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| <b>TITLE: INITIAL REVIEW – CRITERIA<br/>FOR IRB APPROVAL</b> | <b>SOP NO.: IRB 403</b> |
| <b>EFFECTIVE DATE: 10-6-2025</b>                             | <b>REVISION NO.: 01</b> |

## **1. PURPOSE**

- 1.1.** The UMBC Institutional Review Board (IRB) must ensure all regulatory criteria are met before approval is to conduct research is granted.
- 1.2. SCOPE:** This policy applies to non-exempt human subject research conducted at UMBC.

## **2. POLICY**

All research proposals involving human subjects must meet specific criteria before study-related procedures can begin. These criteria are based on three core principles from the Belmont Report: respect for persons, beneficence and justice; they are explicitly outlined in the Common Rule regulations ([45 CFR 46111](#)). All regulatory criteria must be met, including any applicable state or local laws. In addition, unique criteria specific to UMBC may also apply and must be met. To ensure all regulatory criteria and additional requirements are met, the UMBC IRB uses a checklist system.

The criteria for approval and other applicable requirements are outlined in the board member checklist. Assigned IRB reviewers must complete this checklist to ensure that all approval criteria and requirements are met.

More detailed information about the approval criteria and other requirements is provided according to specific topics. Board members may access supplemental guidance on the UMBC IRB or HRPI websites or on the UMBC Quali Protocol online system.