Screening and Recruitment

There is no requirement to consent subjects in order to record identifiable private information for the purposes of screening, recruiting, and determining the eligibility of prospective subjects for a research study. This exception also applies to legally authorized representatives providing such information for a prospective subject. The recruitment and screening procedures for a research study should be outlined in the protocol when the study is submitted for IRB review. The IRB should determine that there are adequate privacy and confidentiality safeguards in place for these activities when reviewing the study protocol.

Requirements for Informed Consent for Screening, Recruiting, or Determining the Eligibility of Subjects (45 CFR 46.116(g))

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions is met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

If the information or biospecimens used for the purpose of screening, recruiting, or determining the eligibility of prospective subjects include protected health information (PHI), the investigators must obtain written HIPAA Authorization from all participants in the research study *prior to the use or disclosure of the PHI for any research-related purpose*, unless the IRB has issued a waiver or alteration.

This exception from obtaining informed consent does not apply to screening procedures that include creating/obtaining new information through means other than oral or written communication with, or obtaining new biospecimens (e.g. blood, stool, saliva samples) from, the subject as part of the research. Obtaining information or using stored biospecimens for reasons other than establishing eligibility requires prior consent.

Recruitment by Physicians

Under privacy laws, physicians may talk directly to their own patients about recruitment into a research study. If the physician is not the investigator, the recruiting physician needs an authorization to release any protected health information about the patient to the researcher.

The investigator may rely on the authorization to contact the patient about recruitment. A second authorization is needed for actual participation in the research study.

Physicians may not be paid for recruiting subjects. They may be compensated for other research-related activities. Such compensation must be commensurate with the amount of effort.

Recruitment by investigators

The recruitment of subjects, which is considered the start of the informed consent process, and the feasibility of recruiting must be considered and planned before initiation of a study and must continue throughout the study. For this reason, the IRB must review the methods, materials, procedures, and tools used to recruit potential research subjects before they are implemented.

Some of the more commonly used tools of recruitment include direct advertising (flyers, posters, press releases, brochures), media advertisement (newspaper, TV, radio, Web sites), recruitment letters, review of medical charts and computerized databases, and presentations at community meeting places. IRB review and approval is necessary to ensure that the information related to recruitment is not misleading to subjects, coercive, and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the protocol and the informed consent document.

If the investigator is an employee of the covered entity, he may review medical records to obtain a list of potential eligible subjects if this process is outlined in the protocol and has received IRB review and approval. In most cases, recruitment using this method would then involve the patients' physician contacting the potential subjects directly. The IRB will review such recruitment strategies on a case-by-case basis to ascertain sensitivity of the information involved, risk to patient privacy, possibility of coercion, and practicality of using such a method.

Any amendment to existing recruitment methods or implementation of new recruitment methods after study approval must be reviewed and approved by the IRB.

Using records or PHI to determine if a study is feasible

An investigator wishing to access PHI and/or medical records to determine the feasibility of a research study should submit a Representation of Activities Preparatory to Research form to the Woman's Hospital Research Center for IRB review. Please refer to the Review of Data Preparatory to Research policy for guidance on this submission process.

Recruitment by phone

The first contact prospective subjects make is often with a research assistant or coordinator via phone to provide information about the specific study. The study coordinator does not have to

follow a written script; the conversation should be informative and also answer any questions from the prospective subject with the consent form serving as a guide for the discussion. The IRB must have assurance that any information collected about prospective subjects will be appropriately handled.

This conversation may lead to screening for eligibility. Screening individuals to obtain and record information to determine eligibility involves obtaining identifiable private information and is considered human subjects research subject to 45CFR46. The IRB may approve the screening procedures for the study without obtaining prior informed consent of the prospective subject only if the solicited information is limited to the minimum necessary for determining eligibility and if the procedures are limited to:

a). obtaining information through oral or written communication with the prospective subject (or legally-authorized representative), or

b). obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

Broadcasts

When advertisements are to be taped for broadcast, the IRB must review and approve the final audio/video tape. The IRB can review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate content. The review of a taped message prepared from IRB-approved text may be accomplished through expedited review procedures.

New advertisements after IRB approval of research

If an investigator decides to begin advertising for subjects after the study has received IRB approval, the advertisement shall be considered as an amendment to the protocol. This is usually considered a minor amendment and may be submitted for expedited review.

For studies involving investigative agents

Advertisements for recruitment into investigational drug or device studies should not use such terms as “new drug”, “new medication” or “new device”. The test article must be described as investigational.

Phrases as “receive a new drug, treatment or device” imply that all or some subjects will be given newly-approved products of proven safety, efficacy and/or benefit. Describing the investigational agent as “new” is considered misleading. When the research involves investigational drugs and/or devices, no claims should be made that the test article is safe or effective for the purposes under investigation, or that the test article is in any way equivalent or superior to any other drug, biologic or device. Such representation would not only be misleading, but would also be a

violation of the FDA regulations at 21CFR312.7(a) concerning the promotion of investigational drugs.

Internet recruiting

For Internet recruitment sites, IRB review and approval is required. All clinical trials must also be registered on clinicaltrials.gov.