Part 8 – Studies Regulated by FDA and Use of Investigational Articles

The US FDA enforces the Food, Drug and Cosmetic Act and other laws and regulations governing the use of drugs, biologics, and devices for treatment and in research studies. This section describes when or under what circumstances an Investigational New Drug (IND) application or Investigational Device Exemption (IDE) is needed, and describes IRB responsibilities with respect to protocols involving investigational test articles.

I. INTRODUCTION

Refer to HRPP OM Part 8.I

II. RESEARCH INVOLVING INDS OR IDES

Refer to HRPP OM Part 8.II

A. Investigational Drugs and Biologics

Refer to HRPP OM Part 8.II.A
Refer to IRBMED Guidance – Investigational New Drug Application

B. Investigational Devices

Refer to HRPP OM Part 8.II.B
Refer to IRBMED Guidance – IDE Application

1. Generally

2. Significant Risk (SR) / Non-Significant Risk (NSR) Determinations

Refer to HRPP OM Part 8.II.B.1-3

Refer to FDA *SR / NSR Device Determinations*

3. Device Studies Exempt from IDE Requirements

Refer to HRPP OM Part 8.II.B.5

C. Humanitarian Use Devices (HUD)

If the proposed use is to collect safety and effectiveness data for a new indication, the IRBMED will require the investigator submit an IDE application to the FDA, as well as the eResearch Standard Application (not the HUD application). If the use falls under the labeling of the Humanitarian Device Exemption (HDE) or is used off-label under the HDE, an IDE is not required and falls under Section IV, below.

III. EXPANDED ACCESS

Refer to HRPP OM Part 8.III

A. Investigational Drugs and Biologics

Refer to HRPP OM Part 8.III.D

1. Treatment INDs

Refer to HRPP OM Part 8.III.D

2. Group C Treatment IND

Refer to HRPP OM Part 8.III.D.2

3. Open Label Protocols or Open Protocol INDs

Refer to HRPP OM Part 8.III.D.1

4. Parallel Track Studies

Refer to HRPP OM Part 8.III.D.3

B. Expanded Access to Investigational Devices

Refer to HRPP OM Part 8.III.E.

1. Treatment IDE

Refer to HRPP OM Part 8.III.E.2

Also see: *IRBMED Guidance – Emergency Use of Test Articles*.

2. Compassionate Use (Devices)

Refer to HRPP OM Part 8.III.E.1

3. Humanitarian Use (Devices)

Refer to HRPP OM Part 8.VI

a) Physicians are required to submit a HUD application in the eResearch System for on-going use of a HUD for clinical purposes without collection of patient safety and effectiveness data to support a Premarket Approval (PMA). The Principal Investigator is required to ascertain whether the manufacturer will require this data and provide documentation to the IRB. The IRB will assure that the documentation is appropriate.

b) Physicians are required to submit a standard application in the eResearch System for on-going use of a HUD for clinical purposes with collection of patient safety and effectiveness data to support a Premarket Approval (PMA). The Principal Investigator is required to ascertain whether the manufacturer will require this data and provide documentation to the IRB. The IRB will assure that the documentation is appropriate.

c) Also refer to IRBMED Guidance – HUD Requirements for Physicians and Investigators.

4. Continued Access (Devices)

Refer to HRPP OM Part 8.III.E.3

IV. EMERGENCY USE OF INVESTIGATIONAL ARTICLES

Refer to HRPP OM Part 8.IV

V. PLANNED EMERGENCY RESEARCH USING INVESTIGATIONAL ARTICLES

Refer to HRPP OM PART 8.V

VI. FDA SPONSORS AND SPONSOR-INVESTIGATORS

Refer to HRPP OM Part 8.VII

VII. INVESTIGATOR AND IRB RESPONSIBILITIES FOR FDA-REGULATED RESEARCH

Refer to HRPP OM Part 8.VIII

A. Ensuring Review by Appropriate IRB

Refer to HRPP OM Part 8.VIII.A

B. Verification of IND or IDE Acquisition Prior To Release of Final IRB Approval

Refer to HRPP OM Part 8.VIII.B

As part of the eResearch or application, the study team is required to upload all documentation submitted to and received from the FDA regarding IND/IDE information. This information is available to the IRBMED Regulatory team as well as IRBMED Chairs and Board Members via eResearch for review. The Regulatory teams verify that this documentation is included in the eResearch application and check the validity of the IND or IDE number.

C. Oversight of FDA-Regulated Research

Refer to HRPP OM Part 8.VIII.C

D. Investigational Article Accountability

Refer to HRPP OM Part 8.VIII.D

E. Charging for Investigational Articles

Refer to HRPP OM Part 8.VIII.E

Refer to IRBMED Website – Electronic Signature-Part 11 Compliance Certification,

F. Records and Documentation

Refer to HRPP OM Part 8.VIII.F

When a subject withdraws from a clinical trial, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. The informed consent document cannot give the subject the option of having data removed. In the case of a subject's withdrawal, the subject may either consent to follow up (non-interventional, non-invasive) or not. If the patient wishes to provide continual follow-up, the researcher must obtain the subject's consent for this limited participation if it was not described in the original informed consent document.

For further information, refer to FDA Guidance.

G. Required Reporting

Refer to HRPP OM Part 8.VIII.G

H. ICH-E6 and GCP

Refer to HRPP OM Part 8.VIII.H

I. FDA Inspection of FDA-Regulated Research and Related Articles

Refer to HRPP OM Part 8.VIII.I

J. Additional Exceptions

1. Emergency Use Authorizations

In the event of an emergency, or a significant potential for an emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents, the FDA may issue an Emergency Use Authorization (EUA) for use of an investigational agent. In such an emergency:

- IRB review and approval is not required prior to or after administration of the investigational agent.

- Identifiable private information regarding the use may be collected and submitted to the required federal authorities (e.g., FDA, CDC, or Homeland Security).

Contact the IRBMED for additional information, if needed. *Also see* the FDA Guidance Document Emergency Use Authorization of Medical Products.

If a PI later intends to do research on the collected data, IRB approval must be secured at that time.

2. Other Exceptions

The FDA or other federal government entity may issue other types of exceptions. Contact IRBMED for guidance regarding the need for IRB approval in such an event.