Nanomedicine Human Subjects Research: Oversight & Standards

By **Susan M. Wolf, JD**
McKnight Presidential Professor of Law, Medicine & Ethics, University of Minnesota (swolf@umn.edu)

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Abstract (adapted from Fatehi, Wolf, McCullough et al., project consensus recommendations paper in process): Nanotherapeutics and *in vivo* nanodiagnostics are a subset of nanomedicine applications including drugs, biological products, and implantable medical devices incorporating nanoscale materials with properties that can enable new or improved treatments and diagnostics for many diseases and disorders. Human subjects research (HSR) on interventions engineered to exploit capabilities that emerge at the nanoscale is not new, though the volume is increasing. Such research is already subject to existing federal and institutional oversight rules and regulations, including Food and Drug Administration (FDA) and Department of Health and the Human Services (DHHS) regulations on HSR, both of which require HSR protocols to obtain approval from an Institutional Review Board (IRB) based on assessment of safety and ethical soundness for human subjects.

While the current HSR oversight system may work well for the less complex, "passive" formulations in trials and on the market, the nanomedicine field is fast evolving toward more complex, "active," and interactive formulations. Some of these are likely to raise greater HSR challenges in terms of predicting effects (including long-term), assessing when First-in-Human (FIH) trials should occur, and addressing uncertainty surrounding risk and its relation to potential benefit. In addition, some trials may also raise concerns about occupational, bystander, and environmental effects. These issues are not unique to nanomedicine, but the emergence of this field puts pressure on an already overtaxed system for HSR review and oversight. Thus, the challenges of nanomedicine HSR provide an occasion to anticipate evolving challenges and "do it right" by setting up a means of coordinating among the many agencies involved, linking federal and institutional oversight, assuring a science-based approach to HSR issues in nanomedicine, and providing a way to integrate analysis of human subjects concerns with analysis of occupational, bystander, and environmental concerns.

This presentation will describe the project's consensus recommendations on how to approach the full panoply of concerns that may be raised in the context of nanomedicine HSR. The presentation will describe procedural and substantive recommendations for both federal and local institutional oversight.