**Michigan State University Human Research Protection Program**

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| **Instructions and Contact Information** | | | | |
| * Use this appendix when requesting closure for U.S. Food and Drug Administration (FDA) regulated research conducted under an IND or IDE. * CLICK™ IRB   + Include this template with a Continuing Review Submission (when closing the study).   + Upload the completed template to the Continuing Review / Study Closure Information SmartForm page, Question 5. | | | | |
| * If you have questions about completing this form, please contact us. * Phone: 517-355-2180 / Email: irb@msu.edu / Visit hrpp.msu.edu for staff contact or additional information | | | | |
| **Form** | | | | |
| **1** | **Principal Investigator Name:** | | | |
| **2** | **Title:** | | | |
| **3** | **MSU STUDY ID#:** | | | |
| **4** | **Select the appropriate option below:** | | | |
|  | **Drug: IND – Complete Section 1** | | |
|  | **Device:**  **IDE – Complete Section 2**  **Abbreviated IDE – Complete Section 3** | | |
| **SECTION 1 - DRUG – IND** | | | | |
| **A** | **Investigator Recordkeeping and Record Retention (21 CFR 312.62)**  *(a) Disposition of drug. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59.*  *(b) Case histories. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.*  *(c) Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.* | | | |
| **How do you plan to store and protect the records to meet these requirements?** | | | |
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| **B** | **Inspection of Investigator's Records and Reports (21 CFR 312.68)**  *An investigator shall upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to 312.62.* | | | |
| **How will you assure that records or reports will be accessible?** | | | |
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| **C** | **Is the investigator for this study also the sponsor? If yes, complete C1** | | | **No**  **Yes** |
| **C1** | **Recordkeeping and retention for Sponsors (21 CFR 312.57)**   1. *A sponsor shall maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug. These records are required to include, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment.* 2. *A sponsor shall maintain complete and accurate records showing any financial interest in 54.4(a)(3)(i), (a)(3)(ii), (a)(3)(iii), and (a)(3)(iv) of this chapter paid to clinical investigators by the sponsor of the covered study. A sponsor shall also maintain complete and accurate records concerning all other financial interests of investigators subject to part 54 of this chapter.* 3. *A sponsor shall retain the records and reports required by this part for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.* 4. *A sponsor shall retain reserve samples of any test article and reference standard identified in, and used in any of the bioequivalence or bioavailability studies described in, 320.38 or 320.63 of this chapter, and release the reserve samples to FDA upon request, in accordance with, and for the period specified in 320.38.* | | | |
| **Please explain how you will meet these requirements.** | | | |
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| **SECTION 2 - DEVICE – IDE** | | | | |
| **A** | **Recordkeeping and Retention for Investigators (21 CFR 812.140)**  *(a) Investigator records. A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:*  *(1) All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.*  *(2) Records of receipt, use or disposition of a device that relate to:*  *(i) The type and quantity of the device, the dates of its receipt, and the batch number or code mark.*  *(ii) The names of all persons who received, used, or disposed of each device.*  *(iii) Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.*  *(3) Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:*  *(i) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study.*  *(ii) All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.*  *(iii) A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.*  *(4) The protocol, with documents showing the dates of and reasons for each deviation from the protocol.*  *(5) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.*  *(d) Retention period. An investigator or sponsor shall maintain the records required by this subpart 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 premarket approval application or a notice of completion of a product development protocol.* | | | |
| **How do you plan to store and protect the records to meet these requirements?** | | | |
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| **B** | **Inspections (21 CFR 812.145 (b))**  *Records inspection.* *A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.* | | | |
| **How will you assure that records will be accessible?** | | | |
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| **C** | **Is the investigator for this study also the sponsor? If yes, complete C1.** | | **No**  **Yes** | |
| **C1** | **Recordkeeping and Retention for Sponsors (21 CFR 812.140)**  *(b) Sponsor records. A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:*  *(1) All correspondence with another sponsor, a monitor, an investigator, an IRB, or FDA, including required reports.*  *(2) Records of shipment and disposition. Records of shipment shall include the name and address of the consignee, type and quantity of device, date of shipment, and batch number or code mark. Records of disposition shall describe the batch number or code marks of any devices returned to the sponsor, repaired, or disposed of in other ways by the investigator or another person, and the reasons for and method of disposal.*  *(3) Signed investigator agreements including the financial disclosure information required to be collected under 812.43(c)(5) in accordance with part 54 of this chapter.*  *(4) For each investigation subject to 812.2(b)(1) of a device other than a significant risk device, the records described in paragraph (b)(5) of this section and the following records, consolidated in one location and available for FDA inspection and copying:*  *(i) The name and intended use of the device and the objectives of the investigation;*  *(ii) A brief explanation of why the device is not a significant risk device:*  *(iii) The name and address of each investigator:*  *(iv) The name and address of each IRB that has reviewed the investigation:*  *(v) A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device; and*  *(vi) Any other information required by FDA.*  *(5) Records concerning adverse device effects (whether anticipated or unanticipated) and complaints and*  *(6) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.* | | | |
| **Please explain how you will meet these requirements.** | | | |
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| **SECTION 3 – DEVICE - ABBREVIATED IDE** | | | | |
| **A** | **Recordkeeping and Retention for Investigators and Sponsors (21 CFR 812.40(a) and (b) and 812.150(b))**  *(a) Investigator records. A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:*  *(3) Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:*  *(i) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study.*  *(b) Sponsor records. A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:*  *(4) For each investigation subject to 812.2(b)(1) of a device other than a significant risk device, the records described in paragraph (b)(5) of this section and the following records, consolidated in one location and available for FDA inspection and copying:*  *(i) The name and intended use of the device and the objectives of the investigation;*  *(ii) A brief explanation of why the device is not a significant risk device:*  *(iii) The name and address of each investigator:*  *(iv) The name and address of each IRB that has reviewed the investigation:*  *(v) A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device; and*  *(vi) Any other information required by FDA.*  *812.150(b).*  *(5) Records concerning adverse device effects (whether anticipated or unanticipated) and complaints* | | | |
| **How do you plan to store and protect the records to meet these requirements?** | | | |
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