

Human Research Protections Program (HRPP) Newsletter

A Look Ahead: Upcoming IRB Updates Supporting Clarity, Consistency, and Compliance

The IRB is implementing a series of administrative and regulatory updates on a rolling basis to support clarity, consistency, and compliance across review processes and submission guidance.

- **Consent guidance:** Clarifications are underway for select consent sections, including risk descriptions and data use.
- **IRB review criteria:** Updates will clarify when certain federal requirements apply, including Department of Defense (DoD) considerations for some studies conducted outside the United States and Department of Justice (DOJ) requirements for applicable activities. Applicability is determined during IRB review.
- **CICERO application:** Updates clarifying (1) the limitations on which exempt criteria may be applied to FDA-regulated studies and (2) the documentation required when external sites rely on the UMB IRB. These updates are being rolled out in CICERO.

Additional information will be shared as updates are implemented.

UMB IRB Chair & HRPO/IRB Virtual Office Hours

Join us the second Monday of each month from 12 - 1 pm.

Have questions about research, IRB submissions, or review processes?

All are welcome. No reservation is required

<https://umaryland.zoom.us/j/95695695923?pwd=RNkVmEbTox7fbjGaTqGORBojpXAGqJ.1>

IRB Consults Available

Do you need assistance with your IRB protocol design, scientific and regulatory issues, or personalized research guidance for human research studies?

Visit the link below to schedule a meeting with an IRB Vice Chair for expert support.

<https://www.umaryland.edu/hrp/for-researchers/crtmp-request-form/>

CALL FOR IRB MEMBERS

Interested in being part of a collaborative effort that supports ethical, high quality human subjects research?

Learn more about IRB membership by scanning the QR code or visiting:

<https://www.umaryland.edu/hrp/institutional-review-board-irb/join-the-irb/>

