#249-23

Ruthanne Fuller
Mayor

City of Newton, Massachusetts
Office of the Mayor

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June 12, 2023

Honorable City Council
Newton City Hall
1000 Commonwealth Avenue
Newton, MA 02459

To the Honorable City Councilors:

I am pleased to reappoint Matthew Stafford of 40 Belmore Park, Newton 02462 as a member of the Health and Human Services Advisory Council. His term of office shall expire on January 1, 2025 and his appointment is subject to your confirmation.

Thank you for your attention to this matter.

Warmly,

Ruthanne Fuller
Mayor

Newton, MA Boards & Commissions

Application Form

Profile

Matthew (Matt) — First Name
— Middle Initial
Stafford — Last Name

matt.stafford@gmail.com — Email Address

40 Belmore Park — Home Address
— Suite or Apt

Newton — City
MA — State
02462 — Postal Code

What Ward do you live in?

☑ Ward 4

Mobile: (617) 775-6418 — Primary Phone
Business: (203) 432-5771 — Alternate Phone

Yale University — Employer
Assistant Director, Human Research Protection Program — Job Title

Which Boards would you like to apply for?

Health and Human Services Advisory Council : Submitted

Interests & Experiences

Please tell us about yourself and why you want to serve.

Why are you interested in serving on a board or commission?

As a parent in Newton and a student of public health I wish to stay abreast of issues pertaining to my town and I also wish to contribute a fairly lay perspective to the shaping of public health policy in my town.

Upload a Resume

#249-23

Matthew Stafford, MPH
40 Belmore Park
Newton Lower Falls, MA 02462
https://www.linkedin.com/in/matt-stafford-he-him-his-34194735/

he/him/his
Mobile: (617) 775-6418
Email: matt.stafford@gmail.com

SUMMARY

Clinical Research Compliance Executive with 20 years of experience building and overseeing high-performing compliance functions for multi-million-dollar research portfolios. Accomplished in managing change, approaching complex issues, navigating gray areas, and building consensus with imagination, discretion, and integrity. Seeking opportunities to facilitate innovation and excellence as part of an organization dedicated to social justice and health equity.

EDUCATION

BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH
Master of Public Health (MPH)
Concentration: Health Policy and Management

COLUMBIA UNIVERSITY, SCHOOL OF GENERAL STUDIES
Bachelor of Arts (BA)
Major: Middle East and Asian Languages and Cultures

WORK EXPERIENCE

THE PEER CONSULTING GROUP **April 2020 to Present**
IRB Expert Consultant

- Conducting regulatory and ethical pre-review of human research protocols for designated contract clients.
- Developing HHS-compliant protocol and consent form templates.
- Developing SOPs to ensure continued compliance after contract.
- Advising contract clients on an ad hoc basis as questions arise.

BOSTON CHILDREN'S HOSPITAL (BCH) **October 2014 to Present**
Assistant Director, Clinical Investigations

- In addition to responsibilities of the Manager (below), hired, trained, and mentored multiple direct reports who now have leadership roles at BCH and other organizations. Achieved stability with 75% staff retention for over 10 years.
- Created new positions for direct reports to develop supervisory skills and coached direct reports in mentoring roles.
- Created metrics for coaching staff to improve performance, efficiency and quality.
  Served as ranking officer in multiple FDA audits with zero compliance findings.
- Involved with hiring and training multiple regulatory affairs professionals responsible for oversight of and guidance with research involving FDA-regulated articles including investigational new drug (IND) applications, investigational device exemptions (IDE), humanitarian use devices (HUD), nonsignificant risk (NSR) devices and 510k designations.
- Served as resource to investigators and research personnel on matters pertaining to regulatory strategy, compliance requirements, minimizing risk, ethical study design, and interpretation of federal regulations and hospital policies.
- Oversaw the Institutional Review Board (IRB) Office through multiple transitions including office reorganization, staffing changes, move to paperless system and adoption of a new HHS Common Rule.
- Represented the institution at national and local level through Harvard CTSA organizations, the CITI Developer's Group, and on the faculty and planning committees of PRIM&R's annual Advancing Ethical Research conferences.

BOSTON CHILDREN'S HOSPITAL (BCH) **March 2006 to September 2014**
Institutional Review Board (IRB) Manager

- Developed and implemented methods, strategies, mechanisms and Standard Operating Procedures (SOPs) for resolving human subject protection issues, measuring efficiency and assuring quality. Revised same as required by operational and regulatory changes.
- Conducted pre-review and compliance assurance for new and ongoing projects including multicenter clinical trials, biomedical and social/behavioral science research, vulnerable populations, emerging technologies, investigational drugs and devices, and expanded access treatments.
- Coordinated communication between investigators, IRB members, cross-functional units and stem cell committees; assisted with accreditation applications and site visits, receiving personal praise from accreditors.
- Identified, prioritized and implemented policy, procedural and staffing changes that enhanced operational efficiency and improved interactions between the hospital, IRB sponsors and investigators.
- Maintained positive and collegial advisory relationships with hospital leadership, faculty and research community despite challenges in staffing.

NEW YORK BLOOD CENTER (NYBC) LINDSLEY F. KIMBALL RESEARCH INSTITUTE (LFKRI) **April 2004 to February 2006**
IRB Administrator

- First-ever full-time employee dedicated to oversight of human research protections program and IRB.
- Worked closely with General Counsel and Regulatory Affairs to develop and implement NYBC's first internal standard operating procedures (SOPs), required by FDA regulations and by the HHS Common Rule.
- Provided guidance on human subjects research compliance to investigators conducting clinical trials, basic science and translational research protocols from across the NYBC regional network of blood services satellites and LFKRI's multiple laboratories, including Cellular Therapy, Parasitology, Viral Immunology, Genomics, and the National Cord Blood Program (NCBP).
- Created first paperless database of IRB protocols and IRB actions.
- Developed and delivered institutional training for personnel involved with human subjects research.
- Managed content for LFKRI portions of the NYBC internet and intranet sites.
- Served as member of occupational safety committee and inspection team.

COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK (Morningside campus) **November 2001 to April 2004**
Assistant IRB Administrator

- Acquired in-depth working knowledge of federal regulations, state laws, institutional policies, ethical concepts and best practices for human subjects research including the identification of and mitigation of risks to participants, confidentiality measures, and the integrity of a robust informed consent process.
- Advised investigators from among the student bodies and faculties of the Graduate School of Arts and Sciences, the School of Law, the Graduate School of Business, the School of International and Public Affairs, the School of Social Work and the School of Journalism, and the undergraduate colleges.
- On-boarded and trained multiple IRB members representing Psychology, Social Work, Sociology, Political Science, Management, Journalism and Oral History.
- Provided guidance to investigators and department chairs regarding human subjects research ethics and protocol design.
- Coordinated testing and implementation of paperless protocol submission and review system and transition/conversion of legacy protocols to new system.

LEADERSHIP

CITY OF NEWTON HEALTH AND HUMAN SERVICES (HHS) **January 2014 to Present**
Member – Advisory Council

HARVARD CATALYST REGULATORY FOUNDATIONS, ETHICS, AND LAW PROGRAM **March 2013 to Present**
Co-Chair – Social, Behavioral and Educational Research (SBER) Sub-Committee

PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH (PRIM&R) **March 2008 to Present**
Conference Faculty/Mentor/Planning Committee

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI) WORKING GROUP **October 2008 to May 2010**
Content Expert, CITI Human Subjects Curricula Course Development

PUBLICATIONS

Cholka, C. B., & Stafford, M. (2021, March). Chapter 3-1, "Composition of the IRB." In E. Bankert, B. Gordon, E. Hurley, & Shriver, S. (Eds.), *IRB Management and Function, 3rd Edition.* Burlington, MA: Jones & Bartlett Learning.

Corl, S., & Stafford, M. (2014, December). *Developing Timely & Appealing Human Subject Protection Refresher Education Using Education Program Participation, Unanticipated Problem & Internal Audit Data.* Poster Presented at the annual Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) conference, Baltimore, MD.

Taghinia, A., Kuniholm, A., et al. (2014, December). *Challenges in the IRB Review of First-in-Pediatrics Hand Transplantation Research.* Poster Presented at the annual Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) conference, Baltimore, MD.

Witte, E., Bierer, B., et al. (2014, December). *Research Subjects Want to Know: An IRB Asks Investigators to Consider Dissemination Strategies.* Poster Presented at the annual Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) conference, Baltimore, MD.

Stafford, M., Monahan, C. et al. (2013, November). *Case Studies for Assessing and Mitigating Risk in Social, Behavioral and Educational Research (SBER): Creation of Educational Resources for IRB Members and Researchers.* Poster Presented at the annual Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) conference, Boston, MA.

Bowling, K., Dyson, A., et al. (2006, December). *Evolution of a "Departmental Scientific Review" Process: Ensuring Sound Research Design during the Review Process.* Poster Presented at the annual Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) conference, Washington, DC.

VOLUNTEER ACTIVITIES

KRAFT FAMILY BLOOD DONOR CENTER **April 2020 to Present**
Platelet Donor

NEWTON FAMILY SINGERS **January 2016 to Present**
Tenor/Soloist/Promoter

UNDERSTANDING OUR DIFFERENCES (UOD) **January 2015 to June 2019**
Marathon Runner/Fundraising Ambassador/Parent Curriculum Coordinator

ANGIER AFTER SCHOOL PROGRAM (AASP) **May 2012 to June 2019**
Vice-President – Parent Board