

## **The New Human Subject Research Classification System:**

### **1. Research -Non-Clinical with Human Subjects, MSU Investigator-Initiated**

- Typified by human subject research fitting DHHS or FDA definitions [[link to CTSI definition page](#)], but not classified as clinical research or clinical trial research. Examples: agriculture (food testing research); educational research; some in-vitro studies utilizing human tissues that cannot be linked to living individuals; some fisheries and wildlife survey projects; some social science research.
- MSU investigator-initiated is defined as an MSU colleague being a primary or contributing designer of the research endeavor and/or writer of the protocol/scope of work for the research.

### **2. Research -Non-Clinical with Human Subjects, Agency-Initiated**

- Typified by human subject research fitting DHHS or FDA definitions [[link to CTSI definition page](#)], but not classified as clinical research or clinical trial research. Examples: agriculture (food testing research); educational research; some in-vitro studies utilizing human tissues that cannot be linked to living individuals; some fisheries and wildlife survey projects; some social science research.
- Agency-initiated is defined as an agency (ie- industry, federal, state, foundation, etc) being the primary or contributing designer of the research endeavor and/or writer of the protocol/scope of work for the research. MSU is paid for providing services (data, samples, etc) as required by the sponsor-generated protocol, but has no direct input on or influence over the research design or protocol.

### **3. Research- Clinical with Human Subjects, MSU Investigator-Initiated**

- Defined by NIH as 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. Also includes epidemiologic and behavioral studies as well as outcomes research and health services research. Examples: retrospective studies, registries, research that involves collection and research on human specimens or information but that does not involve an intervention.
- Typified by funded, contract or grant-driven research (sponsored by NIH, company, foundation, etc.), or internally funded pilot studies on the path to grant writing. Some clinical research projects may not be externally funded.
- Clinical research that is not specifically defined as a clinical trial, and that is MSU-investigator-initiated. MSU investigator-initiated is defined as a clinical trial wherein the MSU colleague is a primary or contributing designer of the research endeavor and/or writer of the protocol/scope of work for the research. Although clinical trials are a subset of clinical research, they will have a separate classification on the transmittal.

### **4. Research- Clinical with Human Subjects, Agency-Initiated**

- Defined by NIH as 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. Also includes epidemiologic and behavioral studies as well as outcomes research and health services research. Examples: retrospective studies, registries, research that involves collection and research on human specimens or information but that does not involve an intervention.

- Typified by funded, contract or grant-driven research (sponsored by NIH, company, foundation, etc.), or internally funded pilot studies on the path to grant writing. Some clinical research projects may not be externally funded.
- Clinical research that is not specifically defined as a clinical trial, and that is agency-initiated. Agency-initiated is defined as an agency (ie- industry, federal, state, foundation, etc) being the primary or contributing designer of the research endeavor and/or writer of the protocol/scope of work for the research. MSU is paid for providing services (data, samples, etc) as required by the sponsor-generated protocol, but has no direct input on or influence over the research design or protocol. Although clinical trials are a subset of clinical research, they will have a separate classification on the transmittal.

#### **5. Research- Clinical Trial with Human Subjects, MSU Investigator-Initiated**

- Typified by prospective biomedical or behavioral research studies of human subjects that are designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Examples: drug and device trials, some behavioral intervention studies and outcomes research studies. Study design follows phase definitions (which may not necessarily be indicated in project title).
- MSU investigator-initiated is defined as a clinical trial wherein the MSU colleague is a primary or contributing designer of the research endeavor and/or writer of the protocol/scope of work for the research.

#### **6. Research- Clinical Trial with Human Subjects, Agency-Initiated**

- Typified by prospective biomedical or behavioral research studies of human subjects that are designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Examples: drug and device trials, some behavioral intervention studies and outcomes research studies. Study design follows phase definitions (which may not necessarily be indicated in project title).
- Agency-initiated is defined as an agency (ie- industry, federal, state, foundation, etc) being the primary or contributing designer of the research endeavor and/or writer of the protocol/scope of work for the research. MSU is paid for providing services (data, samples, etc) as required by the sponsor-generated protocol, but has no direct input on or influence over the research design or protocol.