Human Research Protection Program Plan

April 2021

Scope

Throughout this document "organization" refers to University of Maryland, Baltimore.

Purpose

This organization is committed to protect the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this organization's plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This organization's Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Program is based on all individuals in this organization along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

Definitions

Agent

An individual who is an employee is considered an agent of this organization for purposes of engagement in Human Research when that individual is on on-duty in any capacity as an employee of this organization.

An individual who is not an employee is considered an agent of this organization for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of this organization.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this organization.

Clinical Trial

A biomedical or behavioral research study of human subjects designed to answer specific questions about therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new therapeutic interventions are safe, efficacious, and effective.

Engaged in Human Research

In general, this Institution is considered engaged in Human Research when this Institution's employees or agents for the purposes of the Human Research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about or identifiable biospecimens from the subjects of the research; or (3) the informed consent of human subjects for the research. This organization follows OHRP guidance on "Engagement of Institutions in Research" to apply this definition.

Human Research:

Any activity that either:

- Is "Research" as defined by DHHS and involves "Human Subjects" as defined by DHHS ("DHHS Human Research"); or
- Is "Research" as defined by FDA and involves "Human Subjects" as defined by FDA ("FDA Human Research").

Human Subject as Defined by DHHS

A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

- **Intervention** means both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Private Information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable Biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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Human Subject as Defined by FDA

An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Investigator

The person responsible for the conduct of the Human Research at one or more sites. UMB recognizes a single individual to serve as the principal investigator of Human Research. If the Human Research is conducted by a team of individuals at a trial site, the principal investigator is the responsible leader of the team.

Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The following activities are not considered Research as Defined by DHHS:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
    - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
    - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
    - Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.
- Secondary research involving non-identifiable newborn screening blood spots
- For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

Research as Defined by FDA

Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Mission

The mission of this organization's Human Research protection program plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this organization.

Ethical Requirements

In the oversight of all Human Research, this organization (including its investigators, research staff, students involved with the conduct of Human Research, IRB members and chairs, IRB staff, the Institutional Official/organizational official, employees, and students) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as "The Belmont Report":

- Respect for Persons
- Beneficence
- Justice

Legal Requirements

This organization commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research must undergo review by an organizationally designated IRB. Activities that do not meet the definition of Human Research (e.g., most classroom activities, quality improvement activities, program evaluation, and surveillance activities that do not meet the definition of Human Research) do not require IRB review and approval and do not need to be submitted to the IRB unless there is a question regarding whether the activity is Human Research.

When this organization is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulation by a federal department or agency who is a signatory of the Common Rule, the organization commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this organization is engaged in FDA Human Research, this organization

commits to apply the FDA-regulations relevant to the protection of Human Subjects.

When this organization is engaged in research in Maryland, this organization follows Maryland State law. When this organization is engaged in research outside of Maryland, this organization follows local law. This organization applies the most stringent law or regulation in a situation where more than one is applicable.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the Human Research Protections Office (HRPO) who will provide a determination.

Other Requirements

This organization will apply the revised Common Rule only to research approved after January 21, 2019.

In lieu of limited IRB review, this IRB will conduct expedited review as applicable.

When reviewing research that involves community-based research, the IRB considers the Community-Based Research Principles at http://www.washington.edu/research/main.php?page=communityPrinciples

When reviewing research that involves community-based research, the IRB obtains consultation or training.

The process the IRB uses to maintain oversight of all open studies, even where laws, codes, and regulations do not require the IRB to conduct continuing review requires submission of a progress report by the Principal Investigator every two years, which is reviewed by HRPO staff, allowing the organization to maintain oversight of the research initially approved using the expedited procedure, as long as the research is ongoing.

All policies and procedures that are applied to Human Research conducted domestically are applied to Human Research conducted in other countries, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process and other language issues
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

All policies and procedures are applied identically to all research regardless of whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process and other language issues
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

For clinical trials, this organization commits to apply the "International Council on Harmonization – Good Clinical Practice E6 and the Declaration of Helsinki. Follow link below for full GCP guidance

https://www.fda.gov/science-research/guidance-documents-including-information-sheets-and-notices/ich-guidance-documents

This organization prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees") and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments.")

When Human Research is conducted or funded by the Department of Justice (DOJ), the organization commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the organization commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), this organization commits to apply DOD Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D[1]. When Human Research is conducted or funded by the Department of the Navy, the organization commits to apply SECNAVINST 39000.39D.

When Human Research is conducted or funded by the Department of Education (ED), this organization commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

When Human Research is conducted or funded by the Department of Energy (DOE), this organization commits to applying DOE O 443.1A and to use "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements."

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this organization commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

When Human Research is subject to Veterans Administration (VA) oversight, this organization commits to apply VHA Handbook 1200.05 requirements, which includes the requirement to apply 45 CFR §46 Subparts C and D, and all regulations pertaining to the participation of veterans as subjects including requirements for indemnification in case of research-related injury pertained to non-veteran subjects enrolled in Veterans Administration (VA) approved research.

When Human Research is subject to the European Union General Data Protection Regulations (GDPR), this Institution coordinates with appropriate partners, including legal counsel to ensure that the research activities conform to broader institutional policies related to GDPR, where applicable, as well as legal counsel's interpretation of study-specific GDPR requirements.

Sponsored Human Research

For both sponsored Human Research this organization abides by its ethical principles, regulatory requirements and its policies and procedures.

	DHHS	DOD	ED	EPA	VA
Subpart B	X	X		X	
Subpart C	X	X			X
Subpart D	X	X	X	X	X

Scope of Human Research Protection Program

- The categories of Human Research overseen include all forms of human research except classified research (Classified research is secret research to which access is restricted by law to a particular hierarchical class of people. A security clearance is required to review classified research.)

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available on the following Web site: http://umaryland.edu/hrp

Human Research Protection Program Components

Institutional Official/Organizational Official

The Vice President & Chief Accountability Officer is designated as the Institutional Official/Organizational Official.

The Institutional Official/ Organizational Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire research review staff.
- Determine what IRBs the organization will rely upon.
- Approve and rescind IRB authorization agreements.
- Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research.
- Determine whether data may be used that was not collected in accordance with the IRB's requirements.
  - If there is over-enrollment into minimal risk studies, the Institutional Official/Organizational Official delegates this responsibility to the IRB Chair or Senior Vice Chair
- Create policies and procedures related to the Human Research Protection Program that are binding on the organization.
- Suspend or terminate IRB approval of research.
- Disapprove research approved by the IRB.
- Grant institutional approval (and if federally funded, after OHRP approval) of research involving prisoners, only after IRB approval.
- Establish a contingency plan for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the study (e.g., the IRB closes, suffers loss due to fire, natural disaster).

The Institutional Official/ Organizational Official has the responsibility to:

- Play a leadership role in establishing and implementing the Human Research Protection Program.
- Ensure the integrity of the Human Research Protection Program.
- Create an institutional culture for respect for human subjects.
- Grant final approval of HRPP Standard Operating Procedures.
- Ensure effective institution-wide communication and guidance on human research.
- Assure compliance with the terms of the FWA and all Federal, State,

and institutional requirements for conducting Human Research.

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
- Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the organization cannot approve research that has not been approved by an IRB designated by the organization.
- Ensure that the IRB Chair(s) and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB.
- Follow-up on findings of serious or continuing non-compliance of IRB staff and IRB members.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas, and where necessary removal of individuals from involvement in the Human Research protection program.
- Ensure that the Human Research Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill educational requirements mandated by Veterans Administration (VA) Office of Research and Development and OHRP.

Human Protections Administrator (HPA)

The individual identified by the Institutional Official as the point of contact with DHHS's Office for Human Research Protections (OHRP) and who

exercises operational responsibility, on a day-to-day basis, for the institution's program for protecting human subjects.

Human Research Protections Office (HRPO)

The Human Research Protections Office is the coordinating office for the Human Research Protection Program.

All members of the organization

All individuals within the organization have the responsibility to:

- Be aware of the definition of Human Research.
- Consult the IRB when there is uncertainty about whether an activity is Human Research.
- Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the Institutional/Organizational Official.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the Institutional/Organizational Official.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.
- For Veterans Administration (VA) research follow this organization's procedures to ensure reporting in writing to the IRB within 5 business days of becoming aware of unanticipated problems involving risks to subjects or others, apparent serious or continuing non-compliance, suspension of IRB approval, termination of IRB approval, and local (i.e., occurring in the reporting individual's own VA facility) unanticipated serious adverse events in writing to the IRB within five business days of. This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements.) The unfounded classification of a serious adverse event as "anticipated" constitutes serious non-compliance.
- Individuals who are responsible for business development are prohibited from carrying out day-to-day operations of the review process.

IRB Executive Committee (EC):

The Executive Committee has been organized to identify and assure careful integration of new and ongoing components of the Human Research Protection Program policies and procedures necessary to optimize the performance of the IRB panels, while maintaining compliance with the Federal regulations and assuring the protection of human subjects.

All non-exempt Human Research must be reviewed by an IRB that has been designated by the Institutional Official/Organizational Official. The list and scope of review for IRBs designated by the Institutional Official/Organization Official to be relied upon are listed in the IRB rosters available from the Human Research Protections Office (HRPO).

This Institution utilizes the IRB to review and approve the use of a Humanitarian Use Device (HUD) before it can be used at a facility for clinical care (with the exception of emergency use).

Community-Based Participatory/Patient-Centered Research

UMB supports investigators to involve community members in the research process, including the design and implementation of research and the dissemination of results, when appropriate.

UMB provides resources to provide support to investigators where there may be challenges recruiting due to community attitudes toward investigators or stigma about the research topic. This is accessible through both the UMB CTSA/Institute for Clinical and Translational Research https://www.medschool.umaryland.edu/career/Resources-for-Research-Faculty/UMB-ICTR/ and the UMB **PAT**ient-centered **I**nvolvement in **E**valuating the effective**N**ess of **T**reatment**S** **(**PATIENTS**)** Program.

UMB ICTR, the first University-wide interdisciplinary hub for Clinical Translational Research, supports the **Community and Collaboration Core (CCC)** whose services include:

- Expert patient- and community-centered services and resources, such as the **PATIENTS program**, help in setting up focus groups, developing participant instruction videos, and more.
- Access to a **Research Vehicle** to transport research staff and supplies into the community.

The UMB PATIENTS Program partners with patients and care providers to answer questions about the best treatment options to improve health and quality of life. (https://www.pharmacy.umaryland.edu/programs/the-patients-program/)
This program engages people from all communities, especially those from underserved and minority populations, in every step of the patient-centered outcomes research (PCOR) process. Through collective efforts, an effective learning health care community is created.
The PATIENTS Program:

- listens to patients' voices in order to ask relevant and meaningful questions.
- aligns research priorities with the values of patients and communities.

- transforms research to make it more relevant and patient-centered.
- train patients, stakeholders, and researchers to become co-developers of PCOR.

The PATIENTS Program engages patients and communities as active partners in the full spectrum of translational research and:

- Identifies community health needs and priorities
- Provides input on relevant research questions
- Contributes to appropriate research design and methods
- Develops culturally sensitive and ethical proposals
- Enhances the recruitment and retention of research participants
- Implements and disseminates research findings more effectively

For successful community engagement to...

- Promote communities as full partners
- Value and respects all stakeholders, rewarding them for their time and expertise
- Increase public support for research
- Improve the health and well-being of the Baltimore community and beyond

In addition, education and information for investigators is available on how to identify relevant community members and local community resources with expertise in hard-to-reach populations. The PATIENTS program partners with patients and care providers to answer questions about the best treatment options to improve health and quality of life. People from all communities, especially those from underserved and minority populations, are engaged in every step of the patient-centered outcomes research (PCOR) process. Through collective efforts, an effective learning health care community is created. Research priorities are aligned with the values of patients and communities to make research more relevant and patient-centered. The PATIENTS Program trains patients, stakeholders, and researchers to become co-developers of PCOR. Support can be to help the researcher/study team in the following areas:

- Create a focus group and interpreting focus group results, or
- Develop participant instruction videos, or
- Assemble an advisory board**,** or
- Connect you with a Citizen Scientist**.** A Citizen Scientist is a community member who has received training on how to review research proposals and offer input on the relevance and feasibility in the proposed population, or
- Assist with writing the community-engagement section of your extramural grant proposal.

Relying on an External IRB

This Institution may rely upon IRBs of another institution or organization provided one of the following is true:

- The IRBs are part of an AAHRPP accredited institution or organization.
- The IRBs are not part of an AAHRPP accredited institution or organization, but where reasonable steps have been taken to ensure that subjects are adequately protected. For example, for research that is no greater than Minimal Risk, there may be an assurance that the IRBs will adhere to applicable ethical standards and regulations. For research that is greater than Minimal Risk, the institutions may agree on more extensive oversight.
- The IRBs are part of an established reliance network (e.g. Smart IRB) that has established contractual and SOP-level procedures to clarify the roles and responsibilities associated with IRB reliance and to establish mechanisms to ensure quality and consistency in the review process among institutions.
- The sIRB has been pre-determined by study sponsor or grant or established by prior arrangement.
- This Institution's investigator is a collaborator on Human Research that is primarily conducted at another institution or organization and the investigator's role does not include interaction or intervention with subjects.
- The Institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

Reliance on an external IRB requires an Authorization Agreement and an active Institutional Profile, as well as a local review for compliance with local policies of the Institution. When Human Research carried out at this institution or by its agents is reviewed by an IRB at another institution or organization, this HRPP will follow established policies and procedures that specify which studies are eligible for reliance, how reliance is determined, and will provide information to researchers about reliance criteria and the process for seeking IRB reliance.

A written reliance agreement must define the responsibilities of the relying organization and reviewing IRB, including but not limited to:

- Determining whether the relying organization applies its FWA to some or all research, and ensuring the IRB review is consistent with requirements in the relying organization's FWA.
- Determining which organization is responsible for reporting serious or continuing non-compliance; unanticipated problems involving risks to subjects or others; and suspensions or terminations of IRB approval.
    - Reporting may be done by the reviewing IRB, the relying organization, or jointly, and will be defined in written agreements

The IRBs relied upon by this Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be approved by one of the IRBs designated by the IO/OO. Officials of this Institution

may not approve Human Research that has not been approved by one of the Institution's IRBs.
- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs' requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.
- Serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

This institution will comply with the determinations of the reviewing IRB, follow reporting and conflict of interest disclosure requirements as specified in the authorization agreement, conduct monitoring, identify an appropriate contact person, ensure researchers have appropriate qualifications and provide local context information (and any updates) to the reviewing IRB.

Serving as the IRB of Record

When this institution provides IRB review for other institutions, this HRPP will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site, through local context information gleaned from the participating sites. This also includes ensuring the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest; and that the IRB separates business functions from ethical review.

The IRB will review the research in accordance with established policies and procedures to determine that research is ethically justifiable, according to all applicable laws, including initial review, continuing review, review of modifications to previously approved research and unanticipated problems involving risks to subjects or others. The IRB will also have the ability to suspend or terminate IRB approval; as well as have the final authority to decide whether researcher or research staff conflict of interest and its management, if any, allows the research to be approved and request audits of research reviewed.

The IRB will notify the researcher (and organization) of its decisions, make relevant IRB policies and records available to the relying institution or organization and specify an IRB contact for communication.

Research Subject Advocate (RSA):

The Human Research Protection Program RSA serves as the liaison between

human subjects, investigators, and the institution and facilitates investigations of all human subject or research staff complaints.

Environmental Health and Safety (EHS) Office:

The Radiation Safety Committee (RSC) and the Institutional Biosafety Committee (IBC) are components within EHS.

- Any research activity involving the deliberate transfer of recombinant DNA or RNA, or DNA or RNA derived from recombinant DNA into one or more humans must be approved by the Institutional Biosafety Committee (IBC) before final IRB approval may be granted. Studies utilizing recombinant DNA or potentially infectious microorganisms in the course of their research, but not for direct and deliberate transfer into humans, may require approval from the IBC prior to final IRB approval and initiation of the experiment.
- Any research activity utilizing a "Select Agent" as defined in 42 CFR 73, 7 CFR 331, or 9 CFR 121 must be approved by the IBC before final IRB approval may be granted.
- Studies utilizing recombinant DNA or potentially infectious microorganisms in the course of their research, but not for direct and deliberate transfer into humans, may require approval from the IBC prior to initiation of the experiment; however, this approval is not required for final IRB approval.

Studies involving radiation exposure (from x-rays or radiopharmaceuticals) of human subjects from routine diagnostic or therapeutic procedures used in a supporting role and which the individual would otherwise not receive as a part of their medical care must be approved by the Radiation Safety Committee (RSC) before final IRB approval may be granted.

Investigational Drug Service (IDS):

Studies involving investigational drugs must be reviewed by an Investigational Drug Service Pharmacist before final IRB approval may be granted.

Division/Departmental/School Signatories:

These individuals are responsible for assessing a study's scientific merit, available resources (i.e., adequate number of qualified staff, adequate facilities, and availability of medical or psychological resources that human subjects may need as a consequence of the research), possible conflicts of interest, and study feasibility.

Legal Counsel:

Legal Counsel has the responsibility to:

- Provide advice upon request to the Institutional Official/Organizational

Official, IRB, and other individuals involved with the Human Research Protection Program.

- Determine whether someone is acting as an agent of the organization.
- Determine who meets the definition of "legally authorized representative" and "children" when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.

IRB members, staff and investigators have access to the University Counsel for legal guidance and interpretation of local, State and Federal laws and regulations as they relate to research. Any HRPO Director may serve as the liaison between the IRB, the HRPO and University Counsel.

If the IRB panels need legal counsel independent of the organization, the Office of the Attorney General of the State of Maryland will be consulted.

Office of Research and Development (ORD) & Center for Clinical Trials

The Research and Development Office and Center for Clinical Trials handles grants and contracts administration and has the responsibility to review sponsor contracts and funding agreements for compliance with Human Research Protection Program Policies and Procedures.

Conflict of Interest Officer and Advisory Committee:

Studies involving an investigator or research staff member with a conflict of interest must be approved by the Conflict of Interest Officer or Advisory Committee before final IRB approval may be granted.

The Conflict of Interest Officer will assure that all conflict of interest disclosures are reviewed in accordance with University policies and Federal regulations including, where appropriate, referral to the Conflict of Interest Advisory Committee and committees established in schools to advise their academic administrators. If the conflict of interest involves a VA study, then a VA representative will be a member of the Conflict of Interest Advisory committee.

Research Integrity Office

The Research Integrity Office houses the University of Maryland Baltimore's Research Misconduct and Conflict of Interest administration. In addition, staff provide Responsible Conduct of Research (RCR) instructional resources.

HIPAA Privacy Officer:

The HIPAA Privacy Officer is responsible for HIPAA privacy oversight at this organization.

School of Medicine Information Systems Liaison:

The School of Medicine Information Systems Liaison is responsible for managing the servers and software that support the electronic IRB system, CICERO.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the Investigator Manual, including COVID-19 pandemic directives and guidance issued by UMB.
- Follow the Human Research Protection Program policies and procedures that apply to IRB members and staff.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Institutional/Organizational Official.
- Be aware of the definition of Human Research.
- Consult the IRB when there is uncertainty about whether an activity is Human Research.
- Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the IO/OO.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the IO/OO.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.
- For Veterans Administration (VA) research follow this Institution's procedures to ensure reporting in writing to the IRB within 5 business days of becoming aware of unanticipated problems involving risks to subjects or others, apparent serious or continuing non-compliance, suspension of IRB approval, termination of IRB approval, and local (i.e., occurring in the reporting individual's own VA facility)

Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

- Oversee the review and conduct of Human Research in their department or school.

- Forward complaints and allegations regarding the Human Research Protection Program to the Organizational Official.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

University of Maryland Medical System (UMMS) Nursing & Patient Care Services Council

The University of Maryland Medical System's Nursing and Patient Care Services Council (UMMS NPCSC) will assist the University of Maryland Medical System Affiliates in the review of research proposals from Nursing and Patient Care Services before the proposal is forwarded to the University of Maryland Baltimore Institutional Review Board. The review of the proposals will include:

- Assessing the curriculum vitae, educational training completed, and the proposed Principal Investigator's qualifications to conduct research.
- Along with the Chief Nurse Executive of UMMS, the Council will make a recommendation to the UMB Institutional Official about the competency of the individual to act as a Principal Investigator.
- An evaluation of the research proposal to ensure completeness of the proposed protocol, a review of the scientific merits of the proposal, and identification of any concerns with the proposal or requested resources.
- Assurances that all documents be submitted and maintained by the Research Council for ethical and regulatory oversight.

COVID-19 Pandemic Task Force & Committees

The University of Maryland Baltimore Human Research Protections Program was concerned about the safety and well-being of its actual and potential research subjects and their families, research personnel and front-line healthcare workers during the COVID-19 pandemic. Having a focused process for the volume and complexity of COVID-19 related investigational drug trials with overlapping timelines for recruitment and enrollment was required.

The University of Maryland Baltimore established a collaborative and coordinated approach to the COVID-19 pandemic, with the safety of research subjects, research personnel and health care workers being the priority. A COVID-19 Research Advisory Task Force established the clinical research guidelines for currently approved minimal risk and greater than minimal risk research, prioritizing critically therapeutic studies (such as oncology). A campus-wide, virtual Q&A session was held to provide information and answer questions regarding the guidelines. The Institutional Official, IRB Chair and HRPP Director led the Town Hall.

The COVID-19 Human Research Coordinating Committee was tasked with bringing key stakeholders together to craft a comprehensive and coordinated response to the influx of human research protocols being developed and submitted that include human subjects related to the COVID-19 pandemic. To that end, the COVID-19 Human Research Coordinating Committee focused on establishing proactive communication, coordination, and collaboration with our COVID-19 research projects as top priority.

The COVID-19 Clinical Research Operations Task Force was created to identify specific challenges and opportunities associated with conducting COVID-19 research, with a recommendation that the Institute for Clinical and Translational Research (CTSA/ICTR) serve as the central point of contact and coordinating center for COVID-19 clinical research. CTSA/ICTR will serve as the liaison between UMB and University of Maryland Medical Center (UMMC) personnel, in particular the frontline healthcare workers (physicans, nursing and ancillary personnel).

In response to an influx of research requests requiring access to biospecimens from patients with COVID-19, a COVID-19 Biospecimen Research Workgroup was formed to efficiently and effectively coordinate and prioritize this type of research. An umbrella protocol was developed and approved for the collection, use, and management of biospecimens necessary for conducting COVID-19 research. Individual requests to secure access to the biospecimens were submitted to the Study Section for review and approval.

Additional initiatives related to COVID-19 included:

- Formulation of COVID-19 Study Section charged with developing guidelines and criteria for evaluating COVID-19 research to prioritize studies prior to IRB review.
- Creation of a Worksheet for Submission to the Study Section for Preliminary Review of COVID-19 Human Subject Research Protocols
- Creation of a COVID-19 Human research Subject review Worksheet for Study Section Review and Ranking.

Integration of the COVID-19 Task Force & Committees within the University of Maryland Baltimore Human Research Protections Program will continue till further notice. Modifications to the structure and functioning of the COVID-19 task force and committees will be informed by evidence-based decisions, with consideration of protection of the safety, rights and welfare of research participants, research staff and front-line healthcare workers.

Additional information can be found at: https://www.umaryland.edu/hrp/covid-19/taskforces-and-committees/

Veterans Administration (VA) Facility Director

The VA Facility Director is responsible for overseeing the creation and implementation of an HRPP for research involving human subjects or human biological specimens commensurate with this facility, the resources of this facility, and the size and complexity of the research program at this facility.

VA Facility Director is responsible for:

- Ensuring that the institution's HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects;
- Overseeing the R&D Committee, and through the R&D Committee the IRB, and other applicable subcommittees of the R&D Committee, facility research office, and all VA investigators and VA research staff who conduct human subjects research at that facility.
- Delegating authority in writing for respective roles and responsibilities for the HRPP. This delegation of authority must provide the organizational structure and ensure leadership for oversight activities for all human subjects research conducted at or by the facility.
- Ensuring provision of adequate resources to support the operations of the HRPP.
- Ensuring independence of the IRB.
- Appointing the facility's IRB voting members in writing when the VA facility operates its own IRB.
- Appointing the Chair and, when applicable, Co-chair(s) or Vice Chair(s) for a term of up to 3 years when the VA facility operates its own IRB.
- Serving as the official representative of the institution to external agencies and oversight bodies, and providing all written communication with external departments, agencies, and oversight bodies.
- Ensuring that a procedure is in place to review and approve recruiting media, including documents, flyers, and advertisements for research that is not VA research prior to being posted or distributed in any form within or on the premises of a VA facility. Posting or distributing may include announcing, distributing, publishing, or advertising the study either electronically, by hard copy, or other means to anyone, including Veterans, clinicians, or other staff (see ORD guidance at http://www.research.va.gov/resources/policies/default.cfm).
- Ensuring appropriate documentation of required actions and responsibilities pertaining to review, approval, conduct and oversight of research conducted at that facility set forth in VHA Directive 1200.05.

- Ensuring that any IRB operated by the VA facility is established in accordance with the requirements of VHA Directive 1200.05 and registered through ORO with the HHS OHRP (see VHA Handbook 1058.03);
- Obtaining approval of the Chief Research and Development Officer (CRADO) if the VA facility wants to establish a new HRPP or change their IRB of Record.
- Ensuring that detailed SOPs are developed and implemented to satisfy all requirements of VHA Handbook 1058.01, including requirements affecting the facility's academic affiliates
- Ensure appropriate auditing of local human subjects research studies to assess compliance with all applicable local, VA, and other Federal requirements including, but not limited to, ORO requirements.
- Each VA-approved human subjects research study must be completely audited in accordance with VHA Handbook 1058.01.
- Each study must be audited for compliance with the regulations and policies on informed consent in accordance with VHA Handbook 1058.01.
- Approve the request for permission to conduct international research at this VA facility and ensuring CRADO approval of international Cooperative Studies Program research is obtained prior to its initiation at the facility.
- For research involving pregnant women, human fetuses, and neonates as subjects, certifies that the medical facility has sufficient expertise in women's health to conduct the proposed research (see guidance at http://www.research.va.gov/resources/policies/default.cfm).
- For research involving children as subjects, approve participation in the proposed research (see guidance at: http://www.research.va.gov/resources/policies/default.cfm).
- Contract for the needed care for a research-related injury if VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required.
- Contract for inpatient care in a non-VA medical facility if it must be provided to a non-Veteran research subject for a research-related injury.
- Provide reasonable reimbursement for emergency treatment in a non-VA facility for a research subject that needs treatment in a medical emergency for a research-related injury.
- Delegate authority in writing for respective roles and responsibilities for the HRPP. This delegation of authority must provide the institutional structure and ensure leadership for oversight activities for all human subjects research conducted at or by the facility.
- Obtain permission from the central research and development officer if the facility wants to establish a new IRB or change the IRB of record, and ensuring any IRB is established according to VA requirements, and has approval from ORO.

- When the facility engages another entity's IRB, ensure that responsibilities are detailed in a memorandum of understanding or authorizing agreement.
- Ensure that IRB members, Researchers, and Research Staff are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations.
- Fulfill educational requirements mandated by VA Office of Research and Development and OHRP.
- Ensure that all persons working in research or performing any research activities have been officially appointed by Human Resources Management.
- Unless a waiver for a part-time research compliance officer is approved by the VA Under Secretary for Health, appoint at least one full-time research compliance officer to conduct annual research consent document audits and triennial regulatory audits, and to assist in VA assessments of regulatory compliance.
- Report any appointment, resignation, or change in status of this VA facility's research compliance officer to Office of Research Oversight (ORO) and VHA Central Office, with a copy to the relevant Office of Research Oversight (ORO) research officer, within 10 business days after the appointment, resignation, or change takes effect.
- Report in writing to Office of Research Oversight (ORO) Research Officer in writing within 2 business days after being notified of any research-related citation or determination of noncompliance by any state or federal agency; or any situation that has generated media attention or Congressional interest.
- Provide follow-up reports detailing any additional findings and appropriate remedial actions to the relevant ORO office at intervals and in a manner specified by that office.
- Provide a copy of any ORO compliance reports regarding the research program to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.
- Report the following research events to ORO Central Office, with a simultaneous copy to the appropriate ORO research officer:
    - IRB changes in number of IRBs and changes in membership rosters.
    - Substantive Memorandum of Understanding (MOU) changes must be reported to ORO Central Office within five business days.
- Ensure that individuals working under a contract with VA cannot serve as VA investigators, but may participate in research in other ways, such as collaborators or consultants.
- Provide a copy of any Office of Research Oversight (ORO) compliance reports regarding the research program to the associate chief of staff for research, Research and Development Committee, any relevant research review committees, and the research compliance officer in a timely fashion.

- Report the following research events to ORO Central Office, with a simultaneous copy to the appropriate ORO research officer:
    - IRB changes in number of IRBs and changes in membership rosters.
    - Substantive Memorandum of Understanding (MOU) changes must be reported to ORO Central Office within five business days.

When this VA Facility uses an external IRB as an IRB of record for single or multi-site protocols this VA facility Director is responsible to:

- Ensure that any IRB designated as an IRB of Record for the facility is not a commercial IRB and is established in accordance with the requirements of the VHA Directive 1200.05 and registered through the ORO to the Office for Human Research Protections (OHRP).
- Establish and sign a memorandum of understanding (MOU) or Authorizing Agreement with other VA facilities or external organization(s) providing IRB services (see VHA Handbook 1058.03 and MOU Checklist: http://www.va.gov/ORO/orochecklists.asp); and
- Ensuring that external IRBs of Record used by the VA facility hold current IRB registrations with FDA/OHRP and provide updates to membership as required by VHA Handbook 1058.03

When this VA facility uses the VA Central IRB, the facility director delegates authority to one or more individuals from the local VA facility to:

- Provide comments or suggestions to VA Central IRB, in response to VA Central IRB's initial review considerations.
- Respond to VA Central IRB's approval of the study on behalf of the VA facility as to whether the VA facility chooses to participate or declines to participate in the study.
- Serve as liaison between the VA facility and both the local site researcher and VA Central IRB.

A VA facility's own IRB, also known as an internal IRB, and the VA Central IRB, cannot serve as an IRB of Record for any non-VA entity except a Department of Defense (DoD) facility, Department of Energy laboratory, or a VA non-profit corporation (NPC).

A VA facility must request CRADO approval if the facility wants its internal IRB to serve as an IRB of Record for a non-VA entity listed above.

Veterans Administration (VA) Research Compliance Officer (RCO)

The Veterans Administration (VA) Research Compliance Officer (RCO) reports directly to the Veterans Administration (VA) Facility Director. Research compliance officer activities may not be determined or managed by the Research Service, research investigators, or any other research personnel. The IRB accept audits conducted by the research compliance officer to fulfill the IRB's auditing requirements.

The Research Compliance Officer has the responsibility to:

- Audit and review research projects relative to requirements for the protection of human subjects including:
    - Annual consent document audits.
    - Triennial regulatory audits on all research protocols.
- Consider auditing research projects more frequently in cases of:
    - Involvement of vulnerable populations
    - Level of risk
    - Phase I or Phase II studies
    - Involvement of FDA approved drugs for which there has been a new safety warning issued, or change in the labeling that indicates increased risks
    - Issues of noncompliance
    - Data confidentiality or security concerns
- Within five business days of identifying apparent Serious Non-Compliance or Continuing Non-Compliance based on an consent document audit, regulatory audit, or other systematic audit of VA research, a research compliance officer must report the apparent non-compliance directly (without intermediaries) to the Facility Director.
    - The report must be made in writing, with a simultaneous copy to the associate chief of staff for research, the Research and Development Committee, the IRB, and any other relevant research review committee.
    - An initial report of apparent serious or continuing non-compliance based on a Research Compliance Officer consent document audit, Research Compliance Officer regulatory audit, or other systematic Research Compliance Officer audit is required regardless of whether disposition of the matter has been resolved at the time of the report.

The Research Compliance Officer has the authority to:

- Serve as a nonvoting consultant, as needed, to the IRB.

    - The research compliance officer may not serve as a voting or nonvoting member of the IRB.
- Attend meetings of the IRB when requested by the IRB.

Veterans Administration (VA) Privacy Officer and the Information Security Officer

The Privacy Officer and the ISO are responsible for:

- Ensuring the proposed research complies with all applicable local, VA and other Federal requirements for privacy and confidentiality, and for information security, respectively, by identifying, addressing, and mitigating potential concerns about proposed research studies.
- Reviewing the proposed study protocol, study specific privacy and security information, and any other relevant materials submitted with the IRB application.
- Identifying deficiencies in the provisions for privacy and confidentiality or information security, respectively, of the proposed research, and making recommendations to the investigator and/or the IRB of options available to correct the deficiencies.
- Following up with the investigator and/or the IRB, in a timely manner, to ensure the proposed research is in compliance with relevant privacy and confidentiality, and information security requirements, respectively, before the investigator initiates the study.
- A final review is required only after the IRB has approved the study to ensure no further changes impact the privacy and security requirements of this study. NOTE: If a study includes information covered under 38 U.S.C. 7332 that will be disclosed outside of VA, the study must include written assurance from the VA researcher, e.g., within the protocol, that the purpose of the data is to conduct scientific research and that no personnel involved in the study will identify, directly or indirectly, any individual patient or subject in any report of such research, e.g., manuscript or publication.

Baltimore Veterans Administration Maryland Health Care System (VAMHCS) and Research & Development (R&D) Committee:

For Veterans Administration (VA) research, the Research and Development (R&D) Committee has responsibility for oversight of each local research program as defined in VHA Directive 1200.01. The VA Maryland Healthcare System (VAMHCS) R&D Committee has delegated its responsibility for scientific review conduct to the University Record for VAMHCS. Following UMB IRB approval, The VAMHCS R&D Committee must review and approve all new research protocols listing VAMHCS as a site of conduct. VAMHCS R&D also reviews and approves some IRB-reviewed modifications to protocols with VAMHCS as a site (i.e. those modifications involving PI change, major procedural change and/or risk elevation).

Education and Training

IRB members, IRB staff, and others involved in the review of Human Research must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program and HIPAA training. (see the IRB Web site for a link to this training). This training is valid for a three-year period, after which time a refresher CITI course or additional training must be completed. IRB staff also train IRB members on the UMB SOPs, checklists, and worksheets applicable to IRB members including regulatory and guidance requirements noted in the section "Other Requirements" section.

Effective January 1, 2017 – NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP). Recipients of GCP training are expected to retain documentation of their training. GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines. Additional information can be found at: https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

The mechanisms for communicating changes in the policies and procedures to all relevant research personnel at UMB and VAMHCS include:

- CICERO email with Hot Topic to Principal Investigators and research staff
- Updates to HRPO/IRB website pages
- Email communication to IRB Executive leadership and IRB members
- Education at fully–convened IRB meetings
- Research community educational sessions, as applicable

Education and Training for Veterans Administration (VA) Research

All individuals involved in conducting VA human subjects research, including the Institutional Official, are required to complete training in ethical principles related to human subjects research conduct. Specific requirements regarding the type and frequency of training are found on ORD's Web site at: http://www.research.va.gov/pride/training/options.cfm. All other applicable VA and VHA training requirements at the local and national level must be met (e.g., privacy and information security training).

Treatment of Research-Related Injuries to Human Subjects at Veterans Administration (VA) Facilities

VA medical facilities must provide necessary medical treatment to a research subject injured as a result of participation in a research study approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. This does not apply to:

1. Injuries due to non-compliance with study procedures.

2. Injuries sustained in research conducted for VA under a contract with an individual or a non-VA institution.

Care for VA research subjects under this Paragraph must be provided in VA medical facilities, except in the following situations:

- If VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required. Under these circumstances, VA facility Directors may contract for such care (38 CFR 17.85(b)(1)).
- If inpatient care must be provided to a non-Veteran under this paragraph, VA facility Directors may contract for such care.

The sponsor cannot bill the injured participant's insurance company for the injury; however, the sponsor is responsible for reasonable and customary costs incurred for treatment of injury reasonably related to the subject's participation in the study described in the scope of work except to the extent that:

- The injury is attributable to the negligence or willful misconduct of an indemnitee; or
- The injury is attributable to failure to administer the test article as required in the protocol or to otherwise substantially follow the protocol.
- If a research subject needs treatment in a medical emergency in a non-VA facility for a condition covered by this paragraph, VA facility directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

Credentialing and Privileging for Research at Veterans Administration (VA) Facilities

Investigators and their staff conducting human subjects research must be credentialed and privileged as required by current local and VA requirements (see VHA Directive 1100.19 and VHA Directive 2012-030, Credentialing of Health Care Professionals, or successor policy). Investigators and their research staff may only perform those activities in a research study for which they have the relevant credentials and privileges.

Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback.

Contact and location information for the IRB Office is either:

Name: Dr. Julie Doherty, DM, MSN, RN, C I P , C C E P
Title: Executive Director, Human Research
Protections Program

620 W. Lexington Street, Second Floor
Baltimore, Maryland 21201
Email: jdoherty@umaryland.edu
(410) 706-5037

Or:

Jan Martinez, MS, CIP, CLSSGB
IRB Manager
Office of Accountability & Compliance
620 W. Lexington Street, Second Floor
Baltimore, Maryland 21201
Email: jan.martinez@umaryland.edu
(410) 706-5037

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported via Ethics Point which is accessible at the bottom of every UMB webpage https://secure.ethicspoint.com/domain/media/en/gui/28588/index.html or addressed to the UMB Chief Accountability Officer.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Institutional Official/Organizational Official has the responsibility to investigate all other reports and take corrective actions as needed.

Employees who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official/Organizational Official or designee.

To make such reports, contact:

Mary MacFadden, RN, MS
Director, Research Subject Advocate
Office of Accountability and Compliance
620 W. Lexington Street, Second Floor
Baltimore, Maryland 21201
Email:mmacfadden@umaryland.edu
(410) 706-5037

To make such reports anonymously and electronically, complete the Whistleblower Hotline form at:
https://secure.ethicspoint.com/domain/media/en/gui/28588/index.html

Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and University requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits, for-cause audits and program evaluations may also be conducted.

The IO/OO may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the Organizational Official such actions are required to maintain the Human Research Protection Program. The IRB may recommend disciplinary actions to the Organizational Official.

Disciplinary Actions

The IO/OO may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the IO/OO such actions are required to maintain the Human Research Protection Program.

Approval and Revisions to the Plan

This Human Research Protection Program Plan is to be approved by the Institutional Official and University President. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official/Organizational Official has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the Institutional Official/Organizational Official the University President has the authority to amend this plan as deemed necessary.

Approved:

DocuSigned by:
Bruce Jarrell
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Date: 4/14/2021

Bruce E. Jarrell, MD
President
University of Maryland, Baltimore

DocuSigned by:
Susan Buskirk
E502667E4987478...

Date: 4/13/2021

Dr. Susan C. Buskirk, DM, MS, CCEP
Vice President & Chief Accountability Officer
Institutional Official
University of Maryland, Baltimore