How to Review Clinical Trial Advertising

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Learning Objectives

- How to identify projects that include advertising
- Methods for determining advertising delivery is ethical and appropriate

Ask about advertising with new applications to IRB

- Sample Text from FHCRC IRB application form – Attachment 1

- Be sure research advertisements posted in corridors or other public places note IRB approval date

Utilize FDA Guidance Criteria

- See criteria in Attachment 2
- Need to avoid coercion
- Make clear it discusses research
- No bait and switch allowed

Other Considerations

- Make sure other sources, such as Library Internet Services or Clinical Trials Offices understand importance of IRB approval of advertising/recruitment messages

- Once message is publicized, everyone needs to be prepared for a response to the advertisement and be available.

Resources

- Attachment 1 – Sample text from FHCRC IRB application (current, 2004)

- Attachment 2 – FDA guidance for review of advertisements (*Guidance for IRBs and Clinical Investigators* -1998)

http://www.fda.gov/oc/ohrt/irbs/default.htm