BROWN

Human Research Protection Program (HRPP)

Studies Involving Drugs and/or Devices

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Drugs, Biologics, Medical Devices, Tobacco and Generally Recognized as Safe (GRAS) Substances

I. What is a Sponsor-Investigator?

A Sponsor-Investigator (SI) means a researcher who both initiates and conducts an investigation. An SI not only is accountable to the roles and responsibilities on the project as the PI, but is also required by the Food and Drug Administration (FDA) to follow the FDA regulations that apply to sponsors.

II. Brown's Institutional Procedures and Resources

SIs must include a completed Medical Device checklist and/or Investigational New Drug checklist with all initial IRB submissions for research that involves a drug or device. These checklists provide guidance in determining if an application for an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application must be submitted to the FDA. In addition, completing these checklists helps ensure that the required information is documented and submitted to the IRB. Sponsor-investigators may also reference the Device/IDE chart and the Drug/IND chart. If you need assistance with any of the checklists, have questions about FDA regulations, or would like a desk audit conducted of your FDA-regulated study prior to an FDA inspection, please contact our Quality Assurance / Quality Improvement Administrator @ christiana_provencal@brown.edu.

III. The Role of the Institutional Review Board

Some investigations require approval by the FDA and the IRB prior to commencing research, while others require only IRB approval. For example, two types of studies are subject to IDE regulation - significant risk (SR) and non-significant risk (NSR) studies. Sponsor-Investigators are responsible for making the initial risk determination and presenting it to the IRB. Unless the FDA has already made a risk determination for the study, the IRB must review the Sponsor- Investigator's determination for every medical device study reviewed and modify the determination if the IRB disagrees with the Sponsor- Investigator's.

IV. Sponsor-Investigator Training

Brown University researchers are required to take CITI training prior to conducting human subject research. Please review the CITI Training requirements for additional information and to link to the CITI course. The FDA's Clinical Investigator Training Courses can also be helpful.

V. FDA Resources

A. Drugs

- FDA regulations of investigational new drugs
- Specifically, see the section regarding the Responsibilities of Sponsors and Investigators
- FDA Information for Sponsor-Investigators Submitting INDs
- The FDA regulations that apply to a variety of Investigator-Initiated INDs by a type of IND
- Reasons for Drug/Biologics Clinical Holds - Avoid
- FDA encourages early collaboration with the agency for very complex and novel drug or biologic technologies for which there are no published guidance documents.
- FDA learning tool designed to advance knowledge of drug regulatory processes. Each case study promotes active learning through exercises, instructor-led discussions, and quizzes.

B. Medical Devices

- FDA regulations of investigational new medical devices
- Specifically, Responsibilities of Sponsors and Investigators
- FDA information for submitting IDEs
- Reasons for IDE disapproval – Avoid (see section 6 of the guidance)
- FDA encourages early collaboration with the agency for very complex novel medical device technologies for which there are no published guidance documents.

C. Biologics

- FDA information for submitting biological INDs or IDEs

D. Tobacco

- Tobacco Product Review & Evaluation

E. Marijuana

- FDA and Marijuana: Questions and Answers

F. Generally Recognized as Safe (GRAS)

- Guidance for Industry: Frequently Asked Questions About GRAS

G. Expanded Access (Compassionate Use)

- Expanded and Compassionate Use processes for drugs, medical devices and biologics

VI. Protocol and Submission Writing Resources

- Generic Protocol Template from the World Health Organization
- FDA IND General Contents and Format
- FDA IND Expanded Access Content and Format

Links to the FDA website provided on this webpage were current as of the posting date, but may be moved or changed in the future. If you notice any broken or outdated links, please email us at irb@brown.edu.