Sponsor-Investigator IDE Training Learning Supplement

IND/IDE Support Program

Children's Hospital of Philadelphia
RESEARCH INSTITUTE

IDE Training Learning Supplement

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Definitions

Clinical Hold
An order issued by the FDA to the sponsor to delay a proposed clinical investigation or suspend an ongoing clinical investigation.

Code of Federal Regulations (CFR)
The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration.

- **21 CFR 812** - Title 21 Food and Drugs, Part 812 – Investigational Device Exemptions (21 CFR 812)
- **21 CFR 50** – Protection of Human Subjects
- **21 CFR 56** – Institutional Review Boards
- **Title 45 Public Welfare, Part 46** – Protection of Human Subjects

Contract Research Organization (CRO)
A person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

Essential Documents
Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.

Food and Drug Administration (FDA)
The government agency that is responsible for assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation.

Implant
An implant means a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants" for purposes of this part.

Independent Ethics Committee (IEC)
A review panel that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and is adequately constituted to provide assurance of that protection. An institutional review board (IRB) is one type of IEC.

Institutional Review Board (IRB)
Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights, safety and welfare of human research subjects.

Investigational device
A device, including a transitional device, that is the object of an investigation.

Investigational Device Exemption (IDE)
An IDE is a regulatory submission that permits clinical investigation of devices.

Investigation
A clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

Investigator
An individual who conducts a clinical investigation (i.e. under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Sub-investigator" includes any other individual member of that team.

Medical Device
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…

- Recognized in National Formulary and United States Pharmacopeia (USP)
- Intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease or condition, or
- Intended to affect the structure or any function of the body, and does not achieve primary purposes through chemical action within or on the body and is not dependent upon being metabolized.

Premarket approval (PMA)
FDA determines that there is sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use(s).

Premarket notification (510(k))
FDA agrees the new device is substantially equivalent to a legally marketed device for which premarket approval is not required (does not frequently require clinical data).

Significant Risk Device
An investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Sponsor
A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator.

- Here at CHOP, the sponsor is not necessarily a funding sponsor (or a pharmaceutical company), at CHOP most times the sponsor is a “regulatory sponsor” that completes and files all required documentation with the FDA and IRBs.

Sponsor-Investigator
An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The requirements applicable to a sponsor-investigator include both those applicable to an investigator and a sponsor.

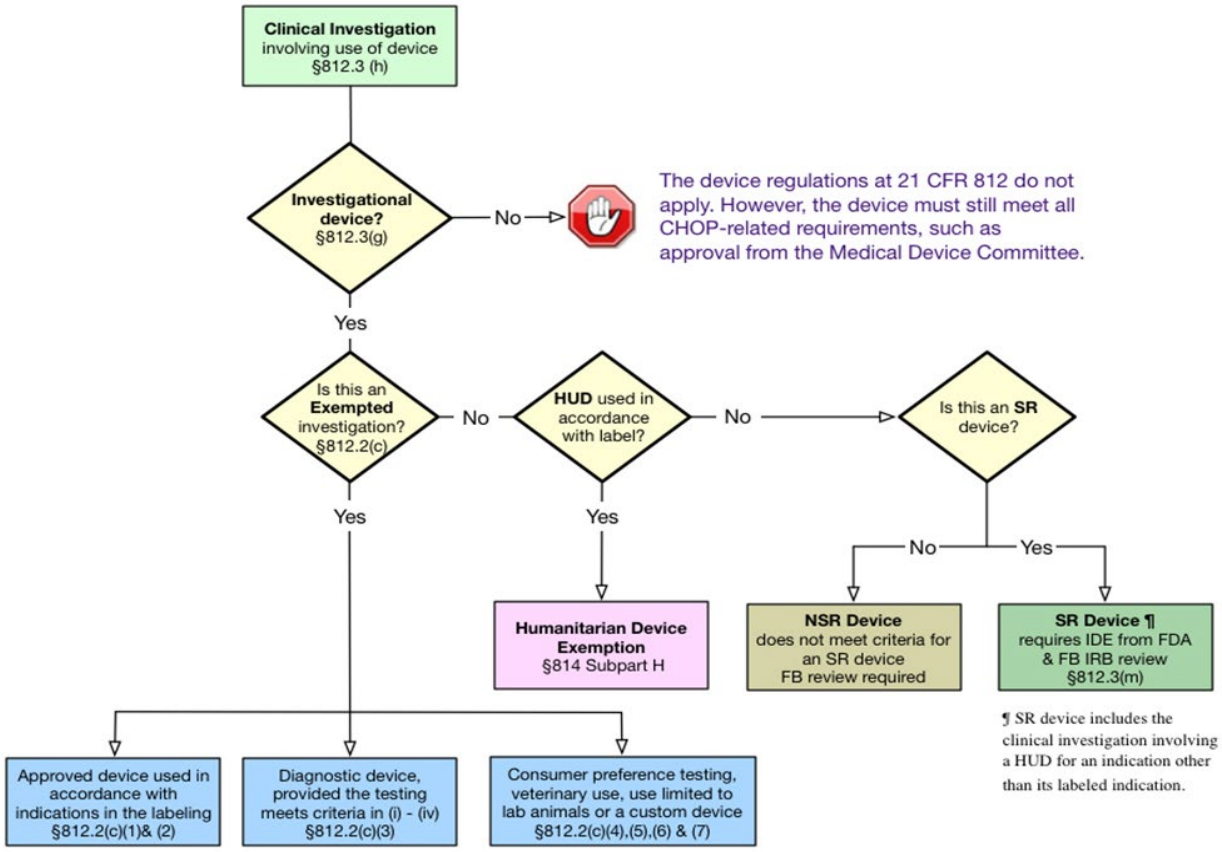
Subject
Subject means a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease.

Termination
Termination means a discontinuance, by sponsor or by withdrawal of IRB or FDA approval, of an investigation before completion.

Transitional Device
A transitional device is a device subject to section 520(1) of the act, that is, a device that FDA considered to be a new drug or an antibiotic drug before May 28, 1976.

Trial Master File
This is the name of the collection of all essential documents and any documentation which is created during the trial that help reconstruct and evaluate the trial conduct. This may include data management, statistics, pharmacovigilance, clinical trial supplies, pharmacy, legal, and regulatory affairs.

Unanticipated Adverse Device Effect
An Unanticipated Adverse Device Effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.



What is an Investigational Device Exemption (IDE)?

An IDE is an approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device.

An IDE approved under 812.30 or considered approved under 812.2(b) exempts a device from the requirements of the following sections of the Federal Food, Drug, and Cosmetic Act (the act} and regulations issued thereunder:

- Misbranding under section 502 of the act,
- Registration, listing, and premarket notification under section 510,
- Performance standards under section 514,
- Premarket approval under section 515,
- A banned device regulation under section 516,
- Records and reports under section 519,
- Restricted device requirements under section 520(e),

- Good manufacturing practice requirements under section 520(f) except for the requirements found in 820.30, if applicable (unless the sponsor states an intention to comply with these requirements under 812.20(b) (3} or 812.140{b) (4}(v)) and
- Color additive requirements under section 721.

Determining if an IDE is Needed

IDE Determination Checklist

INVESTIGATIONAL DEVICE EXEMPT, HUD, SR OR NSR DETERMINATION CHECKLIST

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The purpose of this checklist is to assist CHOP Investigators in determining whether their device study falls under the Exempt HUD, Significant Risk (SR), or Non-Significant Risk (NSR) categories.

PI: _____

Study Title: _____

Date: _____

1. **IDE Exempt Device Study:** Check, if "Yes" —All criteria under one category must be "Yes" for a category to be met. If none of the categories is met, the device is not exempt from an IDE.

Category #1	☐ The device was not regulated as a drug before enactment of the Medical Device Amendments (Transitional Device) ☐ The device is FDA-approved/cleared. ☐ The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling.
Category #2	☐ The device is a diagnostic device. ☐ The sponsor will comply with applicable requirements in 21 CFR 809.10(c). ☐ The testing is non-invasive. ☐ The testing does not require an invasive sampling procedure that presents significant risk. ☐ The testing does not by design or intention introduce energy into a subject. ☐ The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure.
Category #3	☐ The device is undergoing consumer preference testing, testing of modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
Category #4	☐ The device is a custom device as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution.

2. Humanitarian Use Device (HUD): Check, if "Yes".

☐ Humanitarian Use Device used according to its FDA labeling requires only IRB review. If not used according to labeling as part of a clinical investigation, proceed to "**3. Significant Risk (SR Device Study**", to see if an FDA IDE is required. If an IDE does not appear to be required, then, proceed to "**4. Non-Significant Risk Device Study (NSR) - An "Abbreviated" IDE**", and complete the information in Section 4.

3. Significant Risk (SR Device Study: Check, if "Yes". If any box is checked, the device is significant risk and must be submitted to the FDA under IDE guidelines.

☐ Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.

☐ Is purported or represented to be for a use in supporting or sustaining human life and presents potential for serious risk to the health, safety, or welfare of a subject.

☐ Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents potential for serious risk to the health, safety, or welfare of a subject.

☐ Otherwise presents potential for serious risk to the health, safety, or welfare of a subject.

4. Non-Significant Risk Device Study (NSR) - An "Abbreviated" IDE: Check, if "Yes". If none of the criteria of Significant Risk (SR) Device Study in Section 3 is met, the study may be approved by the IRB, and not require an FDA IDE.

☐ Meets none of the above criteria in Section 3 ("Significant Risk (SR) Device Study").

If none of the criteria in Section 3 is met, briefly describe how the protocol-specific device and its planned research use meet NSR device criteria.

Contacts for the IND/IDE Support Office

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Mark Wentworth	wentworthm@chop.edu

Investigational Device Compassionate Use Checklist

INVESTIGATIONAL DEVICE COMPASSIONATE USE CHECKLIST

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Compassionate use of investigational devices may be considered in patients based upon specific criteria detailed in the Code of Federal Regulations (CFR) part 812 guidelines. The following information and checklist are intended to help investigators planning to use an investigational device under FDA compassionate use guidelines.

Definition of Compassionate Use: Use of an investigational device to diagnose, monitor or treat an individual patient or small group of patients with a serious disease or condition when there are no available alternative options.

Criteria for Investigational Device Compassionate Use:

1. The patient has a life-threating or serious disease or condition
2. There is no comparable or satisfactory alternative therapy to diagnose, monitor or treat the disease or condition
3. Potential patient benefit justifies the potential risks of the investigational device

Depending on whether or not there is an Investigational Device Exemption (IDE) for a clinical trial for the device, there are two regulatory pathways governing compassionate use:

1. There is an IDE for the device, or
2. There is no IDE for the device.

Complete either the checklist "Under an IDE", or the checklist "Not Under an IDE" to ensure that the essential elements of FDA compassionate use device guidelines are met.

Proposed Device Use Under an FDA IDE

The IDE Sponsor, who may be the device manufacturer or the physician who has submitted the IDE, should submit an IDE supplement to the FDA requesting approval for a compassionate use under section 812.35(a) to treat the patient. FDA must approve before proceeding with use.

The supplement should include:

• A description of the patient's condition and circumstances requiring treatment, diagnosis or monitoring	☐ Not Done	☐ Done
• Discussion of reasons why alternative therapies are unsatisfactory	☐ Not Done	☐ Done
• Discussion of why the probable risk of using the investigational device is no greater than the probable risk from the disease or the condition	☐ Not Done	☐ Done
• Describing any deviations in the approved clinical protocol that may be needed to treat the patient	☐ Not Done	☐ Done
• The patient protection measures that will be followed: 1. Draft of the informed consent to be used 2. Concurrence by the IRB chairperson 3. Independent assessment by uninvolved physician 4. Authorization from device manufacturer on the use of the device	☐ Not Done	☐ Done

Requirement for follow-up report:		
• Follow-up report submitted by person who submitted the initial compassionate request: 1. Follow-up report to be submitted within 45 days of device use 2. Report to contain summary of patient outcome 3. If any problems occured as a result of using the device, this should be discussed in the follow-up report, and reported to the IRB	☐ Not Done	☐ Done

Proposed Device Use NOT Under an FDA IDE

A compassionate use request for a single patient may be submitted by the physician or maufacturer with the information outlined in "The supplement should include", above, to the FDA, along with a description of the device provided by the manufacturer, to the following address:

Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave
Document Control Center
W066 Rm G-609
Silver Spring, MD 20993

Physicians and manufactures can contact CDRHExpandedAccess@fda.hhs.gov for assistance.

Requirements for compassionate use not under an IDE:

• Provide confirmation that the patient will not be treated until the FDA approves use of the device under the proposed circumstances.	☐ Not Done	☐ Done
• Provide information that includes prelininary evidence of safety and effectiveness that justifies such use, and whether such use would interfere with the conduct of a clinical trial to support marketing approval.	☐ Not Done	☐ Done
• Provide an appropriate schedule for monitoring the patient, taking into consideration the investigational nature of the device and the specific needs of the patient. The patient should be monitored to detect any possible problems arising from the use of the device.	☐ Not Done	☐ Done
Requirement for follow-up report:		
• Follow-up report submitted by person who submitted the initial compassionate request: 1. Follow-up report to be submitted within 45 days of device use 2. Report to contain summary of patient outcome 3. If any problems occured as a result of using the device, this should be discussed in the follow-up report, and reported to the IRB	☐ Not Done	☐ Done

Contacts for the IND/IDE Support Office

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The IDE Application

Before starting an IND Application, you must have the following:

- A well written protocol, using a CHOP IRB approved template
- An informed consent document, using a CHOP IRB approved template
- Manufacturers Brochure for all devices to be used in the study
- 510(k) or PMA Status

IDE Sponsorship: Key Roles

Role	Responsibility
Sponsor	Initiates, but does not actually conduct, the investigation
Investigator	Actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject
Institutional Review Board (IRB)	Reviews, approves (initially and continuing) biomedical research at a given institution
Sponsor-investigator	Means an individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.

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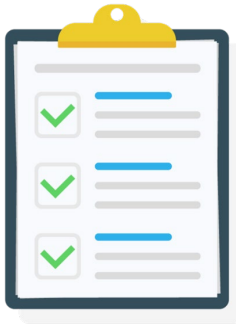
An IDE application shall include, in the following order:



- The name and address of the sponsor.
- A complete report of prior investigations of the device and an accurate summary of those sections of the investigational plan described in 812.25{a) through {e) or, in lieu of the summary, the complete plan.
- The sponsor shall submit to FDA a complete investigational plan and a complete report of prior investigations of the device if no IRB has reviewed them, if FDA has found an IRB's review inadequate, or if FDA requests them.
- An example of the agreements to be entered into by all investigators to comply with investigator obligations under this part, and a list of the names and addresses of all investigators who have signed the agreement.
- A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.
- A certification that all investigators who will participate in the investigation have signed the agreement, that the list of investigators includes all the investigators participating in the investigation, and that no investigators will be added to the investigation until they have signed the agreement.
- A list of the name, address, and chairperson of each IRB that has been or will be asked to review the investigation and a certification of the action concerning the investigation taken by each such IRB.
- The name and address of any institution at which a part of the investigation may be conducted that has not been identified in accordance with paragraph {b) {6) of this section.
- If the device is to be sold, the amount to be charged and an explanation of why sale does not constitute commercialization of the device.
- A claim for categorical exclusion under 25.30 or 25.34 or an environmental assessment under 25.40.
- Copies of all labeling for the device.
- Copies of all forms and informational materials to be provided to subjects to obtain informed consent.
- Any other relevant information FDA requests for review of the application.

The Investigational Plan

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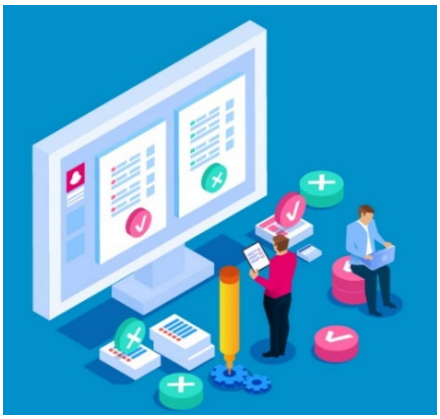
The investigational plan shall include, in the following order:



- **Purpose.** The name and intended use of the device and the objectives and duration of the investigation.
- **Protocol**. A written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound.
- **Risk analysis.** A description and analysis of all increased risks to which subjects will be exposed by the investigation; the manner in which these risks will be minimized; a justification for the investigation; and a description of the patient population, including the number, age, sex, and condition.
- **Description of device.** A description of each important component, ingredient, property, and principle of operation of the device and of each anticipated change in the device during the course of the investigation.
- **Monitoring procedures.** The sponsor's written procedures for monitoring the investigation and the name and address of any monitor.
- **Labeling.** Copies of all labeling for the device.
- **Consent materials.** Copies of all forms and informational materials to be provided to subjects to obtain informed consent.
- **IRB information.** A list of the names, locations, and chairpersons of all IRB's that have been or will be asked to review the investigation, and a certification of any action taken by any of those IRB's with respect to the investigation.
- **Other institutions.** The name and address of each institution at which a part of the investigation may be conducted that has not been identified in paragraph (h) of this section.
- **Additional records and reports.** A description of records and reports that will be maintained on the investigation in addition to those prescribed in subpart G.

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The Report of Prior Investigations

The report of prior investigations shall include reports of all prior clinical, animal, and laboratory testing of the device and shall be comprehensive and adequate to justify the proposed investigation.

The report shall also include:

- A bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety or effectiveness of the device, copies of all published and unpublished adverse information, and, if requested by an IRB or FDA, copies of other significant publications.
- A summary of all other unpublished information (whether adverse or supportive) in the possession of, or reasonably obtainable by, the sponsor that is relevant to an evaluation of the safety or effectiveness of the device.
- If information on nonclinical laboratory studies is provided, a statement that all such studies have been conducted in compliance with applicable requirements in the good laboratory practice regulations in part 58, or if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with this requirement does not justify failure to provide information on a relevant nonclinical test study.

Confidentiality of Data

- FDA will not disclose the existence of an IDE unless its existence has previously been publicly disclosed or acknowledged, until FDA approves an application for premarket approval of the device subject to the IDE; or a notice of completion of a product development protocol for the device has become effective.
- FDA will make publicly available, upon request, a detailed summary of information concerning the safety and effectiveness of the device that was the basis for an order approving, disapproving, or withdrawing approval of an application for an IDE for a banned device. The summary shall include information on any adverse effect on health caused by the device.

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Staged Approval
Approval or Approval with Conditions is granted while certain outstanding questions are answered concurrently with enrollment of a limited number of subjects

May be appropriate when:

- Additional clinical confirmation of the safety profile or the potential for benefit is obtained by reviewing initial data from subjects enrolled early in the clinical investigation before enrolling the entire subject cohort.
- Additional confirmatory non-clinical testing is needed to more fully characterize device performance to adequately evaluate the potential risks of the device, before permitting testing of the entire subject cohort and is conducted concurrently with early enrollment in the clinical investigation.

For Early Feasibility Studies

- Small number of subjects
- Device may be early in development, before final device design
- Approval may be based on less nonclinical data than would be needed to support the initiation of a larger clinical study on a more final device design
- View Guidance: Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies

For Pivotal Studies:

- Successful support of a marketing application under staged approval is not expected until the full planned cohort of subjects is studied.
- A staged pivotal study should only be considered if the additional information that is requested is not expected to result in changes to important elements of the clinical investigation (e.g., endpoints, sample size, stopping rules) or device design.

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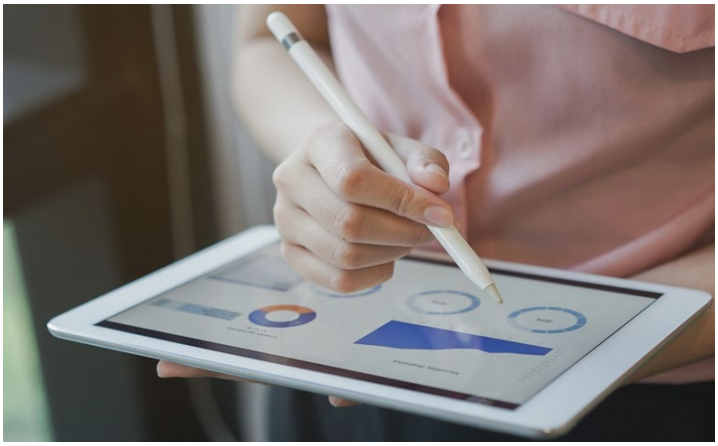
Additional Considerations

Promotion of Investigational Devices
Advertisements should be reviewed and approved by the IRB to assure that they are not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol.

No claims should be made, either explicitly or implicitly, that the device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other device.

Monitoring
For a non-significant risk device investigation, a sponsor may not resume a terminated investigation without IRB approval.

If the non-significant risk study was terminated for unanticipated adverse device effects, the sponsor must also obtain FDA approval.



Maintenance of Records
Records should be maintained in accordance with the CHOP Retention and Destruction of Records Policy (A-3-9)

What is an Emergency Use Investigational Device?

Emergency use is when there is a need to use a device that has not received the FDA's approval or clearance in an emergency to address immediately life-threatening situations. Emergency use may apply if the device is being studied in clinical trials under an investigational device exemption (IDE) such as when a physician who is not part of the IDE clinical study wishes to use the device to treat a patient in an immediately life-threatening situation. Emergency use may also apply if there is no IDE or ongoing clinical studies for the device.

Criteria for Emergency Use

- The patient has a life-threatening condition that needs immediate treatment.
- No generally acceptable alternative treatment for the condition exists; and
- Because of the immediate need to use the device, there is no time to use existing procedures to o ain FDA approval.

A) Is FDA Approval Required Prior to Emergency Use?
    - No. If all of the above criteria are met, an unapproved device may be used in an emergency situation without prior approval from the FDA.
    - The FDA expects the physician to make the determination that the patient's circumstances meet the above criteria to assess the potential for benefit from the use of the unapproved device, and to have substantial reason to believe that benefits will exist. In the event that a device is used in circumstances meeting the criteria listed above, the physician should follow as many patient protection procedures as possible. Such patient protection procedures include obtaining
        - Informed consent from the patient or a legal representative;
        - Clearance from the institution as specified by their policies;
        - Concurrence of the Institutional Review Board (IRB) chairperson;
        - An independent assessment from an uninvolved physician; and
        - Authorization from the device manufacturer.

B) Do I need to report Emergency Use to the FDA?

- Yes. If there is an IDE for the device, the IDE sponsor must notify the FDA of the emergency use within 5 days through submission of an IDE Report {812.35(a)(2)}. This follow-up report should include a summary of the conditions constituting the emergency, the patient protection measures that were followed, and patient outcome information.
- If no IDE exists, the physician should submit to the FDA a follow-up report within 5 days on the use of the device including a description of device used, details of the case, and the patient protection measures that were followed. The report should be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave
Document Control Center
W066 Rm. G-609
Silver Spring, MD 20993

Reports

Type of Report	What goes in it?	To whom and when do I need to submit the report?
UADE Report	Unanticipated Adverse Device Effect Report	Submitted to FDA and to IRB
Withdrawal of Approval	Notification that approval was withdrawn	If IRB approval withdrawn, the investigator must notify the sponsor and the sponsor must notify FDA, all reviewing IRBs and participating investigators within 5 working days. If FDA approval withdrawn, sponsor must notify all reviewing IRBs and participating investigators within 5 working days.
Current List of Investigators	List of the names and addresses of all current investigators and sites.	To FDA; every 6 months unless FDA grants a waiver
Recalls and Device Disposition	Any request that an investigator return, repair, or dispose of any unit of an investigational device, and the reason for the request.	Sponsor reports to FDA and all reviewing IRB's must be notified within 30 working days after the request was made.
Failure to Obtain Informed Consent	A copy of any report by an investigator of the use of a device without first obtaining informed consent	To FDA within 5 working days after receipt of the notice of such use.
Significant Risk (SR) Determination	A report of the IRB determination the device was an SR device (not NSR)	If an IRB determines a device is an SR device and not an NSR as previously determined, the sponsor notifies FDA within 5 working days after the sponsor learns of the IRB's decision.
Progress Report (Annual Report)	Progress report of study conduct in past year (since last annual report)	To the IRB at regular intervals but at least yearly. To the FDA at least yearly.
Final Report	Final report of study conduct	To the FDA and IRB, within 3 months after study termination or completion.
Other reports	Requested information about the investigation.	Upon IRB or FDA request.

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Basic Elements of Reports

- IDE Number
- Device name and indication(s) for use
- Sponsor's name, address, phone number, and fax number
- Contact person

Study Progress

Data from initiation of the study should be reported, unless otherwise indicated

- Brief summary of the study progress in relation to the investigational plan
- Number of investigators/investigational sites (attach list of investigators)
- Number of subjects enrolled (by indication or model)
- Number of devices shipped
- Brief summary of results
- Summary of anticipated and unanticipated adverse effects
- Description of any deviations from the investigational plan by investigators (since last progress report)

Risk Analysis

- Summary of any new adverse information (since the last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, etc.
- Reprints of any articles published from data collected from this study
- New risk analysis, if necessary, based on new information and on study progress

Other Changes

- Summary of any changes in manufacturing practices and quality control (including changes not reported in an IDE supplement)
- Summary of all changes in the investigational plan not required to be submitted in an IDE supplement

Marketing Application or Future Plans

- Progress toward product approval/clearance, with projected date of PMA or 510(k) submission
- Any plans to change the investigation, e.g., to expand the study size or indications, to discontinue portions of the investigation or to change manufacturing practices (NOTE: Actual proposals for these changes should be made in a separate IDE supplement).

General Content for Reports

The IDE regulations do not specify the content of the annual progress or final reports. Therefore, the contents of these reports may largely be dictated by the sponsor. With respect to reports to the IRB, the IRB itself may specify what information it wishes to be included in these reports.

Because FDA does require the information listed below, it is suggested that, at a minimum, the annual progress and final reports to the sponsor and the IRB include the following items:

- IDE number
- Device name
- Indications for use
- Brief summary of study progress in relation to investigational plan
- Number of subjects enrolled
- Number of devices received, used, and, in the final report, the final disposition of unused devices
- Brief summary of results and, in the final report, conclusions
- Summary of anticipated and unanticipated adverse device effects
- Description of any deviations from investigational plan
- Reprints of any articles published by the investigator in relation to the study

Other Reports
The sponsor must provide accurate, complete, and current information about any aspect of the investigation upon request from the reviewing IRB or FDA.

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Appendix 1: Additional Resources

For Additional CHOP IND Guidance, click here: **Getting Started with INDs-IDEs**

Electronic Submission of IDE Materials to CDRH
CDRH has an electronic submission portal which can be used to submit any type of IDE application, initial submission, supplement, report or amendment which would otherwise be submitted by eCopy as a mailed in submission. Contact the IND/IDE Support Office for assistance with this submission process.

Physical Addresses

For devices regulated by the Center for Devices and Radiological Health:
Center for Devices and Radiological Health,
Food and Drug Administration,
Document Mail Center
10903 New Hampshire Avenue, Building 66, Room G609,
Silver Spring, MD 20993–0002

For devices regulated by the Center for Biologics Evaluation and Research:
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For all submissions, be sure to state what the submission is, for example:

- an "IDE application,"
- a "supplemental IDE application," or
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Contact **INDIDE@chop.edu** for Templates or Forms needed for IDE Application Submissions.

IDE Training Learning Supplement

References

- FDA Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors; Frequently Asked Questions About Medical Devices, 2006
- FDA Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors; Significant Risk and Nonsignificant Risk Medical Device Studies, 2006
- FDA Guidance on IDE Policies and Procedures, 1998
- FDA Guidance on Decisions for Investigational Device Exemption Clinical Investigations, 2014
- FDA Code of Federal Regulations (CFR)
    - 21 CFR 812
    - 21 CFR 50
    - 21 CFR 56,
    - 45 CFR 46
- FDA Presentations
  http://www.fda.gov/Training/CDRHLearn/
- FDA Medical Devices Website
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm

Significant Risk vs Non-Significant Risk Devices
http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/UCM118082.pdf

Bioresearch Monitoring
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/BioresearchMonitoring/default.htm

Bioresearch Monitoring Learning Modules
http://www.fda.gov/Training/CDRHLearn/ucm162015.htm

Sponsor responsibilities for significant risk devices
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm049859.htm

Investigator responsibilities for significant risk devices
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm049864.htm