Sponsor-Investigator Responsibilities – Devices
Policies and Procedures TEMPLATE

Instructions for Using this Template

A sponsor-investigator is someone who both initiates and actually conducts a clinical investigation. The sponsor-investigator may conduct the research alone or with others. Investigators who conduct studies involving an FDA test article and for which they hold the IDE must abide by the same regulatory requirements as any other sponsor. The FDA will hold the investigator to the same regulatory requirements as if they were an industry sponsor, regardless of whether the investigator has the same resources.

> ***General Responsibilities of Sponsors – 21 CFR 812.40:*** *Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IDE application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation.*
>
> ***General Responsibilities of Investigators – 21 CFR 812.100:*** *An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with part 50 of this chapter.*

1. A sponsor-investigator is responsible for monitoring the study at his/her own institution (i.e. the University of Utah, Primary Children's Medical Center, VASLCHCS) and, if applicable, all other clinical investigators and institutions participating under the sponsor-investigator's IDE. This template outlines these responsibilities for **device studies**. If the study is not a multi-center study, then some responsibilities will not be applicable and can be omitted.
    a. There are additional requirements for investigations involving an exception from informed consent under 21 CFR 50.24 that are not outlined in this template. For more information regarding these requirements, please contact the IRB.
    b. There are additional requirements for investigations involving a treatment IDE under 21 CFR 812.36 that are not outlined in this template. For more information regarding these requirements, please contact the IRB.

2. Website links to CFR sections are included in the instruction text throughout the document. You should refer to these sections when writing the policies and procedures to ensure you have addressed all necessary requirements.
3. Complete the study information in the header of the document.
4. Replace bracketed items such as [Investigator's Name] on the title pages.
5. Read the guidelines for each section, complete as applicable for your project, and then delete the blue template guidelines.

6. The completed polices and procedures document should be attached to the study in ERICA on the Documents and Attachments page under “Other Documents”. If this document includes an appendix, it should be included in the same document. **Do not** attach supporting documentation separately in ERICA.

Sponsor-Investigator Responsibilities
Devices

Policies and Procedures

Sponsor-investigator: [Investigator's Name]
[Investigator's Title]
[Investigator's Institution]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]
[Email Address]

[Title of Study]

IDE Number: [number]

Internal Co-Investigators

INSTRUCTIONS: *This page may be deleted if there are no internal co-investigators investigators for this study. Delete template text as appropriate.*

[Investigator’s Name]
[Investigator’s Title]
[Investigator’s Institution]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]
[Email Address]

[Investigator’s Name]
[Investigator’s Title]
[Investigator’s Institution]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]
[Email Address]

[Investigator’s Name]
[Investigator’s Title]
[Investigator’s Institution]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]
[Email Address]

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[Investigator’s Title]
[Investigator’s Institution]

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[Email Address]

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[Email Address]

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[Investigator’s Institution]

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[Address 3]
[Phone Number]
[Email Address]

[Investigator’s Name]
[Investigator’s Title]
[Investigator’s Institution]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]
[Email Address]

External Investigators

INSTRUCTIONS: *This page may be deleted if there are no external investigators conducting research under the IDE held by the sponsor-investigator. Delete template text as appropriate.*

[Investigator’s Name]
[Investigator’s Title]
[Investigator’s Institution]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]
[Email Address]

[Investigator’s Name]
[Investigator’s Title]
[Investigator’s Institution]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]
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[Address 3]
[Phone Number]
[Email Address]

[Investigator’s Name]
[Investigator’s Title]
[Investigator’s Institution]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]
[Email Address]

Participating Sites

INSTRUCTIONS: *This page may be deleted if there are no external institutions participating in research under the IDE held by the sponsor-investigator. Delete template text as appropriate.*

[Institution Name]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]

[Institution Name]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]

[Institution Name]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]

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[Address 3]
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[Institution Name]

[Address 1]
[Address 2]
[Address 3]
[Phone Number]

RESPONSIBILITIES

I. Financial Disclosure By Clinical Investigators

A. Financial Disclosure to the Institution

INSTRUCTIONS: *Include a statement that the sponsor-investigator and all participating clinical investigators (including local co-investigators) will disclose their financial interests to the Conflict of Interest Office of their institution. State that the individual investigator (including the sponsor-investigator) will develop a management plan with the Conflict of Interest Office if it is determined that a conflict exists.*

B. Financial Disclosure to the FDA – 21 CFR 54

INSTRUCTIONS: *The requirements in this part apply to any applicant who submits a marketing or reclassification application for a device, and who submits covered clinical studies. See 21 CFR 54.2 (e) for the full definition of "covered clinical studies". An applicant may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements. This section should be deleted if it is not a covered clinical study.*

Describe the process to ensure disclosure of financial interests and maintaining records of financial disclosure for all clinical investigators. Describe how the sponsor-investigator will ensure that financial disclosure records will be retained for 2 years after a marketing application is approved for the device; or, if an application is not approved for the device, until 2 years after shipment and delivery of the device for investigational use is discontinued and FDA has been so notified.

As an attachment or appendix, include copies of the completed FDA 3435 Form(s) and/or FDA 3455 Form(s).

II. Investigational Device Exemptions – Subpart A

A. Labeling of Investigational Devices

INSTRUCTIONS: *Confirm that the investigational device or package label will include all of the required information described in section 812.5 (a). Describe what information will be included on the investigational device label.*

Confirm that the investigational device will not be promoted as safe or effective for the purpose under study.

B. Prohibition of Promotion and Other Practices

INSTRUCTIONS: *Confirm that the investigational device will not be promoted or test marketed unless the FDA has approved the device for commercial distribution. Describe the cost of the investigational device to participants; if there will be no costs to the participants, please state. Verify that any costs to participants are not larger than necessary to recover costs of manufacture, research, development, and handling.*

Confirm that if the data developed by the investigation indicate in the case of a class III device that pre-market approval cannot be justified or in the case of a class II device that it will not comply with an

applicable performance standard or an amendment to that standard, the sponsor-investigator will promptly terminate the investigation. Describe the follow-up that will occur with study participants in the event the investigation is terminated.

III. Investigational Device Exemptions – Subpart B

INSTRUCTIONS: *As an attachment or appendix, include a copy of the complete Application for an Investigational Device Exemption (IDE Application), as described in section 812.20 (b). As an attachment or appendix, include a copy of the FDA IDE confirmation letter or approval letter.*

A. Changes in Investigational Plan

INSTRUCTIONS: *Confirm that the sponsor-investigator will obtain approval via a supplemental application from the FDA and reviewing IRBs prior to implementing a change to an investigational plan, unless the change meets the criteria outlined in section 812.35 (a) (2) through (a) (4).*

Confirm that the sponsor-investigator will obtain approval via a supplemental application from the FDA when including a new site/facility in the investigation of the device. State that documentation of IRB approval for that site/facility will be submitted to the FDA upon receipt.

IV. Investigational Device Exemptions – Subpart C

A. Selecting and Informing Investigators

INSTRUCTIONS: *Include a statement describing how all participating clinical investigators will be qualified by training and experience as appropriate experts to investigate the device. Verify that the investigational device will only be shipped to investigators participating in the investigation and describe the protections in place to ensure compliance with study procedures. Confirm that all participating clinical investigators will be provided with a copy of the investigational plan and the report of prior investigations of the device.*

As an attachment or appendix, include the signed agreements from each participating clinical investigator including all information detailed in section 812.43.

As an attachment or appendix, include a copy of the sponsor-investigator's curriculum vitae or other statement of qualifications. It is appropriate to include as an attachment or appendix a curriculum vitae or other statement of qualifications of each participating clinical investigator. If these curriculum vitae are not included as an attachment or appendix, please state that they will be kept on file with the sponsor-investigator.

As an attachment or appendix, include a copy of the sponsor-investigator's protocol summary or investigational plan.

B. Selecting Monitors

INSTRUCTIONS: *Describe how the study monitor(s) will be qualified by training and experience to monitor the progress of the investigation. Describe the member(s) involved as the study monitor(s). Depending on the design, size, and potential risks of the study, an appropriate study monitor may be an individual or a committee of several members. Provide the names, affiliations, and expertise of members*

of the monitoring group. State that a copy of each study monitor's curriculum vitae or other statement of qualifications will be kept on file.

Describe the monitoring plan, including the following:

- *How often will the study monitor(s) review the study data for non-compliance and participant safety (adverse events, unanticipated problems, etc.)?*
- *How often will the study monitor(s) report findings to the sponsor-investigator?*
- *How often will findings be reported to all participating clinical investigators and reviewing IRBs?*
- *How and under what circumstances will findings be reported to other entities, such as the FDA, DHHS, associated device manufacturing companies, etc.?*
- *What are the "stopping criteria" for the study?*

C. Monitoring Investigations

INSTRUCTIONS: *Describe how the sponsor-investigator will monitor the progress of all clinical investigations being conducted under the IDE, including issues of non-compliance and the safety and effectiveness of the investigational device.*

A sponsor-investigator who discovers instances of non-compliance at his/her own institution (i.e. the University of Utah, Primary Children's Medical Center, VASLCHCS) is required to report those instances to the reviewing IRB according to IRB policy. Describe who will be responsible for preparing and submitting these reports (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.) and how record of these events and corresponding approvals/acknowledgements will be maintained.

A sponsor-investigator who discovers that a participating clinical investigator is not complying with the signed agreement, the general investigational plan, or any other requirement will promptly either secure compliance or discontinue shipments of the investigational device to the investigator and end the investigator's participation in the investigation. Describe the procedures for adhering to this requirement, including, reporting procedures to reviewing IRBs. Describe who will be responsible for preparing and submitting these reports to the IRB(s) (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.) and how record of these events and corresponding approvals/acknowledgements will be maintained. Describe the follow-up that will occur with study participants in the event that an investigator is discontinued from participating in the study.

A sponsor-investigator who determines that the investigational device presents an unreasonable and significant risk to subjects shall discontinue those investigations that present the risk. Termination must occur no later than 5 working days after the sponsor-investigator makes this determination and no later than 15 working days after the sponsor-investigator first received notice of the effect. The sponsor-investigator will also notify the FDA, all reviewing IRBs, and all investigators who have at any time participated in the investigation. Describe the procedures for adhering to this requirement. Describe who will be responsible for notifying the FDA, IRB(s), and participating clinical investigators (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.). Describe the follow-up that will occur with study participants in the event that the study is discontinued for safety reasons.

V. Investigational Device Exemptions – Subparts D-G

A. Assurance of IRB Review

INSTRUCTIONS: *Confirm that the sponsor-investigator and all participating clinical investigators will obtain IRB approval for the study from their respective institutions, including initial approval, continuing review, and changes in the research activity (amendments). State that changes in the research will not be made without IRB approval, except where necessary to eliminate apparent immediate hazards to human participants. Describe who will be responsible for submitting to the IRB for approval (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.) and how record of IRB approvals will be maintained for all participating institutions.*

Confirm that if the sponsor-investigator proposes that the device is a non-significant risk device, but an IRB determines that the device is a significant risk device, the sponsor-investigator will submit a report of the IRB's determination to the FDA within 5 working days of receiving the IRB's determination.

If the study is a multi-center study, describe the process by which participating clinical investigators will report to the sponsor-investigator as soon as possible or within 5 working days a withdrawal of IRB approval from the investigator's institution. Include a statement that the sponsor-investigator will notify the FDA and all reviewing IRBs within 5 working days after the receipt of the withdrawal of approval.

B. Adverse Events Reporting

INSTRUCTIONS: *Confirm that all adverse effects, whether anticipated or unanticipated, and complaints will be recorded. Confirm that safety reports will be submitted to the FDA, all participating clinical investigators, and reviewing IRBs for any adverse events associated with the use of the device that are unanticipated. Describe who will be responsible for preparing and submitting these reports (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.) and how record of these events and corresponding approvals/acknowledgements will be maintained.*

If the study is a multi-center study, describe the process by which participating clinical investigators will report to the sponsor-investigator any unanticipated adverse device effects as soon as possible or within 10 days.

Describe how the sponsor-investigator will ensure that all participating clinical investigators (including the sponsor-investigator) will promptly report to reviewing IRBs all unanticipated problems involving risk to human participants or others according to IRB policies. Describe who will be responsible for preparing and submitting these reports (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.) and how record of these problems and corresponding approvals/acknowledgements will be maintained for all participating institutions.

C. Deviation Reporting

INSTRUCTIONS: *Describe how the sponsor-investigator will ensure that all participating investigators will obtain approval from the FDA, the sponsor-investigator and reviewing IRBs before changing or deviating from the investigational plan if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects.*

Describe how the sponsor-investigator will ensure that all participating clinical investigators (including the sponsor-investigator) will report to the reviewing IRB(s) within 5 working days all deviations from the investigational plan to protect the life or physical well-being of a subject in an emergency. Participating clinical investigators must also report to the sponsor-investigator.

Confirm that if the sponsor-investigator or a participating clinical investigator uses the device without obtaining informed consent, this will be reported to the reviewing IRB(s) within 5 working days after the use occurs. Participating clinical investigators must also report to the sponsor-investigator. Confirm that the sponsor-investigator will report such use to the FDA within 5 working days of receiving notification of such use.

Describe who will be responsible for preparing and submitting these reports (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.) and how record of these problems and corresponding approvals/acknowledgements will be maintained for all participating institutions.

D. Progress Reports and Final Reports

INSTRUCTIONS: *Describe how the sponsor-investigator will ensure that the sponsor-investigator and all participating clinical investigators will submit progress reports to the sponsor-investigator at regular intervals, but in no event less often than yearly.*

Confirm that the sponsor-investigator will submit progress reports to all reviewing IRBs and the study monitor at regular intervals, but in no event less often than yearly. If the device is a significant risk device, confirm that the sponsor-investigator will submit progress reports to the FDA.

Describe how the sponsor-investigator will ensure that all participating clinical investigators will submit a final report to the sponsor-investigator and reviewing IRBs within 3 months after the participating clinical investigator's part of the investigation.

Confirm that the sponsor-investigator will submit a final report to the FDA and all reviewing IRBs upon termination or completion of the investigation. For significant risk devices, confirm that the final report will be submitted within 30 working days of termination or completion; for non-significant risk devices, confirm that the final report will be submitted within 6 months of termination or completion.

E. Withdrawal of FDA Approval

INSTRUCTIONS: *Describe how the sponsor-investigator will notify all participating clinical investigators and reviewing IRBs of a withdrawal of FDA approval of the investigation within 5 working days after receiving notice of the withdrawal of approval.*

F. Current Investigator List

INSTRUCTIONS: *Confirm that the sponsor-investigator will submit to the FDA a current list of the names and addresses of all participating clinical investigators. State that this list will be submitted 6 months after FDA approval and at 6-month intervals from then on.*

G. Recordkeeping and Record Retention

INSTRUCTIONS: *Confirm that in addition to the records previously described in this document, the sponsor-investigator and all participating clinical investigators (as applicable) will maintain the following records during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a pre-market approval application or a notice of completion of a product development protocol. Describe where these records will be stored.*

i. Correspondence

INSTRUCTIONS: *Describe how the sponsor-investigator will ensure that the sponsor-investigator and all participating clinical investigators will maintain record of all correspondence between the sponsor-investigator and other participating clinical investigators, with another sponsor, a monitor, an IRB, or the FDA, including any required reports.*

ii. Records of receipt, use, or disposition of the device

INSTRUCTIONS: *The sponsor-investigator and participating clinical investigators must maintain records of receipt, use, or other disposition of the investigational device. This information must include the following:*

- *the type and quantity of the device*
- *the dates of its receipt*
- *the batch number or code mark*
- *the names of all persons who received, used, or disposed of each device*
- *why and how many units of the device have been returned to the sponsor-investigator, repaired, or otherwise disposed of*

Describe who will be responsible for preparing and maintaining these records (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.). It may be appropriate to include a copy of the device receipt/shipment log as an attachment or appendix.

Describe how the sponsor-investigator will assure that all participating clinical investigators will return to the sponsor-investigator any remaining supply of the device or otherwise dispose of the device as the sponsor-investigator directs.

Confirm that the sponsor-investigator will notify the FDA and all reviewing IRBs within 30 working days of any request that a participating clinical investigator (including the sponsor-investigator) return, repair, or otherwise dispose of any units of a device. Confirm that this report will also notify the FDA of why the request was made.

iii. Case Histories

INSTRUCTIONS: *Describe how the sponsor-investigator will ensure that each participating investigator, including the sponsor-investigator, will prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each participant who is given the investigational device or employed as a control in the study, as described in section 812.140 (a) (3). Please note that it is not required that the sponsor-investigator maintain case study reports for all participating investigators, only the case histories for the sponsor-investigator's institution (i.e. the University of Utah, Primary Children's Medical Center, VASLCHCS). Describe who will be responsible for preparing and maintaining these case history reports (e.g. the sponsor-investigator, co-investigator, study coordinator, etc.).*

It is appropriate to include as an attachment or appendix a copy of the case history report form that will be used. This case history report form should record the information described in section 812.140 (a) (3).

iv. Protocols and Deviations

INSTRUCTIONS: *Describe how the sponsor-investigator will ensure that each participating clinical investigators (including the sponsor-investigator acting as an investigator) will maintain an up-to-*

date protocol summary, as well as documentation of the dates of and reasons for each deviation from the protocol.

It is appropriate to include as an attachment or appendix the protocol summaries from each participating clinical investigator. If these protocol summaries are not included as an attachment or appendix, please state that they will be kept on file with the sponsor-investigator.

v. Documentation for Non-Significant Risk Devices

INSTRUCTIONS: *If the investigational device used in this study is determined to be a significant risk device, this section should be deleted. If the investigational device used in this study is determined to be a non-significant risk device, include a statement that the following documentation will be kept by the sponsor-investigator, available for FDA inspection and copying:*

- *All records described in section 812.2 (b) (1)*
- *All records described in section 812.140 (b) (4)*