	Category	Description	Comments
☐	**Case Studies - Clinical**	Report about one or two individuals identified in the course of clinical care. Publication of the case study is permissible.	The case study must not include any FDA-regulated activities that require IRB approval such as: articles (e.g., drugs, devices, biologics) that have not been approved for use in humans; articles requiring exemption from FDA oversight; articles under an IND/IDE. To expand this activity in the future to include more than one or two cases contact the IRB to determine if IRB approval prior to initiation of the project is required.
☐	**Case Studies – Other**	Report about experiences or observations associated with one or two individuals. Publication of the case study is permissible.	To expand this activity in the future to include more than one or two cases, contact the IRB to determine if IRB approval prior to initiation of the project is required.
☐	**Class Assignments/Research Methods Classes**	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge.	Projects that are intended to result in honors or master's theses, doctoral dissertations, public poster sessions, published articles, or abstracts should review the "standard" and "exempt" application types in section 1-1 and choose the appropriate option. Click here to view the UM policy on class activities.
☐	**Medical Practice**	Standard practice, innovative care, or off-label use of FDA-approved drugs, biologics, devices and other articles or substance that are used in the normal course of medical practice, provided the activity does not involve systematic collection of safety or efficacy data, and is limited to prevention, diagnosis, mitigation, treatment, or cure of disease in affected individuals.	This category includes diagnostic and therapeutic practices.
☐	**Oral History**	Interviews that gather, preserve and interpret the voices and memories of people, communities, and participants in past events as a method of historical documentation. The intent is to document a particular past or unique event in history.	Interview projects asking questions that are not focused on the historical event may exceed the definition of oral history and should review the "standard" and "exempt" application types in section 1-1 and choose the appropriate option.
☐	**Pre-review of Clinical Data Sets (e.g., data, specimen, etc.)**	Activities (e.g., review of medical data, queries, etc.) intended only to assess the feasibility of future research.	Under HIPAA regulations, researchers within the "covered entity" must obtain a HIPAA authorization waiver for review of identifiable protected health information (PHI) in preparation for research. PHI may be used or disclosed without HIPAA consent or authorization if the investigator affirms: (i) the use or disclosure is sought only to review PHI as necessary to assess the feasibility of future research; and (ii) no identifiers linking individuals to their PHI will be retained by the researcher after the feasibility review is complete.
☐	**Quality Assurance and Quality Improvement Activities - Other**	Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs. Examples include teaching evaluations or customer service surveys. Publication of results is permissible.	QI/QA activities that require IRB review include: • testing of issues that go beyond current knowledge based on science and experience; • random allocation of subjects into different intervention or control groups; • deliberately delayed or partial feedback of data collected through the implementation or improvement activity; and 4) activities where participants have the ability to opt in or out.
☐	**Quality Assurance and Quality Improvement Activities - Clinical or**	Systematic, data-guided activities designed to implement promising ways	QI/QA activities or procedures that require IRB review include:

Category	Description	Comments
Procedures	to improve clinical care, patient safety and health care operations. The activity is designed to bring about immediate positive changes in the delivery of health care, programs, or business practices in the local setting. Publication of the results is permissible.	• testing of issues that go beyond current knowledge based on science and experience; • random allocation of subjects into different intervention or control groups; • deliberately delayed or partial feedback of data collected through the implementation or improvement activity; and • activities where participants have the ability to opt in or out.
☐ **Research involving Coded Biological Specimens**	Analysis of coded human specimens where: 1. The specimens were not collected specifically for the proposed study through an interaction or intervention with living individuals, 2. The investigators cannot readily ascertain the identities of the individuals from whom the specimens were obtained either directly or indirectly through a coding system and, 3. The investigator is not a researcher or collaborator on the specimen provider's research.	Examples meeting the description criteria (numbers match the description numbers): 1. The specimen was originally collected for different research study; collected for clinical purposes; or consists of material to be otherwise discarded (waste tissue). 2. The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators; or the provider's institutional or repository written policies prohibit the release of the key to investigators. 3. The investigator for the proposed research is not engaged as a collaborator with the specimen provider in the interpretation or analysis of the specimens. **Note:** If the proposed use of the specimens is in support of an IDE Application (Investigational Device Exemption), you must obtain IRB approval according to the full regulatory criteria, even if the specimens are de-identified. Some research not regulated under Human Subjects research regulations may still require IRB review for HIPAA or other regulations and institutional policies.
☑ **Research Involving Coded Private Information**	Analysis of coded private human data where: 1. The data were not collected specifically for the proposed study through an interaction or intervention with living individuals, 2. The investigators cannot readily ascertain the identities of the individuals about whom the data were obtained either directly or indirectly through a coding system, 3. The investigator is not a researcher or collaborator on the data provider's research (i.e. not collaborating on research involving the same data set).	Examples meeting the description criteria (numbers match the description numbers): 1. The original data were collected for a different research study or for administrative purposes (e.g. Medicare data, hospital discharge data, medical records, electronic information from a clinical database). 2. The investigator and the holder of the key enter into an agreement prohibiting the release of the key to the investigator; or the provider's institutional or repository written policies prohibit the release of the key to the investigator. 3. The investigator for the proposed research is not engaged as a collaborator with the data provider in the interpretation or analysis of the data
☐ **Research Involving De-identified Biological Specimens or Information**	Research involving a de-identified set (data/specimens) which **cannot** be "re-identified" by any known entity.	For further guidance on "de-identified" and "coded," see U-MIC presentation "Anonymous, Coded, and De-identified Data..." or the "Key Definitions" heading at Data Security Guidelines. Do NOT choose this category if dataset includes any HIPAA identifiers.

Category If other, please specify.	Description	Comments
☐ **Activities not engaging UM in human subjects research**	UM study team activity is limited activities that **do not** "engage" the University in human subjects research Examples are usually related to cooperative research with investigators from another institution, and might include: • Performing commercial or other services • Permitting use of facilities for intervention or interaction with subjects by investigators from another institution • Primary analysis of coded information obtained for research purposes at other institutions • Releasing identifiable private information or biological specimens	"Engagement" is described at U-M HRPP OM Part 4.III and OHRP Guidance on Engagement of Institutions in Human Subjects Research. A performance site is always deemed to be "engaged" in human research when it receives a direct grant or other award to support the research. A performance site is "not engaged" in human research if its employees or agents do not intervene or interact with living individuals for research purposes, or obtain individually identifiable private information for those purposes.
☐ **Research Involving Only Decedents (Deceased Individuals)**	Research involving only data or tissue obtained from individuals who are deceased prior to the conduct of the research. There must not be any interaction or intervention with living individuals, or collection of private data or specimens associated with living individuals.	Federal regulations define a human subject as 'a living individual about whom an investigator (whether professional or student) conducting research obtains: 1. data through intervention or interaction with the individual, or 2. identifiable private information' 45CFR46.102(f). Under HIPAA regulations, researchers within the "covered entity" must obtain a HIPAA authorization waiver for review of identifiable protected health information (PHI).
☐ **Research Using Publicly Available Data Sets**	Use of publicly available data sets that do not include information that can be used to identify individuals. "Publicly available" is defined as information shared without conditions on use. This may include data sets that require payment of a fee to gain access to the data.	Research using publicly available data sets where there is no intent to identify an individual is not considered human subjects research. If you are designing a research project that merges more than one public data set and you recognize that this may increase the risk of identification of individual research participants, then you should select "Secondary use of existing identifiable data" in section 1-1, Application Type. For more information refer to U-M's policy on use of publicly available data sets. Publicly available data sets that contain identifiers, such as a telephone directory, may be eligible for Exemption #4.
☐ **Research on Organizations**	Information gathering about organizations, including information about operations, budgets, etc. from organizational spokespersons or data sources. Does not include identifiable private information about individual members, employees, or staff of the organization.	Projects utilizing administrative data may be subject to controls of the organization being studied.
☐ **Standard Public Health Surveillance or Prevention Activities**	The collection and analysis of identifiable health data through public health efforts that primarily involve surveillance; prevention or control of known or suspected diseases, injuries, or other conditions; or to promote the health of a particular community.	HIPAA regulations may still apply.
☐ **Other**	Other **If other, please specify.**	