

SUMMARY

Ms. Sahar Zafar is currently pursuing a DPA focused on Health and Research Policy (ABD) at the University of Baltimore. She currently holds a Master of Science in Biotechnology, with a concentration in Biodefense, and has over 10 years of experience regulating Federal and Department of Defense (DoD) human subjects research (HSR) policies and HSR operations. Ms. Zafar currently manages the Defense Advanced Research Projects Agency's (DARPA) human subjects research protection program by ensuring that all Federal and DoD policies and regulations are followed with the highest ethical standards. She regularly participate as a subject matter expert on Assistant Secretary of Defense Research and Engineering Directorate (ASD R&E) panels for Federal and Defense human subjects research policies at conferences and meetings.

Previously, she worked as a human subjects protection scientist at Walter Reed Army Institute of Research (WRAIR), where she demonstrated deep knowledge of current HSR and DoD policies and their application. Ms. Zafar has assisted multiple Institutional Review Boards (IRBs), Headquarters Level Review IRBs, and other domestic and international research ethical committees in obtaining approval and maintaining regulatory compliance for a variety of research activities. Her ethical and regulatory experience is further complimented by her certifications, work experience, and educational background. Ms. Zafar is currently working on her dissertation titled "Ethical, Legal and Societal Implications of Neuroscience and Technology Research and its Impact on Public Policy," with expected completion in early 2017.

SECURITY CLEARANCE

Top Secret-Sensitive Compartmented Information

Cleared: February 2013

EDUCATION

University of Baltimore, MD

Expected: 2017

Doctorate in Public Administration (all but dissertation)

Health and Research Policy

Johns Hopkins University - Baltimore, MD

Completed: 2008

M.S. in Biotechnology

Graduated: 2009

Concentration: Biodefense

College of Notre Dame of Maryland - Baltimore, MD

Graduated: 2006

B.A. in Biology, Major

Chemistry, Minor (Focus: Pre-med)

EMPLOYMENT

Defense Advanced Research Projects Agency

ECS Federal

June 2011– Present

Booz Allen Hamilton

May 2010 – June 2011

Scientist/Human Subject Research Protection Program Officer

- Manage the Defense Advanced Research Projects Agency's (DARPA) human subjects research protection program by ensuring that all Federal and Department of Defense (DoD) policies and regulations are followed with the highest ethical standards
- Participate as a subject matter expert on Assistant Secretary of Defense Research and Engineering Directorate panels for Federal and Defense human subjects research policies at conferences and meetings
- Actively participate in drafting of Federal and DoD policies governing human subjects research (such as DoDI 3216.02, ANPRM to update the Federal policy on human research, etc.)
- Contributed to the development of DoD wide education training for all Extramural and Intramural research
- Guide DARPA-funded researchers and government employees through the human subjects research review and approval processes
- Update and implement DARPA policies and procedures pertaining to human subjects research
- Assure that DoD human subjects research approvals are granted in a timely fashion by acting as a liaison between DARPA-funded researchers and multiple agencies such as the DoD regulatory oversight offices, including U.S. Army Medical Material Command Human Subjects Research Review Board (USAMRMC HSRRB), Air Force, Navy, and other DoD and non DoD Contracting Agents

- Maintain a database of all DARPA-funded human subjects studies information, including research specific protocols, as well as funding documents
- Maintain DARPA's human subjects research protection website
- Monitor and aid DARPA human subject research approved agents, to obtain necessary certifications and approvals in order to conduct human subjects research
- Educate internal staff as well as DARPA clients on Federal and DoD-specific regulations governing human subjects research, DoD human subjects research approval process, and human subjects research ethical guidelines
- Compose a variety of correspondence and memoranda of approval for the signature of the Human Subjects Protection Administrator (HPA), Assistant Director of Program Management (ADPM), and other Departmental Officials, as necessary
- Develop and maintain an up to date understanding of current Ethical Research Guidelines, Good Clinical Practices (cGCP), and U.S. Food and Drug Administration (FDA) regulations that govern the protection of human subjects and apply them where necessary and/or identify the appropriate resources
- Participate in on-going trainings and conferences related to human subjects protection
- Communicated regularly and effectively with program managers, performers, agents, and appropriate institutional officials
- Accomplished miscellaneous duties assigned by the Director and/or office personnel on a daily basis

Walter Reed Army Institute of Research

Clinical Research Management

Human Subjects Protection Scientist

September 2008 – April 2010

- Assisted the WRAIR Institutional Review Board (IRB), the USAMRMC HSRRB and other domestic and international research ethical committees in obtaining approval and maintaining regulatory compliance for a variety of research activities by providing human subjects research support
- Evaluated and reviewed a wide range of pilot trials to phase I, II, and III clinical studies for compliance with relevant regulatory requirements, federal laws, policies and guidelines governing human subjects protection
- Provided administrative oversight and assessment of Continental United States (CONUS) and Outside the Continental United States (OCONUS) research, recommending revisions to protocols, informed consent forms, and other supporting documentation to ensure regulatory compliance
- Served as a primary liaison between internal departments, the Division of Human Subjects Protection, and oversees laboratories during protocol development and implementation
- Composed a variety of correspondence and memoranda of approval for the signature of the Commander, Deputy Commander, and Departmental Directors
- Assisted in the clearance of manuscripts, abstracts, and posters for presentations and publishing
- Preparation and execution for the monthly WRAIR IRB convened meetings
- Developed and maintained an understanding of current Ethical Research Guidelines, Good Clinical Practices (cGCP), and U.S. Food and Drug Administration (FDA) regulations that govern the protection of human subjects and apply them where necessary and/or identify the appropriate resources
- Assisted in setting up and executing the Collaborative Institutional Training Initiative (CITI) for WRAIR employees and IRB members
- Preparation and execution for off and on site workshops for DHSP staff, IRB members, and Research Divisions at WRAIR
- Recommended revisions to policies in the handling and documentation of the FDA regulated investigational products
- Took accurate notes at the WRAIR IRB meetings and follow up on IRB requested revisions of documentation
- Communicated regularly and effectively with principal investigators, sponsors, and appropriate institutional officials
- Assured quality of records prior and post protocol implementation
- Maintained accurate and orderly records of all IRB documents, protocols, human subjects protection policies and guidelines, army policy letters, IRB Authorization Agreements (IAA), Individual Investigator Agreements (IIA), Memorandum of Understanding/Authorization (MOU/MOA), and Site Assistance Visit (SAV) reports
- Assisted in providing training in Human Subjects' Protection and quality of records to investigators and other staff as needed
- Participated in on-going trainings and conferences related to human subjects protection
- Provided assistance to Clinical Research Management (CRM) Headquarters as needed on proposal writing projects and provide assistance with all job-related progress reports/technical reports
- Accomplished miscellaneous duties assigned by the Director and/or office personnel on a daily basis

Data Administrator

August 2007 – August 2008

- Preparation and execution for the monthly WRAIR IRB convened meetings
- Assisted in the clearance of manuscripts, abstracts, and posters for presentations and publishing
- Provided assistance to Headquarters on proposal writing projects
- Provided assistance with all job-related progress reports/technical reports
- Data entry, filing of study protocol related documents, indexing, photocopying, scanning, and shredding of documents
- Participated in on-going trainings and conferences related to human subjects protection
- Maintained accurate and orderly records of all IRB documents, protocols, human subjects protection policies and guidelines, army policy letters, IRB Authorization Agreements (IAA), Individual Investigator Agreements (IIA), Memorandum of Understanding/Authorization (MOU/MOA), and Site Assistance Visit (SAV) reports
- Assisted Director in preparation for meetings, conferences, and workshops
- Observed appropriate safety and occupational health rules and regulations
- Accomplished miscellaneous duties assigned by the Director and/or office personnel on a daily basis

College of Notre Dame of Maryland**Lab/Teacher's Assistant**

September 2003 – May 2006

- Assisted students in labs and lab set-ups
- Programmed and used computers to store, process and analyze data
- Provided help with grading papers
- Identified, classified, and studied structures of plants and animal species
- Collected and analyzed biological data
- Prepared test solutions, compounds, and reagents for laboratory

CLINICAL/MEDICAL EXPERIENCEJohns Hopkins Hospital**Research Assistant**

December 2006 – January 2007

- Programmed and used computers to store, process and analyze data
- Assisted in clinical research projects
- Collect and analyzed biological data

Washington Hospital**Shadowed various Surgeons**

April 2005

- Dr. Hameed Paracha: Left/right cataract and glaucoma surgery
- Dr. Nik Neiman: Tear duct surgery

Security Crossroads Medical Center**Shadowed Dr. Ramana Gopalan**

May 2003 – April 2005

- Assisted in screening patients, obtaining vital signs, and phlebotomy
- Assisted in minor procedures such as pap smears, EKG, and palpations for abnormalities

University of Maryland Medical Systems**Intern**

September 2001 – May 2002

- Adult Neurology – assisted in patient care
- Child Psychology – assisted in patient care
- Out-Patient Clinic – assisted in registering and admitting patients with HIV/AIDS
- Radiology – assisted in X-ray, CAT scan and MRI
- Shock Trauma – assisted in admitting and triage

Extensive research and experimentation performed in Neurobiology based on information gathered from many sources; Compiled and analyzed test information to determine process or equipment operating efficiency and to diagnose malfunctions in equipment

CERTIFICATIONS, PRESENTATIONS AND AFFILIATIONSCertifications

National Association of Institutional Review Board Managers; Certified IRB Manager

Certified: 2009

Presentations

2016

- North East Conference of Public Administrators (NECoPA), Presented on, “Ethical, and Societal Implications of Neuroscience and Technology Research”

2015

- Public Responsibility in Medicine and Research (PRIM&R); on the DoD HSR Panel

2014

- SPC Educational Conference; Presented on Human Subjects Research Ethical Guidelines and Policies

2012

- DARPA Business Conference; Presented on Human Subject Research Ethical Guidelines and Policies

Affiliations

Neuro Ethics Women Leaders Group (<https://neuroethicswomenleaders.com/>)