eRESEARCH | REGULATORY MANAGEMENT SAND

Edit: Application - HUM00009976

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01-1. Application Type

Note: An Application Type Is Required Before You May Continue.

Hide Help

1-1.1* Select the appropriate application type.

	Application Type	Description
☐	Human Subjects research **involving interaction or intervention** *(formerly Standard, non-exempt research project - or - Exempt)*	Studies that involve either or both of the following: • Interaction, including communication or interpersonal contact between investigator and subject • Intervention, including both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes Interaction/Intervention studies may also have a "secondary research" component.
☑	**Secondary research** uses of private information or biospecimens	"Secondary research" are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other "primary" or "initial" activity, such as other earlier research studies, a biorepository holding specimens obtained with "broad consent," clinical care, educational records. **Do NOT use this application type for:** • Studies that **also** have an interaction/intervention component, such as primary collection of information or biospecimens for the purposes of the study. (Choose instead "Human subjects research involving **interaction or intervention**.") • Projects involving secondary use of information/biospecimens for **only non-research purposes**, such as QA/QI, case studies on one or two individuals, or use in a class to teach research methods. (Choose instead "Activities **not regulated** as human subjects research.")
☐	Activities **Not Regulated** as human subjects research	Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research (45 CFR 46 or 21 CFR 50/56). **IRB review is required** for the following activities **ONLY** to assess compliance with **HIPAA** or other regulations or institutional policies: • Research on existing data or specimens that have been coded before the researcher receives them, but identifiers still exist. • Research Involving Deceased Individuals Only • Pre-review of Clinical Data Sets Preparatory to Research

NOTE: the new "secondary research uses..." application type applies **REGARDLESS** of the timing of data/ biospecimens.
This is the appropriate application type for secondary research analysis of retrospective or prospective materials - or BOTH - so long as there is not ALSO an interaction/intervention component.

Some research limited to secondary use is eligible for Not Regulated determination. Usually it is still preferable to select Secondary Research Uses.

If U-M's activity in a study is limited to analysis of coded data/biospecimens collected for the purposes of the study (i.e. primary analysis), select 'Not Regulated' and (in section 04-1) 'U-M not engaged.'

		• Standard Public Health Surveillance or Prevention Activities **IRB review is not required for the following activities**, but researchers may wish complete this brief application to generate a determination letter for funding or publication purposes, or to request IRB review to confirm the "Not Regulated" determination: • Case Studies • Class Activities • Journalism/Documentary Activities • Oral History • Quality Assurance and Quality Improvement Activities • Research on Organizations • Research using Publicly Available Data Sets
☐	Projects **lacking immediate plans for involvement of human subjects**, their data, and/or their specimens	Activities such as training grants, program projects, center grants, or multi-phase studies not involving human subjects until later years. Before release of funding, some agencies may require IRB acknowledgement of the future use of human subjects. These projects are sometimes referred to as "umbrella projects" or "dry applications."
☐	**Single-patient Expanded Access Drug or Biologic (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational drug or biologic, outside of a clinical trial, under a single-patient IND issued by the FDA for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational drug or biologic is made. • Submission for IRB review and approval is required, prior to use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational agent.** • This includes both one-time use and continuing therapy.
☐	**Single-patient Expanded Access Device Use (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational device, outside of a clinical trial, when this is the only option available for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational device is made. • Submission for IRB review and approval is required, prior to device use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational device.** • This includes both one-time use and continuing therapy.
☐	**Humanitarian Use Device** (HUD) under a HDE	Non-research, on-label use of an HUD under a Humanitarian Device Exemption (HDE)
☐	Requesting Review by a **Non-UM IRB**	Use ONLY to request deferral of IRB oversight for UM activities to a non-UM IRB. Do not use Multi-site Research application type when U-M is **only** a performance site - select Standard application type.
☐	**Multi-site Research** where U-M is a Coordinating Center and/or IRB of Record	Select when U-M is any of the following: • Data Coordinating Center; • Clinical Coordinating Center; or • IRB of Record for non-U-M sites (for U-M to be IRB of Record you must contact your IRB for prior acknowledgement). When U-M is **also** a performance site, a separate application is required for local site

Threatening Circumstances
• FDA Expanded Access (including non-emergency single-patient use)

Humanitarian Use Device (HUD)
A HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.

• For clinical care use of a HUD under an HDE# (Humanitarian Device Exemption) where the HDE holder will **not** collect safety and effectiveness data to support a Premarket Approval (PMA) application complete the **"Humanitarian Use Device" Application**.
• For clinical care use of a HUD under an HDE# (Humanitarian Device Exemption) where the HDE holder **will** collect safety and effectiveness data to support a Premarket Approval (PMA) application complete a **Standard Application**.
• For emergent use or off-label use of an HUD that has received approval under a Humanitarian Use Device application at UM, go to the approved HUD workspace and complete an **ORIO 'Report to Oversight Entity' submission**.
• For emergent use of an HUD that is not previously approved under a Humanitarian Use Device application at UM, complete the "**Emergency one-time use** of an investigational or unapproved device" application.
• For investigational, off-label use of a HUD submit a **Standard Application** (and an Investigational Device Exemption (IDE) application to the FDA).