FISCAL YEAR 2025

# HUMAN RESEARCH PROTECTIONS PROGRAM ANNUAL REPORT



Presented to

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UNIVERSITY of MARYLAND BALTIMORE

OFFICE OF ACCOUNTABILITY AND COMPLIANCE


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# HIGHLIGHTS

In FY2025, the Human Research Protections Program (HRPP) at UMB advanced its mission of safeguarding research participants while supporting innovative, compliant research. Through successful federal oversight reviews, expanded education and outreach, strategic leadership enhancements, and strengthened collaboration across campus, the HRPP continued to foster a culture of ethical research, transparency, and institutional accountability. Highlights include:

- Successful FDA Inspection:
  - Routine FDA inspection of the IRB in January 2025 resulted in no findings, affirming compliance with 21 CFR Parts 50 and 56 and validating UMB's strong IRB processes.
- High-Volume IRB Operations:
  - 5,462 transactions processed (new protocols, continuing reviews, modifications, and reportable information) through full board and expedited review pathways.
  - Achieved timely, thorough reviews supported by process improvements, staff training, and strong investigator collaboration.
- Strategic Leadership Enhancement:
  - Hiring a new HRPP Executive Director to strengthen program coordination, streamline decision-making, and unify human research protections efforts.
  - Executive Director joined the reimagined Research Compliance Coordinating Council to enhance cross-departmental collaboration and elevate HRPP's institutional role.
- Expanded Communication & Education:
  - Launched IRB/HRPO Virtual Office Hours, Tip of the Month, and a Monthly HRPP Newsletter, reaching broad audiences with timely updates and best practices.
  - Delivered 40 educational sessions to 790 attendees, enhancing researcher knowledge and regulatory understanding.
- Enhanced Cross-Functional Collaboration:
  - Welcomed a UMB Office of Emergency Management representative to IRB meetings to improve emergency planning awareness and integrate risk management.
- Operational Resilience & Single IRB Readiness:
  - Implemented staff cross-training to ensure continuity and flexibility in managing reliance agreements for multi-site studies.
- Improved ClinicalTrials.gov Compliance:
  - Developed an automated outreach system to improve trial registration and reporting accuracy, strengthening transparency and accountability.


# PROGRAM SUMMARY

The University of Maryland, Baltimore's Human Research Protections Program (HRPP) ensures ethical and regulatory oversight of research involving human participants, safeguarding their rights, safety, and well-being. Guided by the principles of respect, beneficence, and justice, the program integrates federal regulations, institutional policies, and best practices to foster ethical research conduct.

Human subjects research operates under federal regulations such as the Common Rule (45 CFR 46), FDA regulations, and other applicable state and institutional requirements. These frameworks establish clear standards for promoting research that is conducted with the highest ethical standards.

The HRPP plays a vital role in supporting the Institutional Official and the Institutional Review Board (IRB) by coordinating oversight activities, ensuring compliance, and providing guidance throughout the research lifecycle.

The program is inherently collaborative, coordinating among multiple institutional stakeholders —from research administrators and compliance officers to investigators and study teams—to implement robust protections throughout the lifecycle of a study. This includes initial protocol review, ongoing monitoring for compliance, and prompt reporting of adverse events or unanticipated problems. This interconnected approach reinforces accountability, transparency, and continuous improvement, while building public trust in UMB's research enterprise.

As research methodologies and technologies evolve, so too must the protections infrastructure— requiring agile policies, resiliency planning, thoughtful oversight, and sustained education to navigate complex ethical landscapes.

# STRATEGIC GOALS

The strategic goals of UMB's Human Research Protections Program (HRPP) provide a framework for advancing ethical research, strengthening compliance, and building institutional trust. As research evolves—with new technologies, collaborative studies, and complex trial designs—the HRPP continues to adapt to meet emerging challenges.

UMB Human Research Protection Program Strategic Goals:

- Communicate compliance activities and responsibilities to leadership
- Communicate OAC services and information, including reporting mechanisms, to the UMB community
- Collaborate and create compliance resolution process efficiencies
- Establish collaborative and effective compliance auditing and monitoring program to promote efficiency and effectiveness in meeting compliance obligations
- Optimizing the accuracy of audit monitoring
- Regular dissemination of audit patterns to foster improved research practices
- Review, revise, and enhance policies and procedures that are the responsibility of OAC
- Development of educational offerings for HRPP components based on stakeholder feedback

These goals focus on continuous improvement, cross-functional collaboration, and participant-centered protections. They emphasize expanding education for researchers, improving operational efficiency, integrating quality metrics, and fostering a resilient, ethically grounded research culture. Together, these goals ensure that UMB maintains robust safeguards while supporting responsible innovation.

# RISK & RESILIENCE

In FY 25 (3rd Q 25), the Human Research Protection Program (HRPP) prioritized risk mitigation and operational resiliency as foundational elements of its strategic vision. Recognizing the dynamic nature of the research environment, the HRPP began to develop and implement a series of initiatives designed to strengthen its ability to anticipate, respond to, and recover from disruptions while maintaining the highest standards of human subjects protection.

***Risks***:
The HRPP operates in a complex regulatory and research environment and key risks to the program include:

- Regulatory noncompliance
- Participant safety and privacy
- Resources/financial constraints
- Evolving research methods
- Technology and system vulnerabilities

***Resilience***:
Aligned with the Office of Accountability and Compliance (OAC) Integrated Resilience Framework, focused on:

- Building institutional capacity
- Enhancing cross-functional collaboration
- Promoting continuity of critical review and oversight functions

Through proactive planning, staff cross-training, and integrated communication strategies, the HRPP will continue to reinforce its commitment to safeguarding research participants and supporting investigators in an increasingly complex regulatory landscape.

# REGULATIONS POLICIES & PROCEDURES

In FY2025, the HRPP conducted with its annual comprehensive review and refinement of its policies, procedures, and regulatory guidance to ensure alignment with evolving federal requirements, institutional priorities, and best practices. Examples of policies, procedures, and guidance documents reviewed and/or updated include:

- HRP-001 SOP Definitions
- HRP-020 SOP Incoming Items
- HRP-021 SOP Pre-Review
- HRP-031 SOP Non-Committee Review Preparation
- HRP-041 SOP IRB Meeting Conduct
- HRP-043 SOP IRB Meeting Minutes
- HRP-052 SOP Post Review
- HRP-055 SOP Financial Conflicts of Interest
- HRP-062 SOP Daily Tasks
- HRP-064 SOP NIH GDS Institutional Certification
- HRP-071 SOP Toolkit Management
- HRP-080 SOP IRB Formation
- HRP-084 IRB Meeting Scheduling and Notification
- HRP-102 Flowcharts
- HRP-101 UMB HRPP plan
- HRP-103 Investigator Manual
- HRP-303 Worksheet -Communication of Research Results
- HRP-306 Worksheet - Drugs
- HRP-307 Worksheet – Devices
- HRP-308 Worksheet Pre-review
- HRP-311 Worksheet Criteria for approval & Additional considerations
- HRP-317 Cognitively Impaired Adults
- HRP-431 Checklist Minutes Quality Improvement Assessment

In FY2025, the HRPP placed a strong emphasis on communicating updates to equip all stakeholders with information to uphold the highest standards of human subjects research.

***For more information or to access HRPP policies, procedures, and guidance, visit the For Researchers Sections at https://www.umaryland.edu/hrp/for-researchers/.***

# Institutional Review Board

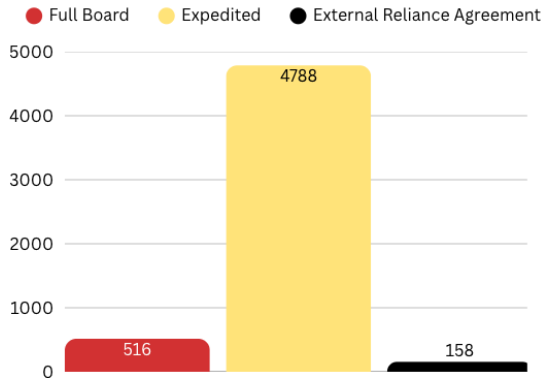
The IRB is responsible for protecting the rights and welfare of individuals participating in research. At UMB, the IRB reviews and approves research protocols and amendments to promote compliance with ethical principles, federal regulations, and institutional policies.

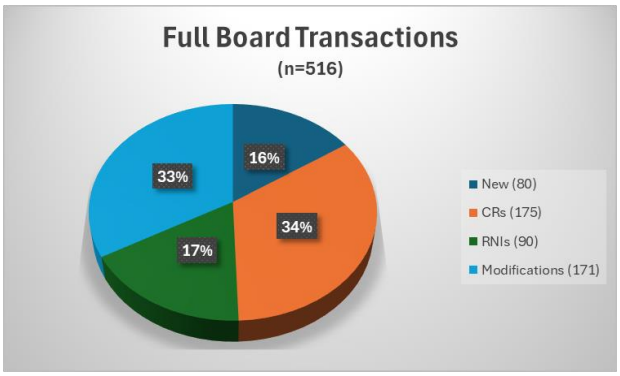
***Composition***:
During FY25, an active recruitment process resulted in the addition of 13 new members, enhancing its expertise and diversity. The new members include:

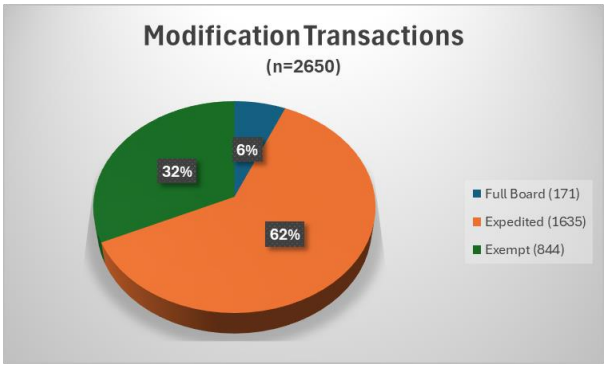
- Affiliated scientist: 10
- Non-affiliated scientist: 1
- Non-affiliated non-scientist: 2

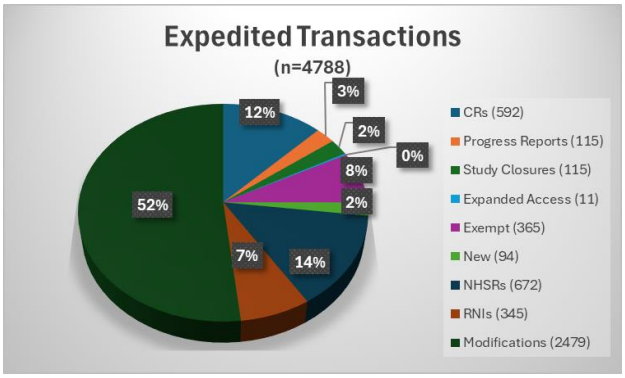
This balanced composition strengthens the IRB's ability to ensure ethical oversight, scientific rigor, and community representation in research review activities.

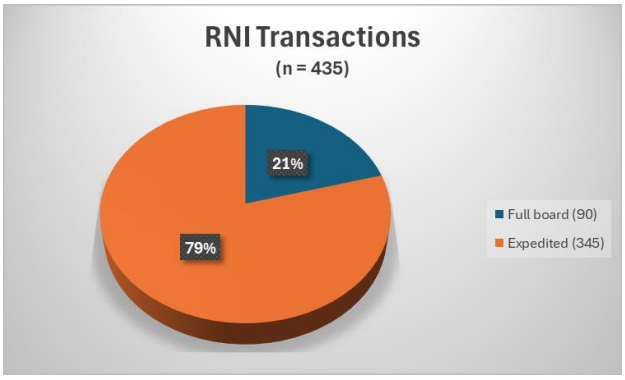
***Performance***:
During FY25, the UMB IRB/HRPO team processed a total of **5,462 transactions** through both full board and expedited review pathways. This includes new protocols, continuing reviews, modification and reportable new information. The volume reflects the complexity of the UMB research portfolio, as well as the IRB's commitment to timely and thorough review processes. This volume of activity was supported by ongoing process improvements, staff training, and close collaboration with investigators.





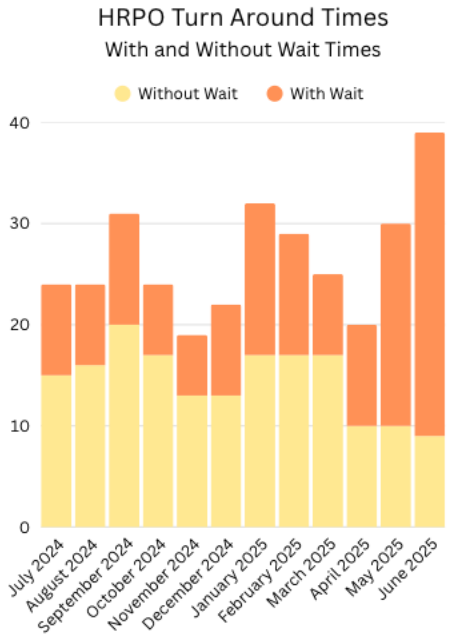

***Operations*:**

The IRB held sixty-eight (68) IRB meetings in FY 25, continuing its commitment to flexibility in review processes.

The IRB Chair, Dr. Jonmark Hirshon, IRB Senior Vice Chair, Dr. Jim Campbell, and the IRB Vice Chairs, Drs. Mili Tapia and Jocelyn Leung, demonstrate a strong commitment to the integrity and effectiveness of the Human Research Protection Program through regular Executive committee meetings focused on regulatory and ethical issues. These discussions provide a vital forum for addressing emerging challenges, interpreting evolving guidance, and ensuring consistency in IRB decision-making. By engaging in collaborative dialogue, leadership fosters a shared understanding of complex topics and reinforces the program's dedication to protecting human subjects while supporting high-quality research.

***Performance:***

**Protocol Reviews**




During FY25, the average processing time for new protocols and continuing reviews was 14.5 calendar days without wait times and 26.59 calendar days with wait times.

Wait times in the approval process refer to the period during which the Principal Investigator (PI) is completing responses to requested clarifications, edits, or additional information.

The average time from submission to the first action by an HRPP analyst or coordinator was 5.10 calendar days.

Prior to receipt for IRB processing, new applications spent an average of 14.84 days in department or specialty review.

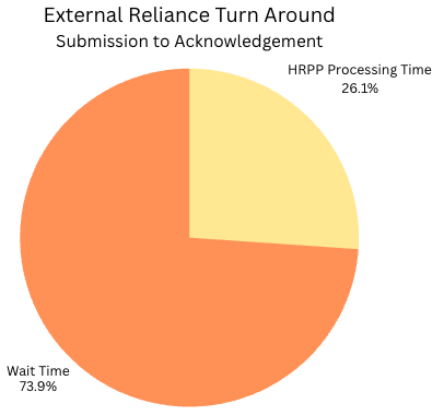
***Modification Reviews:***

The average time from submission to approval for study modification is 7.8 calendar days.

**External Reliance Reviews**

An external reliance acknowledgement occurs when UMB agrees to rely on another institution's Institutional Review Board (IRB) for the ethical review and oversight of a research study,

During FY25, 153 reliance agreements were reviewed with the average processing time for reliance agreements being 11.92 calendar days without wait times and 45.58 calendar days with wait times. The average time from submission to first action by HRPP personnel was 2.32 calendar days.

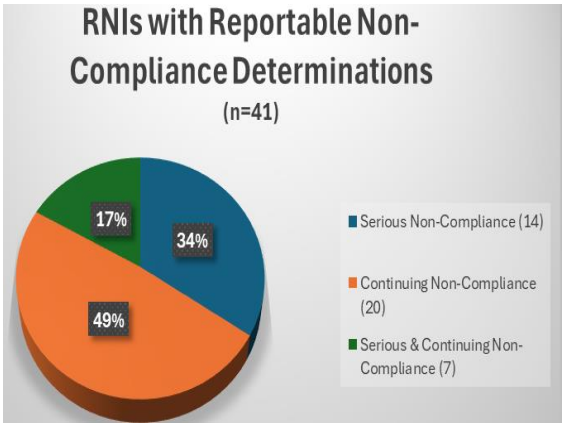


# RESEARCH SUBJECT ADVOCACY AND SAFETY

The UMB Research Subject Advocate and Safety Specialist (RSA&SS) plays a vital role in safeguarding the rights and well-being of research participants. By reviewing the 435 reportable new information reports submitted in FY 25, with ninety (90) requiring full IRB determination and responding to several participant and family concerns, this position ensures that issues related to safety, ethics, and communication are addressed promptly and thoroughly.

Of the ninety (90) reviewed at full board, the IRB determined:

- fourteen (14) constituted serious non-compliance
- twenty (20) constituted continuing non-compliance
- seven (7) constituted serious and continuing non-compliance.




Reporting was required to external oversight agencies in nineteen (19) instances.

The RSA&SS addressed five (5) specific concerns raised by either research participants, their family members, or external stakeholders. These concerns encompassed a range of issues. Also, fifteen (15) Medical, Dental, or Patient Care-related cases were addressed by the RSA&SS, with continued education, and support for clinical staff. The work of the RSA&SS not only reinforces institutional accountability but also fosters trust between the research community and the individuals it serves. This commitment to participant advocacy is a cornerstone of the HRPP's mission to uphold the highest standards of human subjects protection.

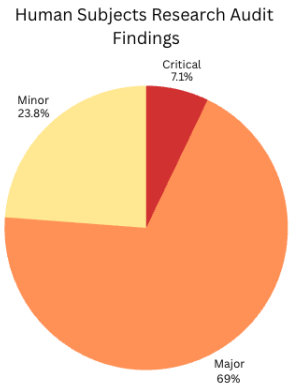
In addition, the RSA&SS played a key role in UMB's activities to preventing protocol expiration, a critical component of maintaining compliance and protecting the rights and welfare of research participants. The RSA&SS proactively engaged with 115 Principal Investigators (PIs) to ensure that continuing review requirements were met in a timely manner. Through regular communication, reminders, and individualized support, the Advocate helps investigators navigate submission timelines and avoid lapses in IRB approval that could disrupt study activities or place participants at risk. Preventing protocol expiration reduces administrative burden, minimizes delays in study progress, and ensures that participant protections remain uninterrupted. This collaborative approach fosters a culture of shared responsibility and accountability.

# AUDITING & MONITORING

Auditing and monitoring are essential components of a strong Human Research Protection Program, providing oversight to ensure compliance with ethical standards and regulatory requirements. These activities help identify areas for improvement, reinforce best practices, and promote accountability across the research enterprise.

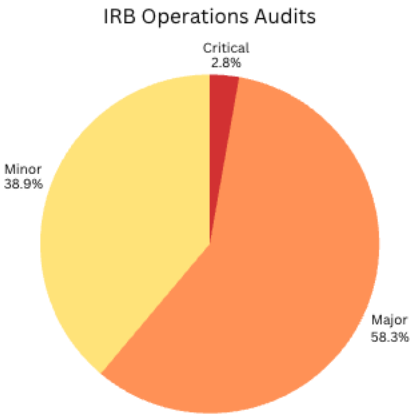
During FY25, six (6) human subjects research audits were conducted. The audits identified:

- 3 critical findings
- 29 major findings
- 10 minor findings




In response to findings, PIs developed corrective action and preventative plans to improve research processes and promote subject safety and welfare.

Eight (8) IRB Operations audits were conducted. The audits identified:




- 1 critical finding
- 21 major findings
- 14 minor findings

When IRB review deficiencies are identified, IRB leadership takes prompt and structured action to address the issues and strengthen review quality. This includes conducting targeted training for IRB staff, revising internal procedures and enhancing review tools or checklists to ensure consistency and regulatory compliance. Management also facilitated case discussions to reinforce ethical standards and improve decision-making. These corrective and preventive measures reflect the HRPP's commitment to continuous improvement and the protection of human research participants.

In 2025, the HRPP conducted quality reviews of 68 IRB meeting minutes to ensure clarity, accuracy, and compliance with federal requirements. These assessments strengthen the integrity of IRB deliberations by verifying documentation of quorum, participation, conflict-of-interest management, and the rationale for decisions. Regular evaluation enhances transparency, supports consistent practices across panels, and reinforces UMB's commitment to ethical oversight and regulatory compliance.

# EDUCATION

Education remains a cornerstone of the HRPP's mission to uphold the highest ethical and regulatory standards in human subjects research. During FY25, the HRPP has continued to invest in comprehensive training initiatives designed to equip investigators, research staff, and HRPO staff and Institutional Review Board (IRB) members with the knowledge and tools necessary to review and conduct research responsibly and in compliance with federal, state, and institutional policies.

During FY25 workshops, and targeted sessions on areas such as data privacy, community-engaged research, and AI in human subjects research were added. These initiatives were informed and aligned with national trends in research ethics education.

***Educational Outreach*:**
The UMB HRPP offered thirty-seven (37) sessions with seven hundred and ninety (790) UMB attendees, including:

- School of Medicine Summer Program- IRB Processes and Investigator Responsibilities
- School of Social Work – A Dialogue with the IRB
- Carey School of Law – Health Law Workshop
- Graduate School Orientation – Intro to IRB/HRPO
- School of Dentistry - Dental Hygiene Students IRB Submission Discussion
- School of Nursing – Informed Consent Approaches
- Intro to Clinical & Translational Research at UMB and VAMHCS
- Research Administrator's Day – JIT& IRB Processes
- RAMP Lunch & Learn – Mock IRB Session
- Biobanking
- Research Quality Management
- Post-Doc Responsible Conduct of Research – IRB Processes
- HRPP Grand Rounds were held on topics related to single IRBs and external reliance agreements.

The HRPP has prioritized accessibility and continuous learning. We enhanced our communication of online education resources, recorded webinars, and self-paced courses, allowing researchers to engage with content on their own schedules. Our team also provided tailored consultations and office hours to support IRB application submissions and address specific educational needs.

Additionally, thirty-five requests (35) were made either by investigators or at the request of the IRB for Clinical Research Training and Mentoring (CRTMP) support. To date, nineteen (19) of those protocols have gone on to secure IRB approval after the investigator's collaboration with the UMB CRTMP faculty. The program is a specialized initiative designed to enhance the quality and integrity of human subjects research across the university.

***Professional Development:***

Ongoing training is critical to maintaining a knowledgeable, responsive, and compliant HRPP. As regulations and research practices evolve, staff education ensures alignment with best practices and supports a culture of ethical research and institutional accountability. In FY25, educational sessions for HRPP staff included:

- Attendance at annual meeting of Primary Responsibility in Medicine & Research meeting (PRIM&R)
- Attendance at annual meeting of Association for the Accreditation of Human Research Protections Program (AAHRPP)
- UMB SPARK Supervisor Academy
- IRB EasyEd—Satisfying the Criteria for Approval
- Harnessing AI for Scholarly Success
- HRPP Huron Toolkit Update with HRPO Staff
- Metrics Update with HRPO Staff
- CIRTification Training Program
- The Evolving Landscape of Human Research with AI
- FDA-Regulated Research Workshop
- OHRP – Advancing Research Participation for LGBTQI+ Individuals
- Single IRB processes and external reliance agreements
- Clinical Trials Registration and Results Reporting Taskforce-Panel on Best Practices for PRS Administrators
- Cloud Security Risk, and Compliance: Managing Security in the Cloud Era
- ICH E6 (R3) is Here- What You Need to Know
- Internal Quality Control: A Guide to Checking Your Work
- Becoming Authentic, Accountable, And Trustworthy

Finally, the HRPP implemented a multi-tiered education strategy for new and revised policies, procedures, and guidance. IRB members received updates through dedicated training, board meetings, and a member SharePoint site, ensuring they were well-prepared to apply changes in protocol review. HRPO staff participated in targeted briefings and cross-functional discussions to support consistent implementation and operational alignment of updated procedures..

# COMMUNICATION

Effective communication is vital to the success of the HRPP, ensuring researchers, IRB members, and stakeholders remain informed, engaged, and equipped to uphold ethical standards. During FY25, the HRPP has prioritized strategic communication as a means to strengthen trust, promote compliance, and foster a culture of ethical research across the institution.

Communication serves as the bridge between policy and practice. By delivering timely updates, clarifying regulatory changes, and providing accessible guidance, the HRPP ensures that researchers, IRB members, and institutional stakeholders are well-informed and equipped to uphold human subjects protections.

In FY25, the HRPP expanded its outreach through:

- Monthly newsletters (n=5)
- "Tip of the Month" features (n=5)
- Targeted email alerts (n=5)

The communications were shared via The Elm and digital platforms to improve accessibility and engagement. Additionally, forty-five (45) CICERO communications were sent to stakeholders. These efforts promoted transparency, supported compliance, and reinforced a culture of ethical research across UMB.

Key announcements shared with the research community included:

- FDA IRB Visit Outcome (January 2025)
- Updates to the informed consent document (ICF) template
- Certificates of Confidentiality – changes in processing
- Single IRB reporting requirements for studies relying on an external IRB (HRPO Grand Rounds)
- After IRB approval: What needs to be reported to the UMB IRB? (HRPO Grand Rounds)
- Introduction of the UMB IRB Chair and HRPO/IRB Virtual Office Hours
- DHHS Office of Human Research Protections and Office of Research Integrity videos: The Lab and The Research Clinic
- Baltimore SOCRA and UMSON Research Seminar: "Scary Compliance!"
- Monthly Research Seminar: "A Regulatory Binder QA Journey"
- UMB Research Compliance Strategic Plan Virtual Town Hall (December 3, 2024)
- UMB Contracts presentation
- UMB guidance for NIH Stop Work Orders

Through these efforts, the HRPP streamlined messaging, reduced information silos, and created new opportunities for two-way dialogue with the research community.

# FUTURE INITIATIVES

The Human Research Protections Program (HRPP) remains committed to fostering a culture of ethical research through continuous education, enhanced communication, and strategic innovation**.** In the coming year, we will assess the impact of training programs, expand innovative delivery methods, and collaborate with institutional partners to ensure researchers are well-prepared to navigate the evolving landscape of human subjects research.

***Strengthening Systemwide Collaboration***

- Engage with the USM IRB Administrators Group to share expertise and align best practices.
- Serve as the Embryonic Stem Cell Research Oversight (ESCRO) committee of record for another USM institution, streamlining oversight and ensuring consistency.

***Building Capacity and Resilience***

- Explore the development of a Single IRB (sIRB) of record framework to support multi-site research and enhance institutional resiliency allowing UMB to serve as the reviewing IRB for partner institutions.
- Cross-train staff to enhance capacity for complex reviews, ability to respond to regulatory changes, and promote continuity of service.
- Improve the time-to-study activation workflow, ensuring that studies move from submission to approval more efficiently without compromising quality or compliance.

***Leveraging Technology and Innovation***

- Create and deploy AI-powered microlearning opportunities that are accessible on demand.
- Launch a unified compliance web portal to centralize policies, forms, and training resources.
- Introduce an AI-powered chatbot to provide real-time, 24/7 guidance on submissions, amendments, consent, and regulatory requirements—improving accessibility and reducing response times.

Together, these initiatives reflect the HRPP's ongoing commitment to innovation, collaboration, and continuous improvement. By integrating new technologies, expanding partnerships, and streamlining operations, the HRPP continues to strengthen ethical oversight while supporting a responsive, researcher-friendly environment for high-quality human subjects research.

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