Does the activity involves Research?

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

Systematic investigation: a formal scientific inquiry characterized by the following: 1) the formulation of a hypothesis or experimental question 2) the requirement of adherence to a predefined plan for the data collection and analysis 3) the performance of data analysis to evaluate the hypothesis or experimental question 4) the results of the inquiry are intended to be replicable.

Generalizable Knowledge: information resulting from a systematic investigation that has the following characteristics: 1) it is intended to be disseminated through professional publication and/or formal presentation 2) it may be applicable to circumstances other than those under which the systematic investigation was conducted.

Yes

Does the research activity involves Human Subjects?

There are essentially two ways in which a living individual becomes a human subject:

1- An investigator who is conducting research obtains data about the living individual through interventions or interactions with the individual.
   - Intervention: physical procedures by which data are gathered and/or manipulation of the subject or the subject's environment
   - Interaction: includes communication or interpersonal contact between investigator and subject.

2- An investigator conducting research obtains individually identifiable private information about a living individual (e.g., by reviewing medical records or specimens).
   - Individually identifiable information: The identity of the individual to whom the specimen or the data pertain can be readily ascertained or readily associated with the information by the investigator.
   - Private Information: 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). Private information 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) in order for obtaining the information to constitute research involving human subjects.

Yes

Review the next six flow diagrams to determine if the study activity qualifies for any of the exemptions under the regulations.

No

STOP: Activity is not Human Subjects Research.

No

STOP: Activity is not research.
Exemption Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
Does the research involve only the use of one or more of the following:

- Educational tests,
- Survey procedures,
- Interview procedures, or
- Observation of public behavior?

Will the information obtained be recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects?

Could any disclosure of the subjects’ responses outside the research reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

**Exemption Category 2**: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or loss of insurability, or be damaging to the subjects' financial standing, employability, or reputation. (Under Subpart D, for research involving children, this exemption, (45 CFR 46.101(b)(2), applies regarding educational tests. However for research involving survey or interview procedures or observations of public behavior this exemption does not apply to research covered by Subpart D, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.)
Does the research involve only the use of one or more of the following:

* Educational tests (cognitive, diagnostic, aptitude, achievement)
* Survey procedures,
* Interview procedures, or
* Observation of public behavior?

Submit an application to the IRB requesting exemption under category 3

**Exemption Category 3:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statutes(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
Determination of Exemption Category 4 – Study of Existing Data, Documents, Records, Specimens

(Prior to using this chart you should already have determined that your project does constitute human subject research)

**Question**
Does the human subjects research qualify for exemption 4?

Does the research involve only the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens?

(EXISTING means already available before the research proposal is submitted to the IRB.)

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**Exemption Category 4**: research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (Retrospective)

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**Are these sources publically available?**

- Yes
  - Submit an application to the IRB requesting exemption under category 4
  - **Not eligible for exemption under Category 4 - Perhaps expedited review may apply**

- No
  - Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?
    - Yes
      - Submit an application to the IRB requesting exemption under category 4
      - **Not eligible for exemption under Category 4 - Perhaps expedited review may apply**
    - No
      - Not eligible for exemption under Category 4 - Perhaps expedited review may apply?
**Determination of Exemption Category 5 – Public Benefit or Service Programs**

(Prior to using this chart you should already have determined that your project does constitute human subject research)

This exemption is for projects conducted by or subject to approval of Federal agencies, and is most appropriately invoked with authorization or concurrence by the funding agency.

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**Exemption Category 5:** Research and demonstration projects that deliver a public benefit (e.g. financial or medical benefit under Social Security) or service (e.g. supportive, social or nutritional services under the Older Americans Act) which are conducted by or subject to the approval of department or agency heads (i.e. federal authority), and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. For projects to qualify for this category, the project must be conducted pursuant to specific federal statutory authority, there may be no statutory requirement that requires IRB review, and the project may not involve significant physical invasion or intrusions upon the privacy of participants.
Determination of Exemption Category 6 – Food Taste and Acceptance Studies
(Prior to using this chart you should already have determined that your project does constitute human subject research)

Exemption Category 6: Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. department of Agriculture.