

# Human Research Protections Program (HRPP)

## Introduction

The Medical College of Georgia (MCG) Office of Human Research Protection (OHRP) Policies, Procedures and Standard Operating Procedures (SOP) apply to all research conducted at MCG, MCGHI and the Charlie Norwood VA Medical Center. These are in addition to any Institutional Review Board (IRB) specific policies and procedures such as the Human Assurance Committee (HAC) Policies and Procedures or the Chesapeake Research Review, Inc. (CRRI) Investigator Manual or the Veterans Health Administration (VHA) 1200.5 requirements.

## What is Research?

HHS regulations define *research* at 45 CFR 46.102(d) as follows: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

A systematic investigation is an activity that involves a prospective research plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a research question.

Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), form policy, or generalize findings.

FDA regulations at 21 CFR 56.102 (c) defines research as any experiment that involves a test article and one or more human subjects. The FDA regulation further states that "...The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.

Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under Section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to requirements for prior submission to the Food and Drug Administration under these Sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding non-clinical laboratory studies.

## What is a Human Subject?

The Medical College of Georgia (MCG) Office of Human Research Protection (OHRP) utilizes the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) definition of Human Subjects:

Health and Human Services (HHS): (or the regulations of any other federal agency that follows the Common Rule) apply to the organization. The activities subject to the HRPP include

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“research involving humans as participants” as defined by the HHS regulations. Human Subject: 45 CFR 46.102(f) defines human subject as 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) identifiable private information.

Food and Drug Administration (FDA): Human subject: 21 CFR 56.102(e) defines human subject as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. 21 CFR 56.812 (p) defines a human subject as an individual who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.

### **What are Human Derived Materials?**

- Medical records, electronic or hard copy
- Data storage (i.e., database, spreadsheet, or other document or electronic type)
- Data obtained from questionnaires, surveys, interviews, etc.
- Fetal material including the placenta, amniotic fluid, fetal membranes, and umbilical cord
- Placenta removed at delivery
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
- Pathological specimens
- Diagnostic specimens (blood, sputum, urine, hair and nail clippings) collected
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction or permanent teeth if routine patient care indicates a need for extraction
- Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric acid solution to the tongue
- Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
- Sputum collected after saline mist nebulization
- Excreta and external secretions (including sweat)
- Primary cell lines (or those not generally available through commercial sources)

Note: There are also cultural or ethnic groups whose beliefs are such that they may object to the use of any samples of human tissue for research. One must be aware of these boundaries and respect them in the research design and conduct.

### **What Regulations Do We Have to Follow?**

Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) regulations apply to all research in compliance with the institution’s federalwide assurance (FWA). This means that all research is treated the same way regardless of funding source or status. Please contact our office for guidance if you have questions regarding our institution’s FWA requirements.

### **Purpose and Applicability**

## **Human Research Protections Program (HRPP)**

The Medical College of Georgia (MCG) established the Human Research Protection Program (HRPP) to monitor, evaluate, and continually improve the protection of human research subjects; dedicate resources sufficient to do so; exercise oversight of research protection; educate investigators and research staff about their ethical responsibility to protect research subjects; and when appropriate provide a mechanism to intervene in research and to respond directly to concerns of research subjects. This program applies to all research conducted under the auspices of MCG, MCG Health, Inc and the Charlie Norwood VA Medical Center. MCG has designated the Office of Human Research Protection (OHRP) to function as the HRPP.

The MCG OHRP web site contains the policies, procedures, forms and educational guidance for the Institutional Review Boards (IRBs), OHRP and the members of our research community involved in the conduct of human subject and/or human derived materials research. Our research community includes the Medical College of Georgia, Medical College of Georgia Health System, Inc. (MCGHI) and the Charlie Norwood VA Medical Center (VAMC). Members of this research community are the faculty, staff and students of each institution. The web site emphasizes that the responsibility for the protection of human research subjects is shared between the investigator, the institution, the Institutional Review Boards (IRBs), and OHRP. The web site is divided into sections that outline the interrelated responsibilities of the different components of the Human Research Protections Program (HRPP).

All human subjects and/or human derived materials research conducted in our research community must comply with the policies and procedures outlined on this web site. All research projects involving human subjects and/or human derived materials conducted by or in our research community must receive the designated Institutional Review Boards (IRBs) approval prior to initiation of the research.

### **Establishing New Policy and Procedures and Periodic Review and Revision of Current Policy and Procedures**

The OHRP web site will be revised as needed to ensure that the web site remains current and reflects current practice. Once the need for revision is identified via external agency audits, internal review, revision to regulations or guidelines, etc., the web site will be promptly revised. The OHRP will evaluate aspects of the HRPP and the policies and procedures as needed and may recommend revisions to the web site accordingly.

MCG's HRPP policies and procedures are based, in part, on the relevant federal regulations and guidance, state and local laws, relevant MCG policies and procedures and generally accepted standards within the human subject protections field. The HRPP web site is a collaborative effort of the OHRP with our IRBs and other key stakeholders of our research community. Working together, human research protection program (HRPP) policies and procedures are established and updated on the OHRP web site.

When the need for new or revised policies and procedures is identified, the Human Protections Administrator (HPA), the key stakeholders and/or individuals involved, which may include research faculty, will form a working group with the OHRP staff to draft the policy. The Clinical Research Education and Advisory Team (CREATe), an OHRP Advisory Committee, may also participate in any revisions. The HAC Chairperson, the HAC members, representatives from

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Chesapeake Research Review, Inc. (CRRI), appropriate advisory committees with representation from the impacted areas established by the OHRP Director on an ad hoc basis, and, when applicable, the Charlie Norwood VA Medical Center (VAMC) will review the draft policies. Final policy drafts are presented to the OHRP Director, the HAC Chairperson and/or the Vice President of Research for approval and implementation.

### **Measurement and Improvement of the Human Research Protection Program**

The institution monitors and measures the effectiveness of the human research protection program by reviewing the form “Annual Review of Human Research Protection Program” provided by the OHRP. This review is conducted annually in conjunction with fiscal year budget evaluation and preparation period.

If it is noted during the review that improvements are needed, the Vice President for Research in conjunction with the OHRP Director prepares a plan of improvement to be implemented. After implementation, these changes are monitored and measured to determine the effectiveness of improvements. If additional changes are required, these are identified and reviewed.