TITLE: NON-HUMAN SUBJECTS RESEARCH	SOP NO.: IRB 401a
EFFECTIVE DATE: 10-6-2025	REVISION NO.: 01

1. **PURPOSE**

1.1. The UMBC Institutional Review Board (IRB) oversees research involving human subjects. This policy provides the definitions that pertain to the determination of whether an activity meets the definition of human subject research and which activities will require IRB review.

1.2. SCOPE: This policy applies to activities that are potentially considered research conducted at UMBC.

2. **DEFINITIONS**

2.1. Food and Drug Administration (FDA) regulations define *clinical investigations* as: a) use of a drug other than the use of an approved drug in the course of medical practice; b) use of a medical device other than the use of an approved medical device in the course of medical practice; c) gathering data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, including a dietary supplement that bears a nutrient content claim or a health claim, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biological product for human use, or an electronic product. In the above criteria “approved” means “approved by the FDA for marketing.” FDA has defined clinical investigation to be synonymous with research.

2.2. Activities are *human subject research* when they meet the Department of Health and Human Services (DHHS) definition of “research” and involves the DHHS definition of a “subject”, or that meets the FDA definition of “clinical investigations” and involves the FDA definition of a “subject”.

2.3. DHHS regulations define *interaction* as communication or interpersonal contact between investigator and subject.

2.4. DHHS regulations define *intervention* as physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2.5. DHHS regulations define *private information* as 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) for obtaining the information to constitute research involving human subjects.

2.6. Research

2.6.1. DHHS defines *research* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2.6.2. FDA defines *research* as activities that meet the definition of "clinical investigations".

2.7. Subject

2.7.1. Under DHHS regulations *subject* means a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

2.7.2. Under FDA regulations, individuals are considered a *subject* when they become a participant in research, either as a recipient of the test article or as a control. If the research involves a medical device, individuals are considered a "subject" when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

3. POLICY

The UMBC IRB will review activities conducted at the institution and its affiliates when it is:

1. Human subject research as defined in FDA regulations.

2. Human subject research as defined in DHHS regulations.

3. Human subject research that meets the DHHS definition of research, regardless of the source of funding.

UMBC has agreed to a federalwide assurance (FWA) to apply the DHHS regulations. The terms of the assurance apply to all federally funded research conducted at the institution. Generally, the UMBC IRB applies the DHHS regulations to all human subject research conducted at the institution and its affiliates, regardless of the source of funding. Research that is not federally funded and that is outside of the FWA is subject to the same scrutiny except where otherwise described in UMBC IRB policy.

Research that does not meet the definition of research involving human subjects must be determined by the UMBC IRB staff, not an individual investigator, with certain exceptions (see exceptions below).

- The UMBC IRB has a list of datasets/repositories that it has found to be stripped of identifiers and which is publicly available. As a result, research using this data does not rise to level of "human subject research". Research projects involving analysis of secondary data from these pre-approved, publicly available datasets/repositories do not require prior UMBC IRB approval (see Investigator Guidance Series: Secondary Analysis of Existing Datasets).

- Medical Case Reports may not require prior UMBC IRB approval (see SOP 408: Medical Case Reports).

For the purposes of his policy, the following activities **are not** considered research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted supported, requested, ordered, required, or authorized by a public health authority.

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

- Authorized optional activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

The UMBC IRB has an abbreviated application (Kuali Protocols → Review Type → Non-Human Subject Research) that may be submitted to obtain a determination of non-human subject research. The IRB Chair makes the final determination and HRPI staff draft a notification letter of the final determination.

All research proposals that appear to meet the DHHS and/or FDA definition of human subject research require a full new study application and IRB review as with any other new study application.

4. Procedures

4.1. Non-Human Subject Research

4.1.1. Investigators who believe their research activities do not meet the regulatory definition of human subject research should submit an

IRB protocol application in Kuali and select the Review Type: “Non-Human Subject Research.” If a full new study application is submitted that does not meet the regulatory definition of research, it may still receive a determination of non-human subject research.

4.1.2. All information submitted by the investigator is reviewed using the IRB internal checklist. Determinations of non-human subject research are made by HRPI staff who may consult with the IRB Chair or IRB Manager, if necessary. Additional information may be requested via the Kuali application, as needed.

4.1.3. If a determination of non-human subject research is made, the investigator is notified via Kuali. A notification letter of NHSR determination is uploaded to the Admin. Notes & Files section of the respective Kuali protocol. This letter is visible to the investigator and should be included in their research project files.

4.1.4. If the HRPI staff member determines that the project meets the regulatory definition of human subject research, the review proceeds as with any other new study application.