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NEWSLETTER

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IRBco review of medical device research: Guidance for PIs and CROs for getting IRB approval to perform medical device research

A medical device is 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 the official National Formulary, or the United States Pharmacopeia, or any supplement to them, 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 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; and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

The study device would need an Investigational Device Exemption (IDE) from the FDA to allow it to move through interstate commerce in order to be used in a

clinical study to collect safety and efficacy data.

It would also be needed to study a new intended use for a legally marketed device. The IDE regulations divide all studies with medical devices into 3 categories:

1. Exempt – These studies mostly utilize marketed devices in accordance with their labeling.
2. Non-significant risk – These studies are determined by the FDA as exempt from IDE regulations and the devices as non-significant risk. If there is no FDA determination, the board at IRBco can make the determination but the study will follow abbreviated IDE regulations.
3. Significant risk – The studies with these devices require a formal IDE determination from the FDA and the protocol imprinted with the IDE number.

At IRBco we provide the sponsor with a device determination checklist to make a preliminary categorization of risk which assists us to make the right determination.

Devices which are no more than minimal risk can also be expedited for review if they do not require an IDE application or if it is an approved device by the FDA and is used in accordance with its labeling. IRBco approved expedited studies in 4 days on an average in the past year from the time of complete submission. ■

FDA Issues Draft Guidance: Guidance for IRBs, Clinical Investigators and Sponsors - Considerations When Transferring Clinical Investigation Oversight to Another IRB

In May 2014, FDA issued draft guidance for IRBs, clinical investigators and sponsors titled, “Considerations When Transferring Clinical Investigation Oversight to Another IRB”.

FDA Issues Draft Guidance continued…

During this transfer of oversight, FDA requirements place the responsibility on clinical investigator and sponsor in clinical investigation of new drugs and medical devices, respectively. The FDA also recommended the following plan when transferring IRB oversight:

1. Documenting the studies for which IRB oversight is being transferred.

2. All pertinent records for the study must be available for FDA review for a period of 3 years from the date of study completion. The responsibility of records maintenance must be clearly defined between the original and the receiving IRB.

3. An effective date of transfer of IRB oversight should be established which would help prevent any lapse in IRB coverage.

4. The receiving IRB may decide whether to conduct an initial review, continuing review or wait for the next continuing review date to conduct an assessment of the study(ies).

5. Depending on the date of study assessment by the receiving IRB, the date of next continuing review will have to be established.

6. The new IRB information should also be reflected in the consent forms and the subjects who have already signed the consent form should be notified of this change.

7. All key parties involved in this transfer of oversight should discuss their responsibilities before implementing the transfer. The sponsor should also update the associated IND or IDE with the new IRB information.

8. The receiving IRB will revise its existing registration if it decides to review new types of FDA regulated products. The original IRB will revise its registration to indicate if it ceases to review certain types of FDA regulated products or plans to disband. This revision should take place within 30 days of such change. ■

What's going on at IRBco?

✓ IRBco is now accepting all submissions on our new and improved electronic portal - AllianceNet. AllianceNet is a 100% web-based, state-of-the-art submission system, which provides streamlined submissions for multi-center as well as single-site studies.

The highly secure and user-friendly AllianceNet portal provides 24/7 access to all IRB-related study documents to the sponsor, CRO and site staff. The submission process is quick with convenient access to previous submissions and guidance documents. The portal ensures rapid IRB turnaround times and provides clients with instant notification of the IRB determinations.

Our clients have expressed tremendous satisfaction with submissions through AllianceNet. And as always, at IRBco, client satisfaction remains our top priority!■

Contact IRBco

Interested in learning more about IRBco? Our team is ready to answer your inquires regarding your organization's specific IRB needs.

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