Informed Consent, Transfer to New IRB & Humanitarian Device Exemption – Recent FDA Guidances

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FDA recently issued three guidance documents that impact clinical trials and that we explore below: Informed Consent Information Sheet(draft guidance), Considerations When Transferring Clinical Investigation Oversight to Another IRB (final guidance) and Humanitarian Device Exemption: Questions and Answers (draft guidance).

1.Informed Consent Information Sheet

This draft guidance was released in July 2014 and is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent. At 42 pages, it covers a lot of ground and goes into much more detail than previously provided on a number of topics. Here is a limited selection of topics, some of which are requirements and others of which are agency suggestions (e.g. "shoulds"):

a. use of exculpatory language – examples provided (from earlier draft guidance on specimens)

b. description of benefits and risks of control product and of alternative treatments

c. assessment of likelihood of risks occurring

d. description of currently medically recognized standard of care (which may be off-label)

e. subject injury compensation

f. emergency contact

g. costs to subjects – much more detail than current information sheet (1998)

h. IRB waivers

i. alternative methods of obtaining informed consent

j. dating the informed consent form

k. short form informed consent

l. disclosure of financial relationships and interests

m. 8th grade reading level

n. IRB review procedures

o. re-consenting subjects if circumstances change

p. multi-center study considerations

q. review of patient records, including screening before enrollment

r. non-English speaking subjects, including both anticipated and unanticipated – see Section V.B of the draft guidance

s. subjects with impaired consent capacity – Section V.E (the draft guidance also refers the reader to the EFIC guidance from April 2013)

t. children as subjects

u. study suspension and termination.

2. Considerations When Transferring Clinical Investigation Oversight to Another IRB

This final guidance dated May 2014 outlines steps to consider when transferring oversight of an ongoing study to another IRB that is not part of the same institution. It also addresses special situations, such as transfer to another IRB in the same institution, temporary transfer of IRB review responsibility and transfer of a study to a new site if an investigator moves to a new institution. The guidance is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-when-transferring-clinical-investigation-oversight-another-irb .

3. Humanitarian Device Exemption (HDE): Questions and Answers

In March, FDA released draft guidance that contains questions and answers on Humanitarian Use Device ("HUD") designations and the HDE application requirements, as well as FDA's application review process. The guidance also addresses what types of HUDs are eligible to make a profit, HDEs and pediatric patients, what happens at a facility after it receives FDA approval of an HDE, the role of IRBs when it comes to HUDs, and the use of HUDs in emergency use situations. The end of the guidance includes a helpful decision tree for IRB review of HUDs.

If you have any questions or would like more information about these developing issues, please contact the following:

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