



SABUNE WINKLER

Partner

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Sabune Winkler brings over 16 years of experience as a senior manager and legal and regulatory leader. She has assisted and advised academic medical centers, hospitals, universities, institutional review boards (IRBs), the National Institutes of Health (NIH), and other health care and research organizations with matters related to:

- Clinical Trial Agreements
- Service Agreements
- Master Agreements
- Single, central, and other IRB reliance arrangements for multi-site research
- Sponsored research and other collaborative research agreements
- Research compliance and research misconduct
- Grants Management
- Use of human subjects and animals in research

Prior to joining Outside GC, Sabune directed numerous interinstitutional regulatory initiatives at both a national and regional level via Harvard Catalyst, Harvard Medical School's clinical and translational science center. Previously, she was in-house counsel for legal and research matters at Beth Israel Deaconess Medical Center and negotiated clinical trial agreements and other research agreements for Dana Farber Cancer Institute and Partners Healthcare Corporation (now Mass General Brigham). These experiences, combined with Sabune's time as a Harvard Medical School fellow and as an investigator, have furnished her with a deep understanding of complex regulatory schemes and transactional matters that biomedical organizations must navigate. She has the proven ability to develop and implement legal, regulatory and business solutions that work.

EDUCATION

Northeastern University School of Law,
J.D.

Bates College, B.A.

SECTORS AND SERVICES

[Regulatory Compliance & Training](#)
[Life Sciences](#)

CREDENTIALS

Bar Admissions

Massachusetts

Sabune established and directed regulatory initiatives for Harvard Medical School and its 18 affiliated hospitals – all innovative in their nature and unprecedented in scope and breadth. As the primary strategist, she worked closely with counsel, regulatory officers and hospital leadership to implement a coordinated approach among the Harvard affiliates to speed research through contracts, as well as harmonized approaches to regulatory guidelines and policy. Sabune shared these innovations broadly through speaking engagements and collegial exchange; the Master IRB, IACUC and IBC agreements she created have become national models.

With the success of Sabune's regional initiatives, Harvard Catalyst was invited by the NIH to lead a project to implement IRB reliance arrangements for multi-site research. Leading a US team of "Ambassadors" from research institutions across the US, Sabune developed a platform designed to ease common challenges associated with initiating multi-site research and provided a roadmap for institutions across the nation to implement the NIH Single IRB Review Policy. Over 800 institutions have signed on to the "SMART IRB" treaty that she spearheaded. Additionally, Sabune led the process of transforming the National Human Genome Research Institute (NHGRI) IRB from a single IRB to a central IRB for 13 academic sites in support of research that catalyzed a dramatic improvement in the care of people with mysterious and previously undiagnosed conditions.

Sabune has been a frequent speaker at local and national conferences, and webinars on IRB reliance and other topics pertaining to research, and she has authored a number of papers related to the legal and ethical issues raised by academic and clinical research.

Sabune holds a J.D. from Northeastern University, and a B.A. from Bates College. She pursued advanced study in June 2013-2014 through a fellowship in medical ethics at Harvard Medical School, Division of Medical Ethics; and she was also an Administrative Fellow at Harvard University in 2015 where she was identified as a future Harvard leader.

When not advising clients, you might find her learning about food by working as a cheese monger or as a mushroom farmer. Sabune and her family live in Concord, MA.