UNIVERSITY of MARYLAND BALTIMORE

FY 2026

Human Research Protection Program

Office of Accountability and Compliance |
University of Maryland Baltimore

ANNUAL REPORT

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HIGHLIGHTS

In FY2026, the Human Research Protections Program (HRPP) at UMB advanced its mission of safeguarding research participants while supporting innovative, compliant research. Through a successful accreditation visit, 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 AAHRPP re-accreditation site visit
  - In June 2026, demonstrating continued excellence in human research protections and compliance with accreditation standards. HRPP components specifically recognized by AAHRPP included the PATIENTS Program and the Office of Emergency Management.
- High-Volume IRB Operations:
  - 5,227 transactions were processed (new protocols, continuing reviews, modifications, and reportable information) through full board and expedited review pathways.
  - Maintained timely and comprehensive review processes through targeted process improvements, ongoing staff development, and effective collaboration with investigators.
- UMB IRB Chair, Dr. JonMark Hirshon, invited to be a panelist for : "Belmont Report at Belmont: Where Modern Human Research Protections Were Shaped." The event will bring together leaders in research ethics and the public to reflect on the Belmont Report's lasting impact on the protection of human research participants and its influence on modern research oversight.
- Strategic Leadership Enhancement:
  - Hired a new HRPP Executive Director to strengthen program coordination, streamline decision-making, and unify human research protections efforts.
  - Executive Director will join the Research Compliance Coordinating Council to enhance cross-departmental collaboration and elevate HRPP's institutional role.

- Expanded Communication & Education:
  - Continued with IRB/HRPO Virtual Office Hours, Tip of the Month, and a Monthly HRPP Newsletter, reaching broad audiences with timely updates and best practices.
  - Delivered 34 educational sessions to 750 attendees, enhancing researcher knowledge and regulatory understanding.
- Implemented a refresher on Departmental/Scientific Feasibility Review, reinforcing the importance of early scientific and operational evaluation to support successful study conduct and regulatory compliance.
- Advanced community consultation and public engagement efforts
  - Support for Exception from Informed Consent (EFIC) research, with OAC leadership participating in both community focus groups and broader stakeholder outreach to listen to community perspectives on emergency research conducted without prospective informed consent.

PROGRAM SUMMARY

The University of Maryland, Baltimore's Human Research Protections Program (HRPP) provides comprehensive ethical and regulatory oversight for research involving human participants, with a primary focus on protecting their rights, safety, and welfare. Grounded in the ethical principles of respect for persons, beneficence, and justice, the HRPP integrates federal regulations, institutional policies, and recognized best practices to promote responsible and ethical research.

Human subjects research is governed by a complex framework of requirements, including the Common Rule (45 CFR 46), FDA regulations, and applicable state and institutional policies. Together, these standards establish the foundation for conducting research that meets the highest ethical and regulatory expectations.

The HRPP serves as a critical partner to the Institutional Official and the Institutional Review Board (IRB), coordinating oversight activities, supporting regulatory compliance, and providing guidance to investigators and study teams throughout the research process.

As a collaborative program, the HRPP works closely with a wide range of institutional stakeholders—including investigators, research staff, compliance personnel, and research administrators—to ensure robust protections are embedded across all stages of a study. Its responsibilities span protocol review and approval, ongoing compliance monitoring, and the timely assessment and reporting of adverse events and unanticipated problems. Through this coordinated approach, the HRPP promotes accountability, transparency, and continuous quality improvement while strengthening public confidence in UMB's research enterprise.

As research methods, technologies, and data environments continue to evolve, the HRPP must remain adaptable and forward-looking. Effective human research protections require responsive policies, resilient oversight structures, proactive risk management, and ongoing education to address emerging ethical and regulatory challenges in an increasingly complex research landscape.

The Research Compliance Coordinating Council continued to serve as an important forum for communication, coordination, and collaboration among key research stakeholders, fostering a shared approach to research oversight and compliance activities across the institution. Through updates and discussions on critical topics such as time to

study activation, grants management, international research, artificial intelligence, and other emerging issues, Council members exchanged information, identified opportunities for process improvement, and strengthened cross-functional partnerships. The Council also facilitated timely updates on major institutional initiatives, including AAHRPP re-accreditation preparations and the upcoming site visit, the IRB Applications Reimagined project, future research submission platform enhancements, customer experience initiatives, strategic alignment efforts of the HRPP, and updates to research web resources. These ongoing interactions promoted transparency, enhanced organizational alignment, improved awareness of compliance and operational priorities, and ensured that stakeholders remained actively engaged in advancing a coordinated, efficient, and effective research compliance program.

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 26, 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

The resiliency planning implemented by the HRPO/IRB proved highly effective during a period of position reductions and organizational realignments, enabling the program to maintain continuity of operations, regulatory compliance, and high-quality review processes despite reduced staffing resources. Through proactive workforce planning, cross-training of personnel, redistribution of critical responsibilities, and the standardization of key operational procedures, the HRPO/IRB was able to preserve institutional knowledge and minimize disruptions to protocol review timelines and investigator support services. Leadership regularly assessed workload demands and strategically aligned available staff with mission-critical functions, ensuring that essential regulatory, administrative, and oversight activities continued without compromising ethical review standards or participant protections. In addition, enhanced collaboration among team members, clear communication regarding role transitions, and the use of documented processes and performance monitoring tools helped maintain productivity and accountability throughout the restructuring period. As a result, the HRPO/IRB successfully adapted to staffing changes while sustaining operational effectiveness, supporting stakeholders, and demonstrating

organizational resilience in the face of significant workforce challenges

REGULATIONS POLICIES & PROCEDURES

In preparation for its upcoming AAHRPP site visit, the HRPP conducted a comprehensive self-evaluation of its policies, procedures, and regulatory guidance during 1Q and 2Q FY26. This review process included a systematic assessment and refinement of program operations to ensure continued alignment with federal regulations, AAHRPP accreditation standards, institutional priorities, and recognized best practices in human research protections. Policies and procedures that were modified included:

- HRP-001 SOP Definitions
- 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-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

In FY26, the HRPP placed a strong emphasis on communicating programmatic and regulatory updates to ensure all stakeholders remained informed and equipped to uphold the highest standards of human subjects research protections.
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

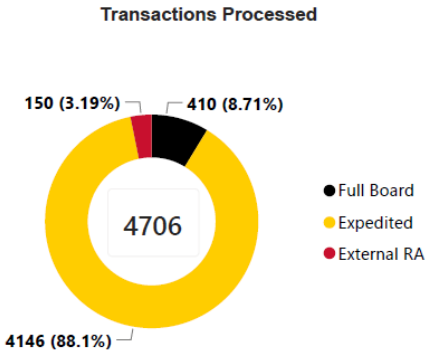
The IRB is responsible for protecting the rights and welfare of individuals participating in research. At UMB, the IRB reviews and approves research protocols and amendments to promote compliance with ethical principles, federal regulations, and institutional policies.

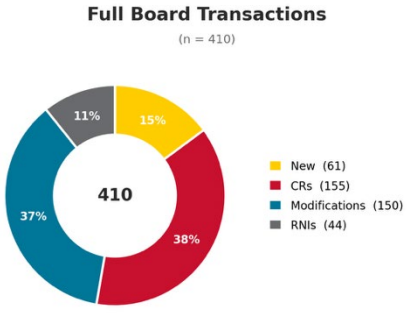
Composition:
During FY26, an active recruitment process resulted in the addition of 13 new members, enhancing its expertise and diversity. The new members include:

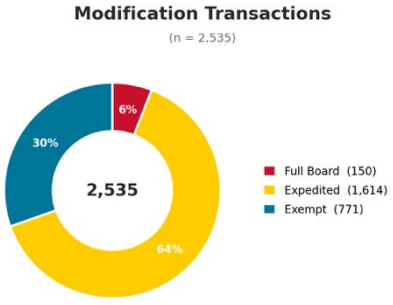
- Affiliated scientist: 10
- Non-affiliated scientist: 1
- Non-affiliated non-scientist: 2

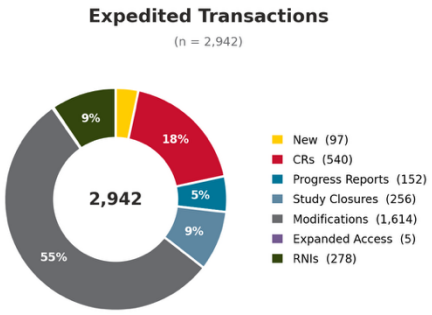
This balanced composition enhances the IRB's capacity to provide ethical oversight, uphold scientific rigor, and ensure meaningful community representation in research review activities.

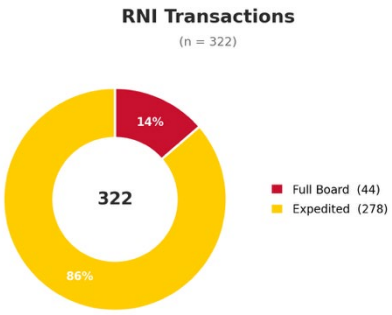
Performance:
During FY26, the UMB IRB/HRPO team processed a total of 5,227 transactions through both full board and expedited review pathways. This includes new protocols, continuing reviews, modification and reportable new information. The volume reflects the complexity of the UMB research portfolio, 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 seventy-five (75) IRB meetings in FY 26, continuing its commitment to flexibility in review processes.

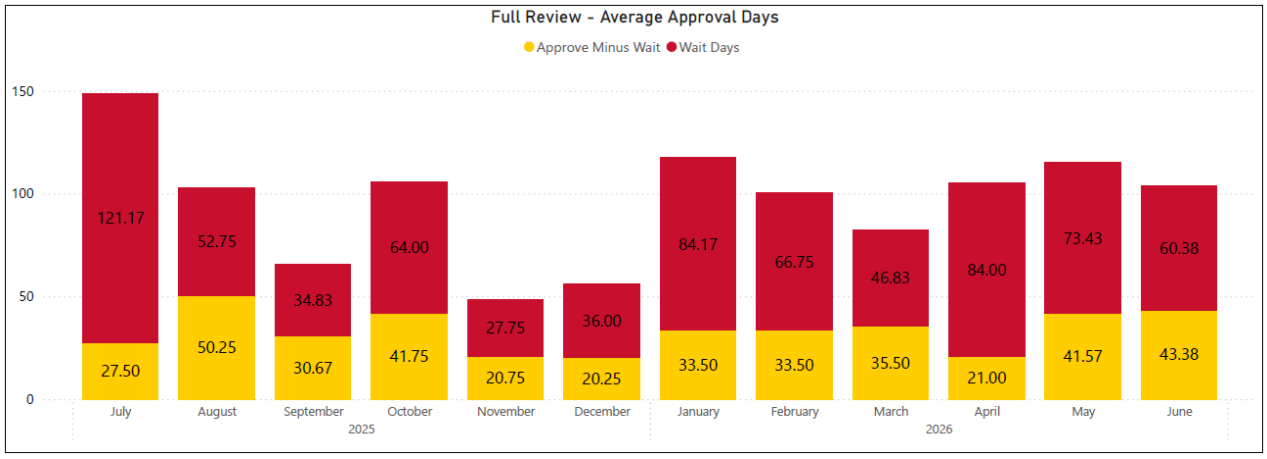
Under the leadership of IRB Chair Dr. Jonmark Hirshon, IRB Senior Vice Chair Dr. Jim Campbell, and IRB Vice Chairs Drs. Mili Tapia and Jocelyn Leung, the Human Research Protection Program (HRPP) benefits from a strong and sustained commitment to ethical oversight, regulatory compliance, and continuous program improvement. Through regularly convened Executive Committee meetings, these leaders provide strategic direction on complex regulatory, ethical, and operational issues that impact human subjects research. These sessions serve as an important venue for reviewing emerging trends, discussing new federal and institutional guidance, evaluating challenging protocols, and ensuring that IRB policies and decisions remain consistent, well-reasoned, and aligned with the highest standards of participant protection.

The collaborative engagement of HRPP leadership strengthens both the quality and integrity of the research oversight process. By fostering open dialogue and the exchange of diverse perspectives, the Executive Committee promotes a shared understanding of evolving ethical considerations and regulatory requirements across the IRB. This proactive approach supports informed decision-making, enhances consistency in protocol review, and helps address emerging challenges associated with increasingly complex research methodologies and technologies. Their collective leadership reinforces the HRPP's mission to safeguard the rights, safety, and welfare of research participants while facilitating the conduct of scientifically rigorous and ethically responsible research. Through thoughtful governance, ongoing communication, and a commitment to excellence, the committee contributes significantly to maintaining public trust in UMB's research enterprise.

Performance:

Protocol Reviews

Full Reviews:



During FY26, the average processing time for new protocols was 34.57 calendar days without wait times and 98.11 calendar days with wait times.

Monthly protocol review metrics were influenced by several outlier protocols that required substantially more time and resources than typical submissions, resulting in month-to-month fluctuations driven by a small number of unusually complex protocols rather than typical review activity.

To provide a more accurate representation of performance patterns and trends in FY27, median metrics will be tracked in addition to existing measures, reducing the impact of outliers and offering a clearer view of typical protocol review timelines.

Average processing times continuing reviews was 14.97 calendar days without wait times and 19.99 with wait times.

Average processing times modifications was 17.91 calendar days without wait times and 28.69 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 for full board items was 2.01 calendar days

Prior to receipt for IRB processing, new applications spent an average of 24.28 days in department or specialty review.

Expedited Reviews:

During FY26, the average processing time for new protocols was 14.57 calendar days without wait times and 32.70 calendar days with wait times.

Average processing times for review of continuing reviews was 3.51 calendar days without wait times and 6.35 calendar days with wait times.

Average processing times for review of modifications was 2.59 calendar days without wait times and 5.11 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.

Prior to receipt for IRB processing, new applications spent an average of 12.66 days in department or specialty review.

Exempt Reviews:

During FY26, the average processing time for new protocols was 5.79 calendar days without wait times and 18.87 calendar days with wait times.

Average processing times for review of modifications was 2.06 calendar days without wait times and 4.72 calendar days with wait times.

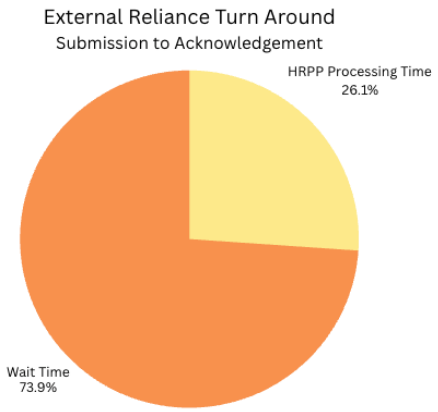
Wait times in the approval process refer to the period during which the Principal Investigator (PI) is completing responses to requested clarifications, edits, or additional information.

Prior to receipt for IRB processing, new applications spent an average of 11.22 days in department or specialty review.

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 FY26, 150 reliance agreements were reviewed with the average processing time for reliance agreements being 8.44 calendar days without wait times and 44.43 days with wait times. The average time from submission to first action by HRPP personnel was 1.22 calendar days. Prior to receipt for IRB processing, new external applications spent an average of 19.29 days in department or specialty review.

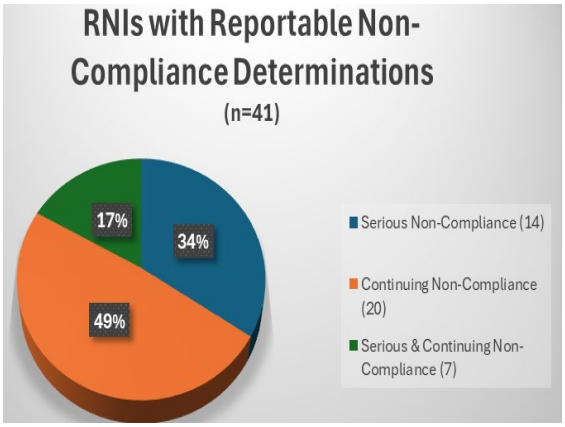


***Non-human subjects research determinations*:**

During FY26, 521 non-human subject research submissions were reviewed with the average processing time being 1.57 calendar days without wait times and 4.02 days with wait times. The average time from submission to first action by HRPP personnel was 0.34 calendar days.

RESEARCH SUBJECT ADVOCACY AND SAFETY

The UMB Research Subject Advocate and Safety Specialist (RSA&SS) plays a critical role in protecting the rights, safety, and well-being of research participants. Through the review of 322 Reportable New Information submissions in FY26—of which forty-four (44) required full IRB determination—and by addressing concerns raised by participants and their families, the RSA&SS helps ensure that issues related to participant safety, ethical conduct, and effective communication are identified and resolved promptly and comprehensively.



Of the forty-four (44) reviewed at full board, the IRB determined:

- Four (4) constituted serious non-compliance
- Four (4) constituted continuing non-compliance
- Three (3) constituted serious and continuing non-compliance
- Two (2) constituted an unanticipated problem involving risk to research subjects or others
- Two (2) protocol suspensions
- One (1) protocol termination

Reporting was required to external oversight agencies in twenty (20) instances.

The RSA&SS responded to nine (9) concerns raised by research participants, family members, and external stakeholders, addressing a broad range of issues related to participant rights, safety, communication, and research conduct. Through these efforts, the RSA&SS strengthens institutional accountability, enhances participant protections, and fosters trust between the research community and those it serves. This dedication to participant advocacy and support remains a fundamental component of the Human Research Protections Program's (HRPP) mission to uphold the highest standards of human subjects protection.

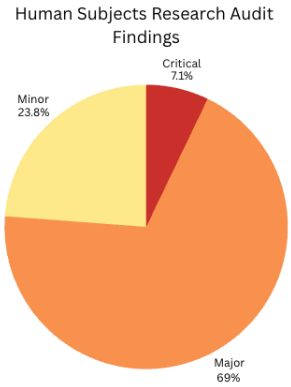
In addition, the RSA&SS played a pivotal role in UMB's efforts to prevent protocol expirations, a critical aspect of maintaining regulatory compliance and safeguarding the rights and welfare of research participants. The RSA&SS worked proactively with two-hundred and thirty (230) Principal Investigators (PIs) to ensure that continuing review and other regulatory requirements were completed in a timely manner. Through ongoing communication, timely reminders, and individualized guidance, the RSA&SS helped investigators navigate submission requirements and deadlines, reducing the risk of lapses in IRB approval that could interrupt study activities or compromise participant protections. By preventing protocol expirations, the RSA&SS minimized administrative burden, supported the uninterrupted conduct of research, and ensured the continuous oversight necessary to protect research participants. This collaborative approach promotes a culture of shared responsibility, compliance, and accountability across the research enterprise.

AUDITING & MONITORING

Auditing and monitoring are fundamental elements of a robust Human Research Protection Program (HRPP), providing critical oversight to ensure compliance with ethical principles, institutional policies, and regulatory requirements. Through the systematic evaluation of research activities, these processes help identify potential areas for improvement, reinforce adherence to best practices, and promote a culture of accountability, quality, and continuous improvement throughout the research enterprise.

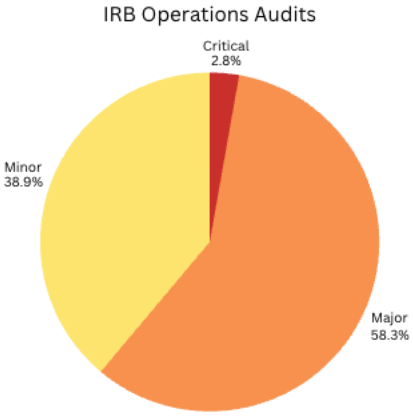
During FY26, six (6) human subjects research audits were conducted. The audits identified:

- 19 critical findings
- 40 major findings
- 17 minor findings



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

Ten (10) IRB Operations audits were conducted, with a total of 331 protocols reviewed. The audits identified:



- 0 critical finding
- 70 major findings
- 4 minor findings

When deficiencies or opportunities for improvement in the IRB review process are identified, IRB leadership takes prompt, structured action to address concerns and strengthen the quality and consistency of human subjects research oversight. Corrective actions may include providing targeted training for IRB staff and board members, revising SOPs, and enhancing review tools, templates and checklists to support regulatory compliance and consistent application of ethical standards.

In FY26, the HRPP completed quality assessments of 75 sets of IRB meeting minutes to promote accuracy, completeness, and adherence to federal regulatory requirements. These reviews help ensure integrity of IRB deliberations by confirming appropriate documentation of quorum maintenance, member

participation, conflict-of-interest management, and the basis for board determinations. Ongoing evaluation of meeting records enhances transparency, supports consistency across IRB panels, and demonstrates UMB's continued commitment to high-quality 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 FY26, 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 FY26 workshops, focused sessions on areas such as AAHRPP, HRPP Emergency Management and AI in human subjects research were added. These initiatives were developed in alignment with nationally recognized trends and emerging best practices in research ethics education.

***Educational Outreach*:**

The UMB HRPP offered thirty-seven (34) sessions with over seven hundred and fifty (750) attendees, including:

- Department or Entity Scientific & Feasibility Review of Research Refresher
- School of Dentistry & Howard University- Practice Based Research Network CORE: IRB Processes and Reliance
- AAHRPP Review Sessions with PIs, staff, HRPO staff, IRB members, Legal, Departmental reviewers
- School of Medicine Summer Program- IRB Processes and Investigator Responsibilities
- Carey School of Law – Health Law Workshop
- Graduate School Orientation – Intro to IRB/HRPO
- School of Dentistry - Dental Hygiene Students IRB Submission Discussion
- Intro to Clinical & Translational Research at UMB and VAMHCS
- HRPP Grand Rounds were held on topics related to single IRBs and external reliance agreements, AAHRPP and HRPP Emergency Management.

The HRPP remains committed to promoting accessibility and fostering a culture of continuous learning. To support the research community, we expanded awareness and availability of online educational resources, including recorded webinars and self-paced training modules, enabling researchers to access learning opportunities at times most convenient for them. In addition, our team offered individualized consultations and dedicated office hours to assist investigators with IRB submissions, navigate regulatory requirements, and address specific educational needs. These efforts help strengthen investigator knowledge, enhance compliance, and support the ethical conduct of research.

Additionally, eighteen (18) requests were made either by investigators or at the request of the IRB for Clinical Research Training and Mentoring (CRTMP) support. CRTMP provides support in study design, methodology, biostatistics, feasibility assessment, protocol development, and overall research planning to strengthen projects before regulatory review. Of the 18 projects that received CRTMP consultation, only one has obtained IRB approval to date; however, the remaining projects are either still in development and have not yet been submitted to the IRB or are currently undergoing IRB review. These observations suggest that early CRTMP engagement can help investigators enhance protocol quality and improve preparedness for the IRB submission process. By consulting with CRTMP during the protocol development phase, investigators are able to identify and address potential scientific, operational, and regulatory issues before formal IRB submission. Early collaboration provides opportunities to strengthen study design, clarify research objectives, refine recruitment and consent procedures, and ensure that required regulatory and institutional elements are incorporated into the protocol. This proactive approach can reduce the need for extensive revisions during IRB review, facilitate more efficient communication between investigators and reviewers, and contribute to shorter review timelines. Additionally, early engagement helps investigators better understand applicable regulatory requirements and ethical considerations, leading to more complete and well-prepared submissions. Collectively, these outcomes support a more efficient review process while reinforcing the HRPP's commitment to protecting research participants and promoting the conduct of high-quality, ethically sound research.

Throughout FY26, the HRPP engaged in extensive outreach and consultation activities with the research community, conducting discussions with more than 100 Principal Investigators (PIs) regarding a broad range of human subjects research topics. These interactions provided investigators with individualized guidance on regulatory requirements, study design considerations, informed consent processes, participant recruitment strategies, exemption and expedited review determinations, protocol amendments, reportable events, and compliance with institutional and federal human research protection requirements. The high volume of consultations reflects both the accessibility of the HRPP and its commitment to fostering a collaborative research environment in which investigators can seek expert advice throughout the lifecycle of their studies. Through these discussions, HRPP staff were able to identify common areas of concern, clarify regulatory expectations, and provide timely recommendations that improved the quality and completeness of research submissions. Early and ongoing engagement with investigators not only enhanced their understanding of ethical and regulatory responsibilities but also helped reduce avoidable delays during the IRB review process by promoting the development of more robust and well-prepared protocols. Collectively, these consultation efforts strengthened investigator support, promoted compliance with human subjects protections requirements, and contributed to a culture of ethical research conduct and continuous quality improvement across the institution.

Professional Development:

Sustained training and professional development are critical to the success of an HRPP. By keeping staff abreast of evolving regulatory requirements, emerging research practices, and ethical standards, ongoing education promotes regulatory compliance, enhances program effectiveness, and reinforces a culture of participant protection and institutional accountability. In FY26, educational sessions for HRPP staff included but were not limited to:

- Attendance at annual meeting of Primary Responsibility in Medicine & Research meeting (PRIM&R) -sIRB and Post-approval monitoring, Local Context, Evolving Landscape of AI Research
- PRIM&R Webinars: Artificial Intelligence (AI) and the Research Landscape; Regulatory Flexibility
- Attendance at annual meeting of Association for the Accreditation of Human Research Protections Program (AAHRPP)
- AAHRPP Innovations - Participant/Community Outreach and Collaboration: Innovative Practices by AAHRPP-Accredited Organizations
- AAHRPP webinar "Evaluation of Practice - What to Expect for the Site Visit
- Innovative Practices by AAHRPP-Accredited Organizations
- CITI webinars: Being Creative when Applying the IRB Exemptions – Parts 1,2 &3; NIH Biospecimen policy, Survey Research,
- UMB Emerging Leaders
- PERCIPIO Trainings on Communication, Change, & Collaboration
- OAC Customer Experience Workshop Series
- HRPP Huron Toolkit Update with HRPO Staff
- SMART IRB Updates & Boot Camp
- IRex Updates
- Applying HIPAA Regulations to Human Research
- Ethical Research Relationships: IRBs and Focus Groups webinar
- ClinicalTrials.gov: Essentials for Academic Medical Centers

The HRPP maintained a comprehensive, multi-faceted education and communication strategy to support the effective adoption of new and revised policies, procedures, and guidance across the research community. IRB members received timely updates through dedicated training sessions, regularly scheduled board meetings, and resources maintained on the IRB SharePoint site, ensuring they remained informed and well-equipped to consistently apply procedural and regulatory changes during protocol review activities. HRPO staff participated in targeted educational briefings, operational meetings, and cross-functional discussions designed to promote a shared understanding of revised requirements and ensure consistent implementation across all areas of program operations. This coordinated approach enhanced organizational alignment, reinforced regulatory compliance, and supported the consistent application of human research protection standards throughout the HRPP.

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 FY26, the HRPP expanded its outreach through:

- Monthly newsletters (n=12)
- "Tip of the Month" features (n=12+)
- Targeted email alerts (n=49)

Communications were disseminated through *The Elm* and other digital platforms to increase visibility, accessibility, and engagement among investigators, research staff, IRB members, and institutional stakeholders. These channels provided timely updates on HRPP policies, regulatory changes, educational opportunities, and research-related initiatives, ensuring that key information reached the research community through multiple touchpoints. A total of 49 CICERO communications were distributed to stakeholders to provide system updates, process guidance, educational offerings and important reminders related to human subjects research administration.

Key announcements shared with the research community included:

- Belmont Report at Belmont: Where Modern Human Research Protections Were Shaped – featuring UMB IRB Chair Dr. JonMark Hirshon
- AAHRPP -Update to the UMB HRPP and Site Visit Preparations
- CICERO single sign-on
- CICERO - Sites Where Research Will Be Conducted Section, Question 6 Expanded
- CICERO: New Reporting Requirement for Studies with Non-UMB Sites Relying on UMB IRB
- Required Refresher Training for Departmental Reviewers: Scientific & Feasibility Review
- Noncompliance or Research Misconduct? Definitions and Policies for Researchers
- Human Research Protections Program Grand Rounds – HRPP FY 2025 Annual Report
- Human Research Protections Program Grand Rounds – Emergency Management
- SON: Survey Research Methods: Question Development and Validation

- Communicating with Patients Workshop Series – HSHSL
- SON: Through the family lens: Using photovoice to understand family communication in serious pediatric illness.
- SON: Clinical Research Best Practices: Regulatory Binder
- Continuity of Operations (COOP) eLearning Tool

Through these efforts, the HRPP enhanced communication and transparency across the research enterprise by streamlining the dissemination of information, reducing communication gaps, and breaking down information silos that can hinder collaboration and awareness. These initiatives improved the consistency and accessibility of guidance, policies, and regulatory updates while fostering stronger engagement with investigators, study teams, and institutional stakeholders. This collaborative approach not only strengthened relationships with the research community but also helps promote greater trust, responsiveness, and shared responsibility for maintaining the highest standards of ethical and compliant research.

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.

Customer Experience Excellence

- HRPP remains committed to delivering responsive, collaborative, and customer-focused support to the research community. Through timely communication, proactive guidance, and partnership with investigators and institutional stakeholders, the HRPP strives to provide high-quality service that promotes compliance, facilitates research, and enhances the overall customer experience across all aspects of human subjects research oversight.

ProPath

- Building expanded proactive supports for researchers to identify compliance needs before they become non-compliance
- Extending structured guidance historically reserved for sponsored trials to larger community
- Building positive relationships early to foster trust

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.
- Building an on-demand library of education and awareness videos available to researchers and research staff

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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If you experience, witness or suspect misconduct, report it to the UMB Hotline.