

Sent: Monday, March 27, 2006 11:13 AM

To: UKORI-IRB-L@LSV.UKY.EDU

Subject: Guidance on Institutional Review Board Review of Clinical Trial Websites

ORI has prepared a new guidance document summarizing the Department of Health and Human Services (DHHS) Office of Human Research Protection (OHRP) guidance regarding IRB review of clinical trial web sites published in the fall of 2005. It is available on the ORI website under [Guidance/Policy Documents](#) web page and scroll down to the "s" listing to download the document "Guidance on IRB Review of Clinical Trial Websites".

The guidance document is also pasted below:

Guidance on Institutional Review Board Review of Clinical Trial Websites

In the fall of 2005 the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) published a guidance document regarding Institutional Review Board (IRB) review of clinical trial websites. This is a synopsis of the information relayed in that guidance.

OHRP consistently has interpreted HHS regulations to provide IRB authority and responsibility for review of study recruitment material. Although websites use a different medium than traditional print or broadcast advertisements, the requirements are the same.

When information posted on a clinical trial website goes beyond directory listings with basic descriptive information (study title, purpose of study, protocol summary, basic eligibility criteria, study site location and contact information for the study site) such information is considered part of the informed consent process and therefore requires IRB review and approval. Information exceeding basic descriptive information includes; descriptions of clinical trial risks and potential benefits or solicitation of identifiable information.

When reviewing clinical trial web sites the IRB should pay particular attention to:

- risk and potential benefit information to make sure it is presented in a balanced and fair manner, not to mislead and/or promise or imply benefit beyond that potentially provided by the research.
- type of incentives offered, monetary and non-monetary (access to services or programs) which can create an undue influence on a potential subjects decision about research participation.
- trial participation being voluntary
- if identifiable information is being collected via the clinical trial website, the plans for protecting the confidentiality of that information

Clinical trial websites that provide only directory listings with basic descriptive information (listed above) about clinical trials in general do not need to be reviewed by an IRB. Examples of these are:

- National Institute of Health (NIH) ClinicalTrials.gov website
- NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query (PDQ))
- Government sponsored AIDS Clinical Trial Information Service (ACTIS)