



## **RESPONSIBILITIES OF AN INVESTIGATOR WHO IS ALSO A SPONSOR**

4/18/2021

As defined in FDA regulations (21 CFR 312.3 and 812.3(o)), a sponsor-investigator is an individual who both initiates and conducts a clinical investigation, and under whose immediate direction an investigational drug or device is administered, dispensed or used. The requirements of a sponsor-investigator include both those applicable to an investigator and those applicable to a sponsor. For further information regarding the responsibilities of a DUHS investigator, refer to the “DUHS Investigator Agreement”.

If an investigator in the proposed research project is also the IND/IDE holder and/or is otherwise subject to FDA regulations related to duties as a sponsor/investigator, the IRB in conjunction with others within the DUHS Human Research Protection Program (HRPP) will evaluate whether the investigator is knowledgeable about the additional regulatory requirements of sponsors and will follow them while conducting the study. The investigator must provide documentation that the IND or IDE has been registered with Duke’s Office of Regulatory Affairs and Quality (ORAQ). The HRPP may require additional oversight and monitoring of these investigators if necessary to assure compliance with additional sponsor regulations.

If a question arises about whether an IND or IDE is required for a Duke investigator-initiated clinical research study, either during the IRB approval process or during the course of an investigation, the process described in the Duke HRPP policies titled “Research Involving Drugs or Biologics” or “Research Involving Devices” will be followed.

In addition to the requirements of 21 CFR 312 and 21 CFR 812, investigators who hold an IND or IDE must also meet all regulatory requirements pertaining to sponsors, appearing in other FDA parts, as applicable, such as:

### **For Drugs or Devices:**

- 21 CFR 11 (Electronic records and electronic signature)
- 21 CFR 54 (Financial Disclosure by Clinical Investigators)

### **For Drugs and Biologics:**

- 21 CFR 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General)
- 21 CFR 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)
- 21 CFR 312 (Investigational New Drug Application)
- 21 CFR 314 (Drugs for Human Use)

- 21 CFR 320 (Bioavailability and Bioequivalence Requirements)
- 21 CFR 330 (Over-The-Counter (OTC) Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded)
- 21 CFR 601 (Biologics Licensing)

**For Devices:**

- 21 CFR 807 (Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices)
- 21 CFR 812 (Investigational Device Exemptions)
- 21 CFR 814 (Premarket Approval of Medical Devices)
- 21 CFR 820 (Quality System Regulation)
- 21 CFR 860 (Medical Device Classification Procedures)

**Institutional Requirements for a Sponsor-Investigator**

All DUHS faculty and staff members who file an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) with the Food and Drug Administration (FDA) must register the IND/IDE with the DUHS HRPP by submitting all documents relevant to the IND/IDE to ORAQ and completing the sponsor-investigator training requirements. Registration and training is required whenever a DUHS faculty or staff member files an IND or IDE regardless of whether or not it will be used in a study conducted at DUHS. All DUHS faculty and staff members who also hold an IND or IDE must meet the FDA regulatory requirements of sponsors and maintain an active IRB approved protocol at DUHS as long as the IND/IDE remains active with the FDA regardless of whether or not the product will be used as part of a study conducted at DUHS.

Investigational medical devices that involve electrical power, will be used within clinical settings at Duke, and are not FDA approved or licensed for human use must be reviewed by the Duke Hospital Department of Clinical Engineering to ensure that they are suitable to be used within the clinical setting.

**Responsibilities of an Investigator**

The investigator is responsible for ensuring that research is conducted according to:

- sound research design and generally acceptable scientific methods,
- the terms of the grant, contract and/or signed agreement(s),
- the obligations specified in the signed Form FDA 1572,
- the study plan (protocol) as approved by the IRB, and
- applicable regulations and laws.

The investigator is responsible for ensuring that IRB approval of the research exists prior to its initiation and again prior to the expiration of IRB approval (at the time of each periodic continuing IRB review of the research). The investigator is

responsible for providing the IRB with sufficient information to make the required determinations under 45 CFR 46.111 and 21 CFR 56.111.

The investigator is responsible for personally conducting or supervising the proposed investigation. The investigator must not make any changes in the research without DUHS IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

The investigator is responsible for ensuring that legally effective informed consent is obtained and documented according to, and to the extent required by, 45 CFR 46.116 and .117, and 21 CFR 50.25 and .27 and 21 CFR 56.109(c).

When some or all of the subjects, such as children, prisoners, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

The investigator and the institution are required to permit and facilitate monitoring and auditing, at reasonable times, by the IRB, its designee, funding agencies, and federal and state regulatory agencies as appropriate.

For research involving more than minimal risk to subjects, the investigator is responsible for ensuring that there is an appropriate data and safety monitoring plan in place.

The investigator must ensure prompt reporting of any unanticipated problem involving risk to subjects or others to the IRB, appropriate institutional officials and state and federal regulatory agencies as appropriate in keeping with the IRB's policy on Problems or Events that Require Prompt Reporting to the IRB.

For sponsor-investigator guidance when applying to FDA for an IND, please contact Duke's Office of Regulatory Affairs and Quality (ORAQ). Information is also available on the FDA webpage at this link:

<https://www.fda.gov/drugs/investigational-new-drug-ind-application/information-sponsor-investigators-submitting-investigational-new-drug-applications-inds>

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