



UNIVERSITY *of* MARYLAND
THE FOUNDING CAMPUS

Human Research Protection Program Plan

February 10, 2016

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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 the 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

This organization is engaged in Human Research when its employees or agents are interacting or intervening with Human Subjects for the purpose of conducting 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 obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

- **Intervention** means physical procedures by which data 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 which the individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained or associated with the information).
- **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.

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.

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 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

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>

All policies and procedures that are applied to Human Research conducted domestically are applied to Human Research conducted in other countries.

For clinical trials, this organization commits to apply the “International Council on Harmonization – Good Clinical Practice E6 and the Declaration of Helsinki.

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 D¹. 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.

Sponsored Human Research

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

¹ Quick applicability table for DHHS Subparts:

	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 without restriction.

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

Organizational Official

The Senior Vice President and Chief Research and Academic Officer is designated as the Organizational Official.

The 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 Organizational Official delegates this responsibility to the IRB Chair or IRB 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.

The 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.
- 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 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 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 Organizational Official.. The list and scope of review for IRBs designated by the Organization Official to be relied upon are listed in the IRB rosters available from the Human Research Protections Office (HRPO).

Upon prior approval of the Organizational Official this organization may rely upon the IRB of another organization provided one of the following is true:

- The IRB is the IRB of an AAHRPP accredited organization.
- This organization's investigator is a collaborator on Human Research at primarily conducted at another organization and the investigator's role does not include interaction or intervention with subjects.
- The organization 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.)

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

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the organization. All Human Research must be approved by an IRB designated by the Organizational Official. Officials of this organization may not approve Human Research that has not been approved by the IRB.
- Suspend or terminate approval of Human Research not being conducted in accordance with the IRB's 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.
- 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.

IRB member and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

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 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)

The Research and Development Office 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

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.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the Investigator Manual.
- 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 Organizational Official.

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.

VA Medical Center Director

- Is responsible for the facility's research program, and is assisted by the Research and Development Committee.
- Oversees all Veterans Administration (VA) Researchers and Research Staff.
- Ensures that all IRB members, Researchers, and research staff are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations.

- Develops and implements an educational plan for IRB members, staff, Researchers, and Research Staff including initial and continuing education.
- Fulfills all educational requirements mandated by the Veterans Administration (VA) Office of Research and Development (ORD) and OHRP.
- Appoints one or more research compliance officers to conduct annual research consent document audits and triennial regulatory audits, and to assist in Veterans Administration (VA) facility's assessments of regulatory compliance.
- Unless a waiver for a part-time research compliance officer is approved by the under secretary for health, each Veterans Administration (VA) facility must designate at least one full-time research compliance officer.
- The medical center director must report any appointment, resignation, or change in status of the Veterans Administration (VA) facility research compliance officer to ORO VHA Central Office, with a copy to the relevant ORO research officer, within 10 business days after the appointment, resignation, or change takes effect.
- Reports to ORO in writing within five business days after being notified of a research problem or event (including serious and continuing non-compliance, unanticipated problems involving risks to participants or others, and suspensions and terminations) for which such reporting is required.
- The medical center director's written report of required regardless of whether disposition of the event has been resolved at the time of the report.
- Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO office at intervals and in a manner specified by that office.
- Provides 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.
- The Veterans Administration (VA) facility director must report the following research events to ORO Central Office, with a simultaneous copy to the appropriate ORO research officer, as indicated in the following:
 - 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.
 - Accreditation problems must be reported to ORO Central Office within five working days.

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 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 IRB meetings of the IRB when requested by the IRB.

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

For Veterans Administration (VA) research, the Research and Development Committee has the responsibility for oversight of the local research program as defined in VHA Handbook 1200.01. The Veterans Administration (VA) Research and Development Committee has delegated its responsibility to conduct scientific review to the IRB. The Research & Development Committee must review and approve all Veterans Administration research and must also review and approve all modifications including those related to biosafety or radiation safety.

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 two-year period, after which time a refresher CITI course or additional training must be completed. IRB staff also train IRB members on the SOPs, checklists, and worksheets applicable to IRB members including regulatory and guidance requirements noted in the section "Other Requirements."

Investigators and research staff must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program. See the IRB Web site for a link to this training. This training is valid for a two year period (two years for Veterans Administration (VA) investigators also), after which time a refresher CITI course or additional training must be completed.

The mechanisms for communicating changes in the policies and procedures to all individuals in the organization 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 IRB meetings
- Research community educational sessions , as applicable

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:

Name: Julie Doherty, RN, MSN
Title: Director, Regulatory Compliance
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, Maryland 21201
Email: jdoherty@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 to the Assistant Vice President, Human Research Integrity and Compliance.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The 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 Organizational Official or designee.

To make such reports, contact:

Name: Julie Doherty, RN, MSN
Title: Director, Regulatory Compliance
620 W. Lexington Street, Second Floor
Baltimore, Maryland 21201
Email: jdoherty@umaryland.edu
(410) 706-5037

To make such reports 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 may also be conducted.

The Organizational Official 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.

Approval and Revisions to the Plan

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

Approved:

Jay A. Perman, M.D.
President
University of Maryland, Baltimore
Chief Executive Officer

Approved:

Bruce E. Jarrell, MD, FACS
Organizational Official
Chief Research and Academic Officer
Senior Vice President
University of Maryland, Baltimore

February 10, 2016