



DATE: October 2, 2017

TO: NIH Scientific Directors
NIH Clinical Directors

FROM: Deputy Director for Intramural Research (Institutional Official for NIH Federal-wide Assurance)

SUBJECT: **Revised Policy on Holders of INDs and IDEs at NIH**

We have been concerned about variations in current practice regarding who holds Investigational New Drug applications (INDs) and Investigational Device Exemptions (IDEs) at NIH, since there is a wide range of practice designating persons and entities to act as sponsors. The fulfillment of the sponsor's responsibilities is not uniform and leads to variations in performance depending on the sponsor's understanding. The following is a clarification of policy.

New NIH Policy:

Effective January 15, 2018, existing and new INDs and IDEs at NIH shall be held by the Institute or Center (IC) rather than by the Principal Investigator on the clinical protocol. The mechanism for implementing this will vary by IC and could be fulfilled by an IC entity (e.g., CTEP), a central shared service center sponsored by an IC or ICs, the Office of the IC Clinical Director, an extramural office, etc. It will be the responsibility of the IC to establish how it conducts business and to document its practice to me as the NIH Institutional Official. Oversight will be through the Assistant Director for Regulatory Affairs in OIR.

Further, the individual PI, who no longer is the official IND/IDE holder, may be designated as the "Sponsor's Representative" to document the link between PI and Sponsor. Ultimately, the NIH as an institution bears official responsibility that is fulfilled at the IC level.

Finally, the NIH has established a goal of utilizing an electronic system to track and monitor all INDs and IDEs in the future.

For those of you who still have individual PIs holding INDs and IDEs, please send me your plans to migrate to an institutional support office and indicate the current number of INDs and IDEs held in your IC that need to be migrated. For those who have INDs or IDEs held institutionally, indicate your mechanism for doing this and your total number of INDs and IDEs.

Please provide this information by October 31, 2017.

Sincerely,

Michael M. Gottesman, M.D.