

**Department of Health and Human Services (HHS)
Office for Human Research Protections (OHRP)**

Guidance on Institutional Review Board Review of Clinical Trial Websites

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Scope:

This document provides guidance to Institutional Review Boards (IRBs) for the review of information provided to potential research subjects through clinical trial websites. This guidance, which applies to HHS-conducted or -supported research, describes the circumstances for which IRB review of clinical trial websites is required and provides some points to consider in the review process. It also describes the circumstances for which IRB review of clinical trial websites is not required.

NOTE: Some protocols described on clinical trial websites also may be subject to Food and Drug Administration (FDA) regulations. The reader is advised to consult with FDA about its regulatory requirements and guidance in this area.

Target Audience:

Research institutions, IRBs, investigators, and sponsors.

Introduction:

Websites, along with print and broadcast advertisements, are commonly used by investigators and institutions to recruit research subjects. In some cases, the information provided on these websites may constitute the earliest components of the informed consent process.

In May 2002, the HHS Office of Inspector General (OIG) issued a report, *Clinical Trial Websites: A Promising Tool to Foster Informed Consent* [<http://oig.hhs.gov/oei/reports/oei-01-97-00198.pdf>]. The OIG report recommended that OHRP:

- Provide further guidance to IRBs on clinical trial websites.
- Clarify that risk and benefit information in trial listings is subject to IRB review and approval.
- Require IRB review of any prescreening used for specific trials.

The OIG report noted:

“Current guidance does not require IRB review if the clinical trial listing is limited to the following basic trial information: title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for further information. This is a sound policy that we do not propose to change. However, some

Web sites we reviewed provide more than the prescribed basic trial information mentioned in current guidance. In these instances it is unclear to IRBs whether review of the listing is required.”

The OIG report also recommended that the review of pre-screening activities should address any relevant privacy and confidentiality issues.

Regulatory Background:

HHS regulations at 45 CFR 46.109(b) require that IRBs ensure that information given to subjects as part of informed consent meets the requirements specified in the regulations at 45 CFR 46.116.

HHS regulations at 45 CFR 46.116 state:

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The HHS regulations also state at 46.111(a)(4) that, among other requirements, an IRB must determine that informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by HHS regulations at 46.116. The IRB may require that information, in addition to that specifically mentioned in 46.116, be given to the subjects when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of subjects (46.109(b)).

The regulations at 45 CFR 46.116(a) and (b) list the informational requirements for informed consent.

Guidance:

One method of recruiting subjects is through advertisements (e.g., posted notices and newspaper or magazine advertisements, websites). OHRP consistently has interpreted HHS regulations to provide IRB authority and responsibility for review of study recruitment material, including advertisements. Although websites use a different medium than traditional print or broadcast advertisements the requirements are the same.

When Is IRB Review of Clinical Trial Websites Required?

When information posted on a clinical trial website goes beyond directory listings with basic descriptive information, such information is considered part of the informed consent process and therefore requires IRB review and approval. Basic descriptive information includes:

- study title
- purpose of the study
- protocol summary
- basic eligibility criteria
- study site location(s), and
- how to contact the study site for further information.

Information exceeding such basic listing information includes descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information.

What Points Should IRBs Consider When Reviewing Clinical Trial Websites, if Appropriate?

As with the review of all recruitment materials, IRBs should pay particular attention to risk and potential benefit information to ensure it is presented in a balanced and fair manner. The information presented should not mislead, for example, by promising benefits or implying a benefit beyond that potentially provided by the research.

IRBs reviewing clinical trial websites also should assess the types of incentives, if any, are being offered to prospective subjects. Monetary and non-monetary incentives (e.g., access to services or programs) can create undue influence on a potential subject's decision about research participation. IRBs must ensure that the clinical trial website makes clear that participation in a trial is voluntary, and that incentives for participation are not so great that they compromise a prospective subject's assessment of the risks or affect the voluntariness of his or her choices.

Some clinical trial websites ask viewers to answer questions regarding eligibility for a specific clinical trial. If identifiable private information is collected via the clinical trial website, the IRB should review plans for protecting the confidentiality of that information. The IRB should ensure that the website clearly explains how identifiable private information might be used.

Informed consent must be obtained for the collection of any information about the respondent unless the IRB has determined that the informed consent requirement can be waived. There are only two circumstances under which the regulations give IRBs authority to waive the requirements for obtaining informed consent.

The first waiver authority is applicable only to research activities designed to study certain aspects of state or local public benefit or service programs; the conditions under which this waiver may be authorized by an IRB are detailed at 45 CFR 46.116(c).

The second waiver authority is described in the HHS regulations at 45 CFR 46.116(d) as follows:

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) the research involves no more than minimal risk to the subjects;
- (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) the research could not practicably be carried out without the waiver or alteration; and
- (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(Note that research involving children as subjects requires parental permission and child assent unless waived (46.408).)

When Is IRB Review of Clinical Trial Websites Not Required?

Clinical trial websites that provide *only* directory listings with basic descriptive information about clinical trials in general (as listed above) do not need to be reviewed by an IRB. Examples of clinical trial listing services that do not need IRB review and approval include the National Institutes of Health (NIH) [ClinicalTrials.gov](https://clinicaltrials.gov) website, the NIH National Cancer Institute's cancer clinical trials listing ([Physician Data Query \[PDQ\]](https://www.cancer.gov/physician_data_query)), and the government-sponsored [AIDS Clinical Trials Information Service \(ACTIS\)](https://www.actis.gov).

If you have specific questions about how to apply this guidance, please contact OHRP by phone at (866) 447-4777 (toll-free within the U.S.) or (240) 453-6900, or by e-mail at ohrp@hhs.gov.