TITLE: RESEARCH ACTIVITIES EXEMPT FROM IRB REVIEW	SOP NO.: IRB 401b
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 defines what research may be exempt from IRB review and the procedures for determining when research may be exempt from IRB review.

1.2. SCOPE: This policy applies to research conducted at UMBC.

2. **DEFINITIONS**

2.1. ***Limited IRB review*** is a process that is required only for certain exemptions and does not require an IRB to consider all the IRB approval criteria in 45 CFR 46.111. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations are met.

2.2. ***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3. **POLICY**

Human subject research that is categorized as exempt research is exempt from most of the requirements in the federal regulations for protection of human subjects. Exempt research must be no greater than minimal risk and must fit within an exemption category. Investigators are expected to adhere to principles of sound research design and ethics and follow any applicable state laws and University policies.

The UMBC IRB utilizes the exemption categories 1-6 as outlined in 45 CFR 46.104 for federally funded research. The UMBC IRB does not utilize broad consent and the exemption categories intended for research using broad consent (categories 7-8) are not applied at UMBC. The UMBC IRB designated additional exemption categories (A-E) for research with no federal oversight. The exemption categories (federal and non-federal) are posted here:

3.1. For the following non-Federal exemption categories (A-E), the research must meet the following criteria in addition to all specification of the exemption category:

3.1.1. Criteria for non-Federal exemption categories (A-E)

- Research is not subject to FDA regulations;
- Research is not federally funded;
- Research is not contractually or otherwise subject to federal research requirements, including but not limited to research conducted under the Department of Veterans Affairs or under an NIH Certificate of Confidentiality;
- Research does not involve prisoners as participants;
- Research meets the University's ethical standards governing the conduct of the research, including appropriate provisions for the protection of privacy and confidentiality when identifiable and coded information are used.

3.1.2. Exemption Categories

A. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, where this information is personally identifiable or coded.

B. Research involving the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml [37 Tbsp] in an 8 week period and collection may not occur more frequently than 2 times per week; OR

2. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml [3.4 Tbsp] or 3 ml per kg [0.28 tsp per lb] in an 8 week period and collection may not occur more frequently than 2 times per week.

C. Prospective collection of biological specimens for research purposes by noninvasive means.

D. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not eligible for exempt review under this category.)

E. Research on individual or group characteristics or behavior (including, but not limited to, research or perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, collection of recordings (voice, video, digital, or image), program evaluation, human factors evaluation, or quality assurance methodologies, unless:

    1. Information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

For the purposes of this policy, IRB staff who are designated IRB members are termed IRB reviewers. Exemptions are determined by an IRB reviewer. In limited circumstances, investigators may obtain an exemption determination using a guided application process in the UMBC Kuali System. Guided exemptions are only offered for eligible projects based on answers in the new study application and cannot be requested by investigators. Investigators have the option to request that an IRB reviewer make the exemption determination rather than relying on the guided application process.

Exemption determinations are recorded and stored in Kuali. If an IRB reviewer believes that a study proposal may be eligible for exemption but poses ethical concerns, it will be reviewed as with any other new study application.

All exempt reviews conducted by an IRB reviewer meet the requirements of a limited IRB review by ensuring that when appropriate, the research plan includes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Investigators are not given an option to use the guided exemption if a limited IRB review is required. UMBC retains the authority to suspend or terminate IRB approval of research approved with a limited review.

Continuing review is not required for studies determined to be exempt. To keep the study open and active with the UMBC IRB and Human Research Protection Program (HRPP), an Annual HRPP Progress Update must be submitted.

Substantive changes to the exempt study must be submitted via amendment application to ensure the study still qualifies for exempt status considering the changes. Exempt studies must adhere to the UMBC IRB reporting requirements for unanticipated problems and deviations. Exempt studies must be closed with the IRB once the research activities are complete.

4. PROCEDURES

4.1. Exempt Research

4.1.1. The investigator submits a new study protocol application in Kuali.

4.1.2. Based on the responses provided in the new study application, some study proposals may be eligible for a guided exemption. If eligible, the investigator is given the option to receive a guided exemption or to request that the application be referred to an IRB reviewer for an exemption determination. If the investigator opts for the guided exemption, the investigator will follow all prompts and agree to all stipulations in Kuali in order to receive confirmation from Kuali of the exemption determination.

4.1.3. The IRB reviewer conducts a review of the research proposal using the IRB internal checklist (Determining if Human Research is Exempt from IRB review) within Kuali. When one or more of the exemption categories are applicable to the research, the IRB reviewer documents the applicable category(ies) using the internal checklist and makes the final exemption determination.

4.1.4. All exemption determinations are communicated to the investigator via Kuali, and includes the applicable category(ies) justifying the exemption determination.

4.1.5. If the IRB reviewer determines the proposal is not eligible for an exempt determination, including limited review, the IRB reviewer will move the application to an expedited or convened board review. The research may only be tabled or disapproved by the convened IRB.