HUMAN SUBJECT RESEARCH DETERMINATION *

Not all investigations involve research. Not all research involves humans.

Does your project involve Research (a systematic investigation designed to develop or contribute to generalizable knowledge)?

Yes? Keep going.

No? Stop. Your project is not research.

Is it an **Investigation** (a searching inquiry for ascertaining facts; detailed or careful examination)?

Yes? Keep going.

No? Stop. Your project is not research.

Is it **Systematic** (carried out according to a plan)?

Yes? Keep going.

No? Stop. Your project is not research.

Is it **Designed** (following a behavior devised) to **Develop** (form the basis of in the future) or **Contribute** to knowledge (add to facts and understanding).

Yes? Keep going.

No? Stop. Your project is not research.

Is it **Generalizable** (will the knowledge the systematic investigation is designed to develop or contribute be widely and universally applicable)?

Yes? Keep going.

No? Stop. Your project is not research.

IF ALL YES THEN YOUR PROJECT IS RESEARCH. NOW IS THIS HUMAN RESEARCH?

Will you be obtaining information or biospecimens about living individuals?

Yes? Keep going.

No? Stop. Your project is not research.

Will you obtain the information through *interaction* (communication or interpersonal contact) with an individual?

Yes or No? Keep going.

Will you use, study or analyze information or biospecimens obtained through *interaction*?

Yes? Your project is human research.

No? Keep going.

^{*}Use for studies regulated by DHHS. Not meant for studies regulated by FDA.

Will you obtain information or biospecimens through *intervention* (physical procedures or manipulation of the person's environment for the purpose of this research)?

Yes? Keep going.

Will you use, study, or analyze the information or biospecimens obtained from the intervention?

Yes? Your project is human research.

No? Keep going.

No? Keep going.

Will you obtain information that is either or both private information?

- About behavior that occurs in context in which person expects no observation or recording is taking place
- Provide for specific purposes by the person where the person can expect the information will not be made public

Yes or No? Keep going.

Can the identity of the person associated with the information or biospecimen be readily ascertained by you?

Yes? Your project is human research. No? Your project is not human research.

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