



Does My Project Involve “Human Subjects”?

You may be doing a research project where you are interacting with humans, but did you know that **not** all research projects that involve humans are actually considered research with “human subjects”? How can that be?

For the Institutional Review Board (IRB) and the Federal entities whose regulations the IRB adheres to, the definition of a “human subject” is:

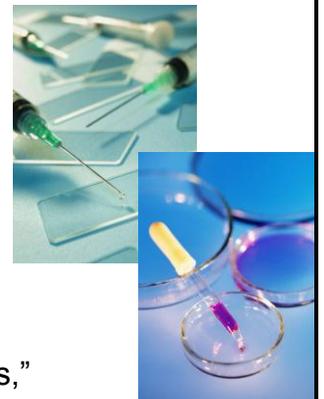
A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information.

There are four important parts of this definition. If you answer **Yes** to three of the four, your project does involve a “human” subject:

1. **Living Individual** – Is the study about a living human?
2. **About Whom** – Is the study about the individual him/herself? Think about it this way – If you are conducting a telephone interview, and are asking the participant questions such as how many acres he/she farms, what does s/he grow, what is the average per acre yield, this project would not be “about whom.” If, on the other hand, you asked the individual, his/her opinion on recent governmental rulings that will impact his/her business, his/her perception of the future of farming in the area, etc., that **would** be considered “about whom.”
3. **Intervention/Interaction** – Does the researcher *intervene* or *interact* with a participant - in person, via the phone, via the internet – conducting interviews, surveys, questionnaires, etc?
4. **Identifiable private information** – Does the researcher collect names or other identifiers so that the data could be linked back to an individual.

Are Biological Specimens considered Human Research? I am obtaining de-identified human specimens from a commercial vendor. Even though these specimens are from humans, do I need to submit a protocol to the IRB?

If your specimens are from a commercial vendor and are anonymous samples, the answer is **NO** you do not need IRB approval. Please check with our office to be certain prior to beginning your project.



If you have any question if your project involves “human subjects,” please complete the “[Does My Project Require IRB Review?](#)” form and submit it to RICRO for review.