1 PURPOSE

1.1. This guidance outlines the additional obligations of having data removed.

2.1.1.2. You may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.

2.1.1.3. If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, you must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.

2.1.1.4. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, you must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent.

2.1.1.4.1. You may review study data related to the participant collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

2.1.2. The Responsible Party for a clinical trial must register the trial and submit results information.

2.1.2.1. A principal investigator of a clinical trial is the Responsible Party if the clinical trial is investigator initiated or if so designated by a sponsor, grantee, contractor, or awardee.

2.1.2.2. Registration is required for the following trials:

2.1.2.2.1. Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products

2.1.2.2.2. Controlled trials with health outcomes of devices, other than small feasibility studies

2.1.2.2.3. Pediatric post-market surveillance required by FDA

2.2. Requirements for studies conducted under an IND

2.2.1. You, or any person acting on your behalf, cannot represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.

2.2.1.1. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

2.2.2. You may not commercially distribute or test market an investigational new drug.

2.2.3. Ensure that the investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under your care; and for the control of drugs under investigation.

2.2.4. Obtain informed consent from each human subject to whom the

2.3.2. If the study is investigator-initiated:

2.3.2.1. Label the device as follows:

2.3.2.1.1. The device or its immediate package must bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with §801.1), the quantity of contents, if appropriate, and the following statement: “CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.” The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and13.1 (t213.2 (i)3.1mb
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2.3.9.

2.5.8.2. Records of receipt, use or disposition of a device that relate to:

2.5.8.2.1. The type and quantity of the device, the dates of its receipt, and the batch number or code mark

2.5.8.2.2. The names of all persons who received, used, or disposed of each device

2.5.8.2.3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of

2.5.8.3. Records of each subject's case history and exposure to the device. Case histories include:

2.5.8.3.1. 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.

2.5.8.3.2. Documents evidencing informed consent and, for any use of a device 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 must document that informed consent was obtained prior to participation in the study.

2.5.8.3.3. 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.

2.5.8.3.4. A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.

2.5.8.4. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.

2.5.8.5. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

2.5.9. Permit authorized FDA employees, at reasonable times and in a reasonable manner:

2.5.9.1. To enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).

2.5.9.2. To inspect and copy all records relating to an investigation.

2.5.9.3. To inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by you to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

2.5.10. Prepare and submit the following complete, accurate, and timely reports:

2.5.10.1. Submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation

as soon as possible, but in no event later than 10 working days after you first learn of the effect.

2.5.10.2. Report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of your part of an investigation.

2.5.10.3. Submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.

2.5.10.4. Notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a