

**Intersection of Stakeholder Activities
with
Human Subjects Research Regulations**

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Goals of Presentation

Addressing three topics

- When stakeholders are considered engaged in research and part of a study team
- What to do if a stakeholder is engaged in human subjects research
- When stakeholders are considered human subjects

When is a stakeholder considered engaged in human subjects research?

**Office for Human Research Protections
Guidance on Engagement of Institutions in
Human Subjects Research**

<http://www.hhs.gov/ohrp/policy/engage08.html>

Guidance is applicable to **non-exempt research**
i.e., research that **DOES NOT** fall under 1 or more
of the 6 categories outlined under the federal
regulations as not requiring IRB oversight

Activities that Constitute Engagement	
Activity	Example(s)
Intervening for research purposes with any human subjects of the research by performing invasive or noninvasive procedures	<ul style="list-style-type: none"> • Drawing blood • Collecting biological samples directly from subjects • Administering individual or group counseling or psychotherapy as dictated by the study protocol
Interacting for research purposes with any human subject of the research	<ul style="list-style-type: none"> • Engaging in protocol dictated communication or interpersonal contact • Conducting research interviews or administering questionnaires • Recording patient/provider interactions • Screening potential subjects to determine if they are eligible for a study
Obtaining informed consent from potential subjects	<ul style="list-style-type: none"> • Approaching potential subjects, describing study procedures, and obtaining permission to collect data about subjects for research purposes
Receiving or analyzing private, identifiable information collected from or about individuals for research purposes	<ul style="list-style-type: none"> • Conducting statistical analysis on identifiable data • Reviewing individually identifiable videotape sessions and providing input on their interpretation

Activities that <u>Do Not</u> Constitute Engagement	
Activity	Example(s)
Performing a commercial or professional service for a research team	<ul style="list-style-type: none"> • A transcription company whose employees transcribe research interviews as a commercial service • A person who translates a consent document into another language for a study team or provides interpretation services during a consent process
Providing feedback to research teams on study instruments or consent documents	<ul style="list-style-type: none"> • A community group provides consultation regarding the reading level of or specific terms used in study documents (e.g., consent forms, recruitment materials, survey instruments)
Providing feedback to study teams regarding planning a research study, formulating a research question, interpretation of study results, or advising regarding recruitment strategies	<ul style="list-style-type: none"> • Patient advisory board members provide feedback to the research team planning a study regarding how they might interpret "usual care" when they go into a visit • A panel of physicians is shown aggregate data from a study and asked to comment on the study team's proposed interpretations of the data set • A community group provides feedback on how to identify and approach research subjects
Informing prospective subjects about the availability of the research	<ul style="list-style-type: none"> • Personnel at a community center provide copies of the consent form for a research study at events but do not obtain subjects' consent for the research

What to do if a stakeholder is engaged in human subjects research

If engaged....

Person's activities would need to be covered by an IRB

- UW may be willing to act as the person's IRB of record
- If UW would be the IRB, the personnel would need to be listed on the UW IRB application in ARROW

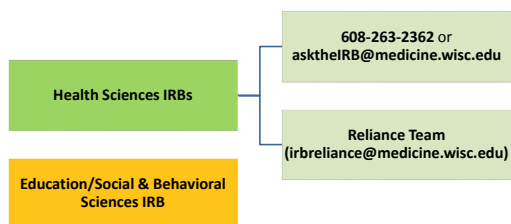
Personnel would be required to complete human subjects training

- UW provides CITI training
- Other training can be accepted by the UW

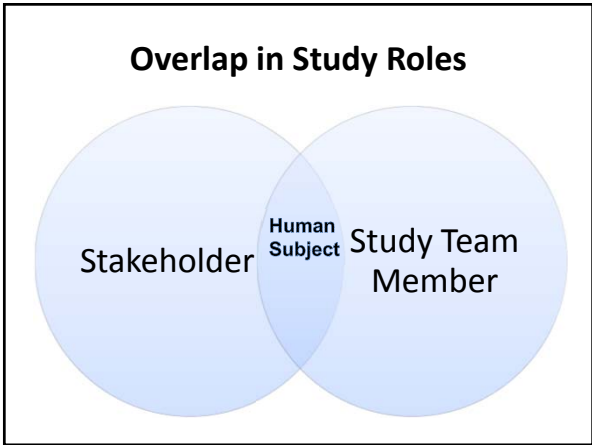
UW PI would be responsible for -

- Ensuring all personnel engaged in human subjects research are:
 - trained on study activities and
 - conducting the research in compliance with the IRB-approved protocol

Consult with the relevant IRB Office



When is a stakeholder considered a human subject?



Characterization of Potential Study-Related Roles*

Activity	STUDY STAFF	STAKEHOLDER/ ADVISOR	HUMAN SUBJECT
• Designs research study	YES	NO	NO
• Provides feedback on study design, study planning or research question formulation	YES	YES	NO
• Advise regarding study implementation/study documents	YES	YES	NO
• Recruit study participants	YES	NO	NO
• Collect identifiable data	YES	NO	NO
• Analyze individual data	YES	NO	NO
• Review and interpret de-identified research data	YES	YES	NO
• Conduct/execute the research intervention	YES	NO	NO
• Advise in recruitment strategies	YES	YES	NO
• Participate in survey development and pilot (no individual retained)	YES	YES	NO
• Provide identifiable private information <u>about</u> themselves that will be used as research data	NO	NO	YES
• Undergo study interventions	NO	NO	YES

*Adapted from slides produced by a Patient-Centered Outcomes Research Institute (PCORI) Eugene Washington Engagement Award Program (EAW-2209, PI: Katherine Bevrans)

Activities that Suggest a Person is a Subject	
Subject	Not a Subject
Individually identifiable information sought by the research team	Individually identifiable information incidentally disclosed to the research team as part of feedback on study procedures, documents or instruments and research team does not record results or only uses aggregates responses
Research team asks individuals for information about themselves	Research team asks individuals for information about their organization or group
Individuals undergo protocol-dictated procedures	Individuals provide feedback on but do not undergo potential study procedures (e.g., feedback on survey for development purposes)
Data from or about individuals recorded with intent to create generalizable knowledge (e.g., collecting data to compare with similar data from other individuals or historical controls)	Interactions with individuals intended to obtain feedback/generate ideas that inform study design and implementation and not to create generalizable knowledge

Not a Research Subject - Examples

You collect oral feedback from a stakeholder board on proposed recruitment script

You audio record a discussion of physicians to get their take on some surprising findings from the study

You administer an anonymous questionnaire to a small group to understand if the sample's needs will be addressed (e.g., transportation to study sessions)

Important Considerations


Issue	What to Do
Making the "human subject" versus "not human subject" distinction can sometimes be challenging, so...	<ul style="list-style-type: none"> Consult with the IRB Be clear on all individuals' roles in your protocol and application Provide rationale to the IRB if you think a group falls outside of the human subjects definition
Informed consent for research is not required with individuals who are not human subjects, however...	<ul style="list-style-type: none"> Adhere to professional standards Be clear on purpose of activity and what is required of individuals Develop informational materials if helpful
Projects can evolve and new questions/methods may emerge, consequently ...	<ul style="list-style-type: none"> Your "non-subjects" may become subjects Check back with the IRB as needed

Questions and Discussion

For Reference

Definition of human subjects research

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”



A human subject is defined as “a living individual *about* whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Intervention and Interaction

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.

Interaction includes communication or interpersonal contact between investigator and subject.

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
- 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)

Must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)
