

Human Research Protections Program (HRPP)

Organizational Leadership, Authority, Structure and Function of the Human Research Protection Program

The MCG OHRP serves as the human research protection program for the following entities:

Medical College of Georgia

The President of MCG serves as the Institutional Official for carrying out the institution's human research protections program. The President serves as the responsible MCG signatory official (Institutional Official) for the FWA, as well as for grants and contracts. The Vice President for Research has assigned the role of the Human Protections Administrator (HPA) to the OHRP Director. The HPA is the primary contact person for human subject protection issues, including the investigation and reporting of non-compliance matters, and plays a key role in ensuring that the institution fulfills its responsibilities under the FWA. In addition to the President, the Vice President for Research, the HRPP is a cooperative effort of four other major shareholders; the institution's administration, the IRBs, the administrative units within the Department of Research Administration (RA) [e.g. Office of Human Research Protection (OHRP), Division of Sponsored Programs Administration, etc.] and investigators, including faculty, staff or students. MCG has assigned the primary duties related to the human research protection program to the MCG OHRP.

Medical College of Georgia Health, Inc. (MCGHI)

MCGHI is a Georgia non-profit corporation that operates the hospitals and clinics of MCG. MCGHI is a "cooperative organization." In this case, MCGHI exists to support the clinical, educational and research activities at MCG. MCGHI was incorporated in the mid-1990s, but it did not assume responsibility for operating the hospitals and clinics until July 1, 2000. Before that time, the "MCG Hospitals and Clinics" were a part of MCG. Now all hospital records and policies are in the custody and control of MCGHI. If MCGHI generates funds in excess of its expenses, a portion of that is paid to MCG. The MCGHI hospitals and clinics consist of the "MCG Hospitals and Clinics," our main adult hospital and outpatient clinics, and the "Children's Medical Center." MCGHI also operates some separate facilities in Augusta and beyond.

The MCGHI has a separate FWA and a Clinical, Research and Education Service Agreement (CERSA) with MCG. MCGHI has designated the MCG HAC and CRRI to serve as the IRBs of record. The OHRP Director serves as the MCGHI liaison between MCG and MCGHI. The liaison participates in discussion and review of MCGHI policy and procedures as it relates to human subjects protection and ensures that MCG IRB/OHRP records are in order for any audits or reviews conducted by agencies inspecting the MCGHI human subject protection program.

IRB review for human subjects research conducted at the MCGHI may undergo HAC or CRRI review as appropriate within institutional guidelines. The Chief Executive Officer (CEO) serves as the Institutional Official for carrying out the institution's human research protections program. The CEO serves as the responsible signatory official (Institutional Official) for the FWA. The CEO assigned the role of the Human Protections Administrator (HPA) to the Risk and Loss Prevention Specialist, Interim Compliance Officer. The HPA is the primary contact person for human subject protection issues, including the investigation and reporting of non-compliance matters, and plays a key role in ensuring that the institution fulfills its responsibilities under the

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FWA. MCGRI has assigned the primary duties related to the human research protection program to the MCG OHRP.

Medical College of Georgia Research Institute (MCGRI)

Medical College of Georgia Research Institute, Inc. (MCGRI) is a separate, non-profit research corporation established for MCG research studies. The Institute is a separate 501 (c) (3) corporation in the State of Georgia. Per industry standard, the proper party for research study agreements at our institution is the MCG Research Institute, Inc. (State law prohibits MCG, a public institution, from entering into agreements with terms longer than one year, and imposes other restrictions that make MCGRI an essential party to our study contracts.) MCGRI subcontracts with MCG, which employs the research staff, for performance of the work in each study. MCGRI has assigned the primary duties related to the human research protection program to the MCG OHRP.

Physicians Practice Group (PPG)

The Medical College of Georgia Physicians Practice Group Foundation (PPG): PPG is an unincorporated association, and it is a "cooperative organization," which means that it has been approved by the Board of Regents as an affiliated but separate entity that helps to further the purposes of the Board of Regents. There are affiliation agreements between PPG and MCG, and PPG and MCGHI. Membership in PPG is limited to MCG faculty physicians and oral surgeons. PPG bills and collects the professional fees from its members' practice. They are also authorized to "conduct and manage" the practice, which means that PPG contracts with managed care companies to establish billing rates for PPG members, and operates a small number of clinics where PPG members practice. PPG does not establish the working hours or conditions for its members, and they do not supervise or control the clinical judgment of its members. PPG members primarily practice at the facilities operated by MCGHI. PPG only maintains the medical and other records for the small number of clinics that it operates. PPG does have non-physician employees, including administrative and clinical staff. PPG has assigned the primary duties related to the human research protection program to the MCG OHRP.

Charlie Norwood VA Medical Center

The Charlie Norwood VA Medical Center has a separate FWA (FWA#00002534) that designates the HAC as their IRB of record. Accordingly, the MCG HAC meets the requirements of the Veterans Affairs (VA) regulations for human subjects research at 38 CFR 16, 17, the Veterans Health Affairs (VHA) handbook, and guidance, memorandums, and policies related to human subjects research. Research involving human subjects conducted at the Charlie Norwood VA Medical Center, by Charlie Norwood VA Medical Center personnel, or by MCG personnel in conjunction with the Charlie Norwood VA Medical Center may be reviewed only by the HAC. The OHRP Director serves as the liaison between MCG and VAMC. The OHRP Director or Assistant Director may attend R&D Committee meetings. The OHRP Director participates in discussion and review of Charlie Norwood VA Medical Center policy and procedures as it relates to human subjects protection and ensures that MCG HAC/OHRP records are in order for any audits or reviews conducted by agencies inspecting the Charlie Norwood VA Medical Center human subject protection program.

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MCG's primary IRB known as the HAC provides IRB review for human subjects research conducted at the Charlie Norwood VA Medical Center under a Memorandum of Understanding (MOU). Projects reviewed for the Charlie Norwood VA Medical Center receive the same HAC review as those conducted at MCG and/or MCGHI. Chesapeake Research Review, Inc. (CRRI) is prohibited from reviewing protocols that involve the Charlie Norwood VA Medical Center as a site.

The Associate Chief of Staff/Research & Development (ACOS/R&D) serves as the Institutional Official for carrying out the institution's human research protections program. The ACOS/R&D serves as the responsible Augusta signatory official (Institutional Official) for the FWA, as well as for grants and contracts. The ACOS R&D assigned the role of the Human Protections Administrator (HPA) to the Administrative Officer (AO). The HPA is the primary contact person for human subject protection issues, including the investigation and reporting of non-compliance matters, and plays a key role in ensuring that the institution fulfills its responsibilities under the FWA.

A Memorandum of Understanding (MOU) serves as the IRB Authorization Agreement (IAA) that outlines the responsibilities of both MCG and the Charlie Norwood VA Medical Center as related to the protection of human subjects and IRB review of research conducted at the Charlie Norwood VA Medical Center. The policies and procedures governing human subjects' research at Charlie Norwood VA Medical Center are detailed on the MCG web site for VAMC.

Augusta Biomedical Research Corporation

Augusta Biomedical Research Corporation (ABRC) was established by the Charlie Norwood VA Medical Center in 1989 pursuant to sections 7361 through 7368 of Title 38 U.S.C. ABRC provides a mechanism for the administration of private and public grants to support the research and education missions of the Charlie Norwood VA Medical Center. Augusta Biomedical Research Corporation is a state chartered corporation/charitable organization and is a 501(c)(3) federal tax-exempt organization. The sole purpose of ABRC is to advance the research and education missions of the Department of Veterans Affairs (DVA), and specifically the Charlie Norwood VA Medical Center, through the support of research-related and education-related activities.