



AUGUSTA
UNIVERSITY

Invites Applications and Nominations for the Position of:

**Director for Human
Research Protection**

**Greenwood
Asher &
Associates®**

The Opportunity

Augusta University (AU) seeks an innovative and strategic Director for Human Research Protection to lead the Institutional Review Board (IRB) Office. Reporting directly to the Senior Vice President for Research, the director is responsible for overseeing and ensuring the efficient and effective operations of the Human Research Protection Program. The IRB Office ensures the research goals of the Augusta University enterprise are met while protecting human subjects involved in research and verifying the enterprise meets compliance standards. The IRB Office also serves as the central contact for facilitating the goals of the enterprise HRPP. The IRB Office provides administrative support for the internal IRBs and a liaison for the external IRBs, monitors and oversees all IRB approved studies, and provides education and training for human research investigators, staff, and IRB members.

The Research Enterprise

Clinical and translational research programs at Augusta University focus on three key areas that disproportionately affect the health of Georgians: cancer, cardiometabolic disease, and neurological disease including stroke. The university is also developing three emerging areas of research strength:

- › regenerative & reparative medicine
- › personalized medicine & genomics
- › public and preventive health

Regenerative and reparative medicine will expand studies of diseases or injuries that impact muscles and skeleton, central nervous system, orofacial, orthopedics, and stroke & neurotrauma. The university's cardiovascular, obesity, and diabetes research fights the greatest threats to the Western world.



Cancer and genomic medicine research are reducing the burden of cancer through superior clinic care, discovery innovation, translational research, and education. Neurological research is unlocking the mysteries of schizophrenia, stroke, Alzheimer's disease, Parkinson's disease, and multiple sclerosis.

Personalized medicine is being developed to customize treatments for individual patients, which public and preventive health measures are working to prevent diseases. The Dental College is improving the diagnosis, prevention, and treatment of disease of the orofacial complex, while the Vision Center is engaging in high impact research and discovery related to visual function and disease, the outcome of which is expected to have far-reaching clinical applications for patients suffering from blindness and visual disorders. The multidisciplinary field of Women's Health is on the cutting edge of research related to the care of women. The newest area of research will be through the very exciting start-up of the Cyber Institute at Augusta University.

The Role of the Director for Human Research Protection

The Director for Human Research Protection is a vital member of the senior leadership team in Augusta University's Office for Research Administration. The director is responsible for overseeing and ensuring the efficient and effective operations of the Human Research Protection Program. The director keeps the Senior Vice President for Research informed of developments, particularly at the federal level, within and related to the director's areas of responsibility, providing recommendations and seeking counsel from the Senior Vice President for Research to ensure the continuous delivery of outstanding service to AU's research community while maintaining and enhancing compliance with ethical and regulatory requirements. Specific to AU's Human Research Protection Program (HRPP), the director serves as the Human Protections Administrator under the university's Federalwide Assurance, as well as according to the Association for the Accreditation of Human Research Protection Programs accreditation and is hence responsible for the appropriate functioning of the HRPP. The director is actively engaged in building and maintaining relationships with internal and external collaborators. Through service on various AU committees, the director influences policy and process and builds consensus and consistency in coordination with other units and schools.

Duties and Responsibilities

Representative duties and responsibilities of the director role include, but are not limited to, the following:

Management of IRB Office

- › Oversee the direction and supervision of the IRB Office personnel to ensure that the IRB operations, education, and compliance missions are evaluated and achieved.
- › Manage the day to day IRB Office functions and IRB Office.
- › Manage IRB Office budget to include the IRB revenue account.
- › Review staffing levels and activity and conduct periodic performance evaluations.
- › Promote research and scholarship within the units of the IRB Office.
- › Oversee functions and services of IRB Operations Manager, IRB Regulatory Compliance Manager, and their staff.

Human Protections Administrator

- › Provide leadership and guidance to the AU HRPP to include the IRB Office, ensuring it is structured and resourced to provide efficient and effective support to the research internal and external communities in compliance with regulatory and legal obligations.
- › Be responsible for the appropriate functioning of the university's HRPP.
- › Serve as an adviser and resource in the field of human subjects' protection, regulatory compliance and quality improvement associated with protocols conducted within the AU Health System including all campuses, AU Health, Inc., Physicians Practice Group and the Charlie Norwood Veterans Affairs Medical Center and to ensure consistency across all research policies and functions and ensuring cross functional data harmonization.

- › Serve as the Human Protections Administrator for the University's Federalwide Assurance, assuring compliance with the federal regulations for the protection of human subjects in research.
- › Serve as the Human Protections Administrator for the Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation, indicating that the university follows rigorous standards for ethics, quality, and human research protection.
- › Lead all AAHRPP accreditation efforts to include maintenance of reaccreditation and annual reports.
- › Collaborate with the SVP for Research, other AVPs, and unit directors at AU regarding the functions and operations of the HRPP.
- › Act as the organizational resource for all human compliance issues and collaborate with researchers on all compliance issues including IRB requirements or human subjects protection issues including dissemination of information to members, investigators and staff on regulatory.
- › Collaborate with colleges and units across the University, addressing areas of concern related to conducting human research.
- › Design and plan special projects designed to enhance office procedures, HRPP performance, overall human subjects protections and general research compliance.
- › Advise the Institutional Official and IRB Chairpersons on matters related to research non-compliance while maintaining a high level of awareness regarding the ethical conduct of research and safeguarding the rights and welfare of human research subjects.
- › Understand and keep abreast of federal and state regulatory environments and university policies relating to human research to ensure the SVP for Research and senior leadership are apprised of research regulatory issues and significant new developments.
- › Acquire and apply DHHS, FDA, and VHA federal regulations for the protection of human subjects to specific research situations which requires an extensive knowledge of both DHHS (45 CFR 46), FDA (21 CFR 50 and 56), and VHA (38 part) human subjects regulations and appreciation of related regulatory, ethical, and compliance principles.
- › Maintain familiarity with other regulations and guidance (e.g. CMS, HIPPA) that may be applicable in human research subjects studies.

HRPP Community Engagement and Outreach

- › Provide oversight and direct administration of the HRPP Community Engagement and Outreach Administrator to include activities and initiatives designed to engage the CSRA and Georgia citizens whom the AU HRPP serves.

Policies, Guidelines, and Applications

- › Oversee the development of policies, guidelines, and applications for the protection of human participants, in conjunction with the Senior Vice President for Research.
- › Provide oversight on new policies, policy interpretation, and revisions when needed.

Building and Maintaining Relationships

- › Actively engage in building and maintaining relationships with the clinical affiliates to which the university provides human research support: Augusta University Health System, Physicians Practice Group, Charlie Norwood VA Medical Center, and Medical College of Georgia at Augusta University Satellite Campuses.

Electronic Systems

- › Ensure the IRBs have robust electronic systems to support the University's HRPP.
- › Identify and assess setting-appropriate electronic IRB management systems, successfully implementing selected systems and submission processes.
- › Ensure that valid, informative and appropriate documents and data reports are generated.

Member of Various Committees

- › Influence policy and process through service on various university committees, such as Conflict of Interest, IRB Leadership, Translational Research Facilitation, and the Augusta University Health Data Governance Council necessary to ensure that human research protections are built in as necessary (example: electronic medical record, research data warehouses, etc.).

Other

- › Provide guidance on human research-related conflicts of interest, procedures, and emergent matters.

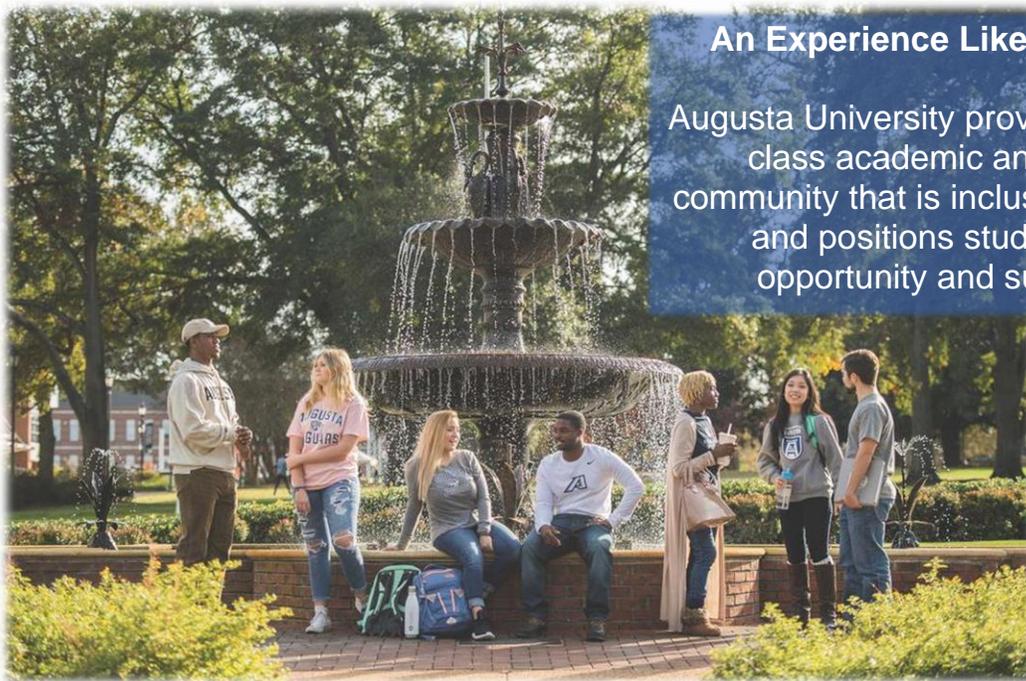
Required Qualifications

- › Master's degree from an accredited college or university.
- › A minimum of five (5) years of directly related experience.
- › Certified IRB Professional (CIP) or Certified IRB Manager (CIM).
- › **OR** Bachelor's degree from an accredited college or university in a scientific or management field, with the Certified IRB Professional (CIP) or Certified IRB Manager (CIM) and a minimum of 8 years of direct experience in a research or regulatory environment, particularly in human research protections.
- › A demonstrated track record of effective leadership in higher education, government, or commercial.

Knowledge, Skills, and Abilities

- › Thorough knowledge of federal regulations, state laws and accreditation standards related to human subjects protections (investigator, sponsor, sponsor/investigator, IRB, privacy board, etc.) as well as the ability to implement those into appropriate training and auditing programs.
- › Effective leadership and management skills, with the ability to develop staff while delegating authority and responsibility.
- › Strong interpersonal, communication, analytical, and organizational skills.

- › Ability to lead a team of diverse units.
- › Ability to deal effectively with difficult situations.
- › Ability to work effectively with a wide range of internal and external constituencies, including faculty members, staff across the University, students, and oversight agencies.
- › Ability to maintain a working environment characterized by effective teamwork and collaboration with peers.
- › Commitment to high ethical standards.
- › The ability to manage confidential information.
- › A deep appreciation of and respect for academic values and culture and an understanding of the critical role that the position.
- › Ability to sustain and broaden a research university's intellectual rigor.
- › Ability to excel in a team environment.



An Experience Like No Other

Augusta University provides a world-class academic and social community that is inclusive, diverse, and positions students for opportunity and success.

About Augusta University

Founded in 1828 and located in Augusta, Georgia, Augusta University is dedicated to training the next generation of innovators, leaders, and health care providers. The University offers undergraduate programs in the liberal arts and sciences, business, and education as well as a full range of graduate programs and hands-on clinical research opportunities. The combination of its nationally ranked business and nursing schools as well as its designation as the state's flagship public medical school and only dental school makes Augusta University a destination of choice for the students of today and the leaders of tomorrow. With locations throughout Augusta and at satellite campuses in Athens, Albany, Rome and Savannah, the university's ten colleges and schools have a statewide impact in Georgia.

In 2012, Augusta State University and Georgia Health Sciences University began the process of consolidation, renaming the consolidated institutions Augusta University. At the annual meeting of the Commission of Colleges of the Southern Association of Colleges and Schools on December 6, 2016, Augusta University's accreditation was reaffirmed. This accreditation marked the administration completion of the consolidation process.

Augusta University's strategic plan, Beyond Boundaries, was introduced in 2017. The plan incorporates education, research and scholarship, clinical care, and outreach and economic development in guiding the institution to discover the true potential of this great university and its health system.

Mission

The mission of Augusta University is to provide leadership and excellence in teaching, discovery, clinical care, and service as a student-centered comprehensive research university and academic health center with a wide range of programs from learning assistance through postdoctoral studies.

Vision

The vision of Augusta University is to be a top-tier university that is a destination of choice for education, health care, discovery, creativity, and innovation.

Values

- > Collegiality
- > Compassion
- > Excellence
- > Inclusivity
- > Integrity
- > Leadership

Accreditation

Augusta University is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools (SACSCOC) toward one-year and advanced certificates and degrees at the associate, bachelor's, master's, specialist's, first professional, and doctoral levels.

Fast Facts:

Total Enrollment: 9,565

- > Undergraduates: 5,675
- > Graduate/Professional: 3,890
- > Female: 64%
- > Male: 36%

2,233 Degrees Conferred:

- > Bachelor's: 993
- > Master's: 569
- > Doctorate &
- > Professional: 433
- > Associates &
- > Certificates: 238

152 Academic Offerings:

- > 46 undergraduate programs
- > 38 graduate programs
- > 19 doctoral & professional programs
- > 49 certificates

Governance: Board of Regents,
University System of Georgia

University Budget (FY 2020): \$1.06B

AU Faculty and Staff: 6,775

For more facts, please visit:
<https://www.augusta.edu/ie/facts/>

Colleges & Schools

- › Medical College of Georgia, 1828
- › College of Nursing, 1943
- › Katherine Reese Pamplin School of Arts, Humanities, and Social Sciences, 1963
- › The Graduate School, 1965
- › The Dental College of Georgia, 1965
- › College of Education, 1968
- › College of Allied Health Sciences, 1968
- › James M. Hull College of Business, 1971
- › College of Science and Mathematics, 2012
- › School of Computer and Cyber Sciences, 2017



Points of Pride

- › Augusta University is Georgia's only public academic health center.
- › Augusta University, home of the Medical College of Georgia, is one of only four public comprehensive research institutions in the state of Georgia.
- › Augusta University offers more than 152 academic programs in ten colleges and schools, including the nation's 13th-oldest medical school; the state's sole dental college; the nationally ranked James M. Hull College of Business; the Pamplin College of Arts, Humanities and Social Sciences; Education; Science and Mathematics; Allied Health Sciences; Graduate Studies; Computer and Cyber Sciences; and Nursing. Augusta University's Medical College of Georgia includes a partnership campus in Athens, Ga., and satellite campuses in the Georgia cities of Albany, Rome, and Savannah.
- › Augusta University's nearly 10,000 students come from over 70 countries and nearly all of Georgia's 159 counties.
- › Augusta University has over 170 student organizations.
- › Augusta University fields teams in NCAA Division I men's and women's golf, and the men's team claimed back-to-back national championships in 2010 and 2011. In 11 other varsity sports, the Jaguars compete in the Division II Peach Belt Conference in basketball, baseball, cross-country, softball, volleyball, tennis, and outdoor track and field.



The City of Augusta, Georgia

Augusta, Georgia is the second-largest metro area in Georgia and is located on the southern bank of the Savannah River midway between the Great Smokey Mountains and the Atlantic Ocean. It is a growing and thriving city with a metropolitan area and recently ranked second in Georgia for Best Places to Live.



Nomination and Application Process

Salary

The position is a full-time, 12-month administrative position with an excellent benefits package. Salary is competitive and commensurate with experience.

How to Apply

Greenwood Asher & Associates is assisting Augusta University in this search. Applications and nominations are now being accepted. For a full application package, please provide a cover letter, CV, and list of five references. Confidential inquiries, nominations, and application materials should be directed to Greenwood Asher & Associates. Submission of application materials as PDF attachments is strongly encouraged. The search will be conducted with a commitment of confidentiality for candidates until finalists are selected. Initial screening of applications will begin immediately and will continue until an appointment is made.

Inquiries, nominations, and application materials should be directed to:

Jim Johnsen
Vice President of Executive Search
Greenwood Asher & Associates
E-mail: jimjohnsen@greenwoodsearch.com

Ann Bailey
Senior Executive Search Consultant
Greenwood Asher & Associates
E-mail: annbailey@greenwoodsearch.com

For more information about the position, please visit: <https://greenwoodsearch.com/current-opportunities/>

For more information about Augusta University, please visit: <https://www.augusta.edu/>

The material presented in this leadership profile should be relied on for informational purposes only. This material has been copied, compiled, or quoted in part from Augusta University documents and personal interviews and is believed to be reliable. While every effort has been made to ensure the accuracy of this information, the original source documents and factual situations govern.

Augusta University is committed to providing equal employment opportunity (EEO) for all individuals without regard to race, age, color, national origin, religion, disability, gender, creed, veteran status, sexual orientation, genetic information, or any other basis prohibited by law.