Determining Whether Proposed Activity is Human Research According to DHHS or FDA Regulatory Definitions

Investigators: Please complete the top text boxes. Submit the form to Xavier University's IRB office at ML 1100, or as an email attachment to irb@xavier.edu. You will be notified in writing of the IRB's determination.

Person Requesting Determination and Contact Information	Name & Degree	Department
	Phone	Mail Location or Mailing Address
	Email	
Title of Project		
Description Including Whether It Means to Contribute to Generalizable Knowledge (via publication, presentation, or otherwise).		

Research for which DHHS regulations or XU Policies may apply

BOTH "Research" and "Human participants" categories OR "FDA" (next page) must be true for IRB review to be required.

☐ The activity involves **RESEARCH** because BOTH of the following are true.

- ☐ The activity is a systematic investigation, including a systematic collection of data.
- ☐ The activity is designed to develop or contribute to generalizable knowledge.

☐ The activity involves intervention or interaction with **HUMAN PARTICIPANTS** because BOTH of the following are true.

☐ Human participants are involved because EITHER of the following is true.

- ☐ The data being collected are about living individuals.
- ☐ The data being collected include genetic/biological material (sputum, tissue, swab, blood, body fluids, etc.).

☐ Intervention or interaction is involved because EITHER of the following is true.

☐ The investigator plans to obtain the data through ANY of the following (select all that apply).

- ☐ Physical procedures performed on or by participants.
- ☐ Manipulation of participants.
- ☐ Manipulation of participants' environment.
- ☐ Communication with participants.
- ☐ Interpersonal contact with participants.

☐ The information collected is BOTH of the following.

☐ Private, because EITHER of the following is true.

- ☐ The information is about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (such as in a home or a private office).
- ☐ The information is provided by the individual for a specific purpose which the individual can reasonably expect will not be made public (such as class assignments or medical records).

☐ Individually identifiable, because EITHER of the following is true.

- ☐ The identity of the individual is or may readily be ascertained by the investigator.
- ☐ The identity of the individual is or may readily be associated with the information (including a master list linking identity and study ID#).

Research for which FDA regulations or XU policies may apply.

AT LEAST ONE of the following three categories must be true for IRB review to be required.

☐ The activity involves the use of an investigational **DRUG** because ALL of the following are true

- ☐ At least ONE of the following is true (select all that apply).
  - ☐ The article is recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to them.
  - ☐ The article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.
  - ☐ The article (other than food) is intended to affect the structure or any function of the body of humans or other animals.
  - ☐ The article is intended for use as a component of any article specified in the above items.
- ☐ EITHER of the following is true.
  - ☐ The article is NOT approved by the FDA for marketing.
  - ☐ The article is NOT being used in the course of medical practice.
- ☐ The article or activity will be used on one or more humans.

☐ The activity involves the use of an investigational **MEDICAL DEVICE** because ALL of the following are true.

- ☐ At least ONE of the following is true (select all that apply).
  - ☐ The article is recognized in the official United States Pharmacopoeia, or official National Formulary, or any supplement to them.
  - ☐ The article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.
  - ☐ ALL of the following are true.
    - ☐ The article is intended to affect the structure or any function of the body of humans or other animals.
    - ☐ The article does NOT achieve any of its primary intended purposes through chemical action within or on the body of humans or other animals.
    - ☐ The article is NOT dependent upon being metabolized for the achievement of any of its primary intended purposes.
- ☐ EITHER of the following is true.
  - ☐ The article is NOT approved by the FDA for marketing.
  - ☐ The article is NOT being used in the course of medical practice.
- ☐ The article or activity will be used on one or more humans.

☐ The activity is **OTHERWISE** subject to FDA regulation because AT LEAST ONE of the following is true.

- ☐ Data from the activity will be submitted to or be held for inspection by the FDA.
- ☐ The activity involves at least ONE of the following FDA regulated articles (select all that apply).
  - ☐ Food or dietary supplement that bears a nutrient content or a health claim.
  - ☐ Food or color additive for human consumption.
  - ☐ Infant formula.
  - ☐ Biological product for human use.
  - ☐ Electronic product for human use.
  - ☐ Other article subject to the Food, Drug & Cosmetic Act.
- ☐ The activity is being done to determine the safety or effectiveness of the drug or device.

For IRB Office Use Only

Determined to be human research requiring IRB review, submission to the IRB is required. ☐

Determined NOT to be human research requiring IRB review, submission to the IRB is NOT required. ☐

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Signature of IRB Chair or Designee | Date