surveys of Stritch medical students using the Tool for Assessment of Cultural Competency Training (TACCT)

- **CHART REVIEW:** review patient charts to examine prescription rates of generic and trade-name statins for all adult patients admitted over a six-month period with certain diagnoses at discharge

- **OBSERVE BEHAVIOR:** train waiting room service representatives to observe and record the types of physician-patient interactions that occur in the waiting room

YOU PLAN TO:

- **EVALUATE AN EDUCATIONAL PROGRAM:** assess the impact of an educational intervention on patients’ healthy lifestyle knowledge by using pre-and post-test questionnaires

- **EVALUATE A NON-MEDICAL CLINIC-BASED INTERVENTION:** improve medical staff to patient communication with the use of a simple tool for in-hospital patients at Loyola and Gottlieb Hospitals. You will:
  - conduct a survey of staff to assess needs and preferences
  - develop a tool
  - implement the tool and use for two weeks
  - conduct follow-up surveys of staff and patients
YOU PLAN TO:

- **SURVEY PATIENTS AND/OR THEIR FAMILIES:** survey parents who stay at the Ronald McDonald House Near Loyola during their child's hospitalization and parents who were eligible to stay at the RMH but chose to stay somewhere else to compare their experiences.

- **SURVEY COMMUNITY MEMBERS:** survey teenagers in Maywood about drug use, safety, sexuality, culture, family, and psychiatric concerns.

- **INTERVIEW PEOPLE WHO AREN'T LOYOLA PATIENTS:** interview homeless persons and employees and volunteers at homeless shelters to gain insight into their perceptions of why homelessness exists and continues.

- **INTERVIEW LOYOLA STAFF:** conduct in-depth interviews with physicians, nurses, and social workers about hospice care.