Is Your Project Defined as Research?

Regarding the design and intent of the project:

1. Is the activity ‘systematic’?
   Fits all of these criteria:
   -- Attempt to answer research questions (in some research this would be a hypothesis)
   -- Methodologically driven (collects data or information in an organized and consistent way)
   -- Data analyzed (e.g. quantitative, qualitative)
   -- Conclusions drawn from results

2. Is the activity designed to develop or contribute to ‘generalizable knowledge’?
   Examples of ‘generalizable knowledge’:
   -- Knowledge contributes to theoretical framework of established body of knowledge
   -- Primary beneficiaries of research are other researchers, scholars & practitioners in field of study
   -- Publication, presentation or other distribution of results intended to inform field of study
   -- Results expected to be generalized to larger population beyond site of data collection
   -- Results intended to be replicated in other settings
   -- Web based publication for professional purposes
   -- For a Masters’ theses or Ph.D. dissertation

Your project is Research

Research means a systematic investigation, including research development and evaluation, designed to develop or contribute to generalizable knowledge.

Does this research involve human subjects or materials?

Yes

Go to Chart #2

Check Research-Without Human Subjects box on transmittal

Your project falls under one of these classifications:

- Education
- Public Service
- Testing/Fee for Service
- Quality Assurance/Quality Improvement
- Construction

Please call Contract and Grant Administration for more information (517-355-5040).
Is your project Human Subject Research activity?

**per DHHS Human Subject Research Definition (Common Rule (45 CFR part 46.102 (d,f)),
or per FDA Clinical Investigation Involving Human Subjects Definition (21 CFR 50, 56, 312, 812)**

**Is Information obtained from living individuals?**

- **Yes**
  - Information obtained:
    - **Through Intervention**
      - Physical procedures by which data are gathered (for example, venipuncture (blood draw))
      - Manipulations of subject or subject's environment performed for research purposes
    - **Through Interaction**
      - Communication or interpersonal contact between investigator & subject
    - **Is Identifiable Private Information**
      - Information about behavior that occurs in context in which an individual can reasonably expect that no observation or recording is taking place
      - Information which has been provided for specific purposes by an individual & which individual can reasonably expect will not be made public
      - Identity of subject is or may readily be ascertained by investigator or associated with information

- **No**

**Does the activity involve a test article and one or more Human Subjects?**

- **Yes**
  - **Test article** means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the PHS Act
  - **Human subject participation** can be as either a recipient of the test article or as a control
  - For clinical investigations or research involving devices, 'Subject' includes use of specimens, even if specimens are unidentified.

- **No**

**Is the test article a drug or device?**

- **Yes**
  - A drug being administered, dispensed to or used for purposes other than the use of a marketed drug in the course of medical practice? 21 CFR 312.3
  - A device for which the experiment used to determine safety and effectiveness, involves a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control?

- **No**

**Your project is not considered Human Subject Research Activity**

All projects involving human subjects need to be submitted to the IRB for their review. Please call the IRB for more information (517-432-4503).
What Type of Human Subject Research Activity is your project?

Is this project Clinical Research?

**NIH Definition:**

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes:
   - Mechanisms of human disease
   - Therapeutic interventions
   - Clinical trials
   - Development of new technologies
2. Epidemiologic and behavioral studies.
3. Outcomes research and health services research.

Is this project a Clinical Trial?

**NIH/FDA Definition:**

A prospective biomedical or behavioral research study of human volunteers that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. There are different kinds of clinical trials, including those to study:

- prevention options
- new treatments or new ways to use existing treatments
- new screening and diagnostic techniques
- options for improving the quality of life for people who have serious medical conditions

Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients/volunteers may enter the study, schedules of tests and procedures, drugs/dosages (if applicable), and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four potential phases:

- **Phase I** clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects).
- **Phase II** clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
- **Phase III** studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.
- **NIH-Defined Phase III Clinical Trial.** An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.
- **Phase IV** studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Go to Chart 4 to determine intellectual property and IDC assignment.

This is Research- Clinical Trial with Human Subjects

This is Research, Non-Clinical with Human Subjects

This is Research- Clinical with Human Subjects

No

Yes
Determination of Intellectual Property Assignment and Corresponding Indirect Cost Rate (IDC) Classification

Are you the primary or contributing designer of the research endeavor and/or writer of the protocol/scope of work for the project?

Yes

Please select the 'MSU Investigator-Initiated' form of your research

Are > 50% of your project expenses at an off-campus location? (see www.cga.msu.edu for more info)

Yes

26% IDC*

No

Please select the 'Agency-Initiated' form of your research

Funding source- Industry?

Yes

26% IDC*

No

Funding source- Federal/other?

Yes

Are ≥ 50% of your project expenses at an off-campus location? (see www.cga.msu.edu for more info)

Yes

52% IDC*

No

Funding source- State of Michigan?

Yes

Call CGA 517-355-5040

* Unless another rate is documented as a general policy from a not-for-profit sponsor and accepted by MSU, or waiver is submitted to and approved by VPRGS