Device Investigational Device Exemption (IDE) Application Guidance

An Investigational Device Exemption (IDE) Application is required when an investigation is not exempt from IDE Device regulations. For non-significant risk (NSR) devices, this will be the Abbreviated IDE (aIDE) Application. For more information on Research with Devices, please see the guidance *Research with Device Products* available here on the IRB website.

The aIDE and IDE templates can be found on the OCR website:
- aIDE template (non-significant risk device)
- IDE template (significant risk device)

A standalone protocol is also required when an investigation is not exempt from IDE Device regulations. The HSERA IRB application may not serve as the IRB protocol for these types of studies. The following template should be utilized: ***Protocol Template- Clinical Trial*** which is available for download online here: **https://irb.upenn.edu/forms.**

An aIDE Application consists of the following three parts that are detailed below:
1. Sections that are likely to, and should be, covered in the protocol that is submitted to the IRB.
2. Sections / documents that are a required part of the aIDE Application but are unlikely to be covered in the protocol and require submission to the IRB.
3. Sections / documents that are unlikely to be covered in the protocol and do not require submission to the IRB. These should be maintained in your study records.

Part 1

Sections of the aIDE Application that are likely to, and **should be, covered in the protocol** that is submitted to the IRB:
- Investigational objectives
- Rationale for conducting the investigation
- Information about prior investigations with the device
- Duration of the study
- Methodology to be used
- A **general device description** of all devices, instruments, etc. being used in the protocol. If multiple existing devices are combined together, this should be clearly described. For any devices that are not exempt from IDE regulations, a Research with Devices form must also be submitted to the IRB, as outlined in the guidance linked above.

Name of Device	Manufacturer	Marketing Status in the U.S.	FDA Device Classification (I, II, III)
Name	Manufacturer's Name	K######	

Name	Manufacturer's Name	PMA#####	

- Analysis demonstrating the protocol is scientifically sound.
- A description of the patient population including the number, age, sex, and condition.
- **IDE Required Records:** Description of records that will be maintained in compliance with IDE regulations.
  - **Device accountability:** i.e. records of shipment & disposition of the device
  - **Adverse device effects** (whether anticipated or unanticipated)
- **IDE Required Reports:** Description of reports that will be maintained in compliance with IDE regulations.
  - Reporting of unanticipated adverse device effects to the FDA and IRB
  - Reporting to FDA and IRB, if an investigator failed to obtain consent
  - Reporting to FDA if an IRB withdraws approval for the study
  - Reporting to IRB and FDA of any device recall, repair, or disposal
  - Reporting to IRB and submission to FDA if the device determination is changed to significant risk from non-significant risk
- **Quality Control Plan**: Include the procedures for quality control /GCP monitoring
- **Safety Monitoring Plan**: Include the procedures for medical monitoring as well as any plans for utilizing an independent DSMB/DSMC

Part 2

Sections / documents that are a required part of the aIDE Application but are unlikely to be covered in the protocol and **require submission to the IRB:**

- **Device instructions for use:** For each product provide a copy of the instructions.
- **Informed Consent and all informational materials** to be provided to subjects
- **Risk Analysis:** The sponsor-investigator is responsible for identifying risks and for determining which risks to accept and which risks require mitigation. The sponsor-investigator is also responsible for evaluating identified risks against risk mitigating strategies. The sponsor-investigator should provide a clear explanation of why the device use presents non-significant risk (or if it presents significant risk).

  The Risk Analysis should consist of a detailed assessment of the risk likelihood to the subjects and risk consequences, and how these risks will be mitigated. Please refer to the tables below. This should include the risk of the device(s) generally, any risks with combining devices (if applicable), risks specific to the participant population being studied, and other risks in the trial related to other procedures.

Risk Likelihood	Descriptor	Assigned value
Rare	Not expected but possible	1
Unlikely	Could occur occasionally	2
Likely	Could occur frequently	3
Expected	Expected to occur in most cases	4
Certain	Will occur on every occasion	5

Risk Consequence	Descriptor	Assigned value
No Health Hazard	No physical effect of the physiological complaints anticipated	1
Limited Health Hazard	Extended procedure time, Physiological complaints, Temporary minor physical effect	2
Moderate Health Hazard	Additional procedure required, Temporary but significant physical complaints, Permanent minor physical effects	3
Severe Health Hazard	Permanent significant physical effects	4
Catastrophic	Life threatening	5

Example Risk Analysis:

Participant Risk	Risk Likelihood	Risk Consequence	Mitigation Y/N	Mitigation Description
Risk 1	Expected	Moderate Health Hazard	Y	Risk mitigation strategy
Risk 2	Unlikely	No Health Hazard	N	N/A

Part 3

Sections / documents that are unlikely to be covered in the protocol and do not require submission to the IRB but **should be maintained in your study records. The IRB withholds the right to request any of this documentation.**

- **Detailed Device Description:** Description of each important component, ingredient, property, and principle of operation of the device and any anticipated changes in the device during the investigation. If multiple existing devices are combined together, this should be clearly described.
- A device description that includes any applicable predicate devices, approved uses of the device, and use on the protocol
  - A predicate is a medical device that may be legally marketed in the U.S. and is used as a point of comparison for new medical devices
- **Device engineering designs and related documents**
- **Name and Contact Information for the following:**
  - **Site Information:** The name and address of each institution at which a part of the investigation may be conducted (that has not been identified in any other section of the aIDE Application).
  - **Quality Control Monitor**: Name and address
  - **Safety Monitoring Designee**: Name and address
  - **IRB:** Include a list of the names, locations, and chairpersons of all IRBs that have been or will be asked to review the investigation
  - **Clinical Laboratory Facilities:** Name and address
- **Investigator Documentation:** Signed Investigator Agreement(s)
- **IDE Sponsor Required Records**:
  - All correspondence with, for example, another sponsor, a monitor or vendor, an investigator, an IRB, or FDA, including required reports.
  - Adverse device effects (whether anticipated or unanticipated) and subject complaints
  - Document the device manufacturer's level of GMP compliance (requirements in 21 CFR 820)
- **Clinical Trials.gov (42 CFR 11)**
  - Register, maintain, and provide results of your trial listing on Clinical Trials.gov.
- **Device Packaging / Labelling (as per 21 CFR 812.5):** Ensure the device is appropriately labeled with the following statement: "CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use."

ADDITIONAL INFORMATION

Guidance on Abbreviated IDEs from the PSOM Office of Clinical Research

For additional assistance, please contact: the Penn Medicine **Office of Clinical Research, Regulatory Unit.**