DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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DATE: November 20, 2018

TO: Clinical Directors
Scientific Directors
Senior Investigators
Tenure-track investigators
Staff Clinicians
Senior Clinicians
Assistant Clinical Investigators

FROM: NIH Deputy Director for Intramural Research

SUBJECT: Allegations of Non-Compliance with Clinical Research Requirements

From time to time, there are events at the NIH related to regulatory requirements resulting in possible harm to human subjects or damage to the integrity of human subjects research at the NIH. In general, we review these as apparent systems failures in which the many checks and balances and reporting requirements at the NIH may have failed to prevent, detect, or correct a significant protocol deviation or a failure to comply with laws, regulations, or standard operating procedures. In some of these cases, investigation of the events is appropriately conducted by the IRB, with development of a corrective action plan. In some situations, an individual may be identified whose actions (or failure to act) are deemed responsible for the problem or series of problems (continuing noncompliance), and an action related to their continued participation in clinical research as a lead or associate investigator is recommended by their supervisor, Clinical Director, or someone in the supervisory chain within the IC. Such action differs from the more routine steps taken by the IRBs to preserve the integrity of individual protocols, such as a clinical hold on enrollment or required protocol modifications. This type of action is also separate and apart from any disciplinary action that may be recommended by the IC supervisory chain in consultation with the NIH Office of Human Resources.

I wish to clarify that before any such action related to conducting or leading clinical research is to be taken, as the Institutional Official with overall responsibility for the conduct of human subjects research at the NIH, I expect to be notified in advance of any proposed action, and I may choose to conduct a further investigation or support the recommended steps. In addition, as part of the alternative dispute resolution process, any NIH scientist can come to the NIH Ombudsperson or me to seek advice. Dr. John Gallin, Associate Director for Clinical Research at the NIH, or Dr. Andrew Griffith, NIH Deputy Director for Intramural Clinical Research, will also be informed about any such situations and may advise me.