Devices in Research

Summary

Guidance to determine how to submit a research study using a device

Guidance

1. Determine if the device is indeed a “Medical Deivce” as defined by the FDA and being used in an investigational manner.

    - Medical Device - an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
        1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
        2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
        3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and

      which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

    - Investigational Manner - Investigation is a clinical investigation or research involving one or more subjects to determine the safety and/or effectiveness of a device.

2. If a device is being used in a research study according to the label or is being used in a non-investigational way (not determining safety and efficacy), the study can be reviewed by the IRB in the standard way based on the regulations (no special steps need to be taken relating to the device. This also applies to *in vitro* devices (lab devices used to run tests on blood for example) so long as they are not the sole device used for diagnosis.

3. For investigational Devices not meeting Exemption criteria, the level of review will be determined based on the sponsor or investigator’s determination of risk. The IRB will need enough information from the study team to make a risk determination. This is usually provided by the sponsor or the FDA.

    <u>Significant Risk Devices:</u>

    - Significant Risk Device - Significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) 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 (4) otherwise presents a potential for serious risk to a subject.

- For Significant Risk Devices, Full Board review is required and the sponsor/investigator must provide the IRB with IDE documentation **from the FDA** prior to full board review.

Non-Significant Risk Devices

- Non-Significant Risk Device – A device that does not meet the definition of Significant Risk (see above).
- The IRB will review to determine if the device meets the criteria for an Abbreviated IDE (by verifying the device does not meet the significant risk criteria).
- If the device appears to be non-significant risk and meets the criteria for an Abbreviated IDE, the study will be placed on the full board agenda. Information on the device as well as documentation from the sponsor/investigator should be provided as study materials. No documentation from the FDA is required.

4. The Full Board has the ability to agree or disagree with the sponsor/investigator's risk determination after review. The IRB may ask for more information or for the sponsor to submit to the FDA for a risk determination.
5. If the IRB agrees with the risk determaintion and the Abbreviated IDE requirements, it will be documented within the approval letter.