TITLE: IRB PROTOCOL RENEWAL PERIOD	SOP NO.: IRB 411
EFFECTIVE DATE: 10-6-2025	REVISION NO.: 01

1. POLICY

This policy outlines a standard approach for selecting IRB protocol renewal periods (length) and requirements at UMBC. This policy allows both the IRB and HRPI to access routine criteria for making these renewal or continuation period decisions. As an institution, UMBC has the authority to define whether to require protocol renewal review processes (including defining the length of approved renewal) of Expedited studies (no more than minimal risk). Exempt studies do not require renewal or continued review. This policy was prompted by the possibility of other, collaborative organizations that may impose varied regulations in addition to those of UMBC. Such organizations may include but are not limited to: FDA (regarding device studies, etc.), DOJ, NSF, NIH, DoD, among other funding sponsors.

Protocols that meet any of the following characteristics are subject to one-year renewals (must undergo review every 365 days for the approval of continuation):

a) Protocols for studies that may fall under the purview of the FDA
b) Protocols for studies that are funded by the DOJ
c) Protocols that were initially approved prior to the 2018 Common Rule
d) Student protocols
e) Protocols where the primary reviewer specially requests a one-year renewal period (with justification)
f) Protocols where the PI has a record of continued noncompliance or serious noncompliance. A record of continued noncompliance or serious noncompliance is defined as a PI having one or more past instances of either form of noncompliance.

If any changes need to be made in the study protocol, the PI must submit an amendment request and receive approval notification before implementing the changes. If an adverse event occurs or is brought to the researchers' attention, the researcher is expected to submit a report immediately.