

Guidance and Procedures Number: 71

Title: Media Interviews

Date of Last Revision: July 5, 2007

I. Introduction

Federal regulations require the IRBs to ensure that adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data are in place. The research team and the IRB share the responsibility for ensuring that subject privacy and the confidentiality of subject data are maintained. In addition, investigators are required to seek voluntary, written informed consent from potential subjects. Therefore, the investigators and the IRB must ensure that any disclosure of subject information, to media outlets or others, is in accordance with the assurances provided to the subjects during the research informed consent process.

II. Media Interviews

Investigators may choose media interviews of subjects participating in a given study as a tool to 1) disseminate information about the research study to the general public or 2) recruit additional subjects.

Subjects should not be required to participate in a media interview as a condition for participation in the research study. Rather, subject selection should be based only on those factors that most effectively and soundly address the research problem. Therefore, the request and consent for participation in a given research study must be separate and apart from any request and consent for participation in a media interview.

While each individual research project must receive prospective IRB approval before an investigator may initiate contact with potential subjects, the UCLA IRB also prospectively reviews and approves each media interview request individually in order to ensure that 1) recruitment for participation in a media interview is free of coercion; 2) subjects are provided with sufficient information regarding their participation in a media interview; and 3) privacy and confidentiality of subjects are in accordance with the assurances provided to them.

IRB review and approval is therefore required for all proposals to involve human subjects in a media interview.

The IRB does not review proposed interviews for compliance with the terms of agreements between the University and funding agencies or product manufacturers. The investigator is responsible for compliance with such terms (e.g., protection of proprietary information).

III. Materials to be Reviewed

Investigators who intend to invite subjects to participate in a media interview must submit an application to the UCLA OPRS to obtain UCLA IRB review and approval for the involvement of research subject(s) in media interviews individually for each media outlet.

The application should be in the form of a modification to the currently approved protocol and must include the following:

- A. Cover letter to describe the following components of the media interview:
 1. identify the media outlet
 2. describe the type of interview, ex. audio-taped interview, audio- and video-taped interview, video-tape of a research procedure, etc.
 3. indicate whether the interview is subject-initiated or researcher-initiated
 4. any other relevant information

- B. Completed first page of the Application to Involve Human Subjects in Research signed by the Principal Investigator

- C. For subject-initiated interview:
 1. Interview-specific consent to participate in a media interview
 2. Investigators must provide the following assurances regarding subject involvement in a media interview
 - Investigator has discussed the proposed interview with the subject by phone, or at a regularly scheduled visit;
 - Investigator will provide the subject with contact information for UCLA Media Relations who can further discuss the media request(s), explain the interview process, and answer any questions that the subject may have.
 - Investigator will provide the subject with a copy of the media interview consent form to review, allowing him/her sufficient time to review the form;
 - Investigator will assure the subject that his or her decision to participate in the media interview will in no way affect their participation in the study or treatment;
 - The investigator will obtain written consent for the media interview from the subject, .
 - Investigator has obtained the subject's consent for participation in the research study using the IRB-approved consent process and document.

- D. For researcher-initiated interview:
 1. Interview-specific consent to participate in a media interview
 2. Investigators must provide the following assurances regarding subject involvement in media interview
 - Investigator will inform the subject by phone, or at a regularly scheduled visit, of the investigator's and the media's interest in conducting interviews;
 - Investigator will provide the subject with contact information for UCLA Media Relations who can further discuss the media request(s), explain the interview process, and answer any questions that the subject may have.

- Investigator will provide the subject with a copy of the media interview consent form to review, allowing him/her sufficient time to review the form;
 - Investigator will assure the subject that his or her decision to participate in the media interview will in no way affect their participation in the study or their treatment;
 - Once the investigator has obtained written consent from interested subjects, UCLA Media Relations will provide the subjects with the appropriate contact information for the media representative.
3. Interview-specific media interview oral contact and consent script

IV. Process of Media Interview

A. For subject-initiated interview

Once a subject approaches the researcher with a media outlet indicating his/her interest in participating in a media interview regarding the research study, the investigator must 1) assess the appropriateness of the request; 2) if the request is deemed appropriate, submit a request for approval to the IRB; 3) once the IRB approval has been received, obtain informed consent from the subject using the IRB-approved informed consent form for the media interview.

B. For researcher-initiated interview

Once the researcher has determined the need for a media interview, and identified a media outlet, the investigator must 1) submit a request for approval to the IRB; 2) once the IRB approval has been received, approach the subject(s) to request his/her participation in the media interview using the IRB approved media interview consent script; 3) once the subject has decided that he/she is interested in participating in the media interview, obtain informed consent from the subject using the IRB-approved informed consent form for the media interview.

Regulations:

21 CFR 50.20
21 CFR 56.111
45 CFR 46.111
45 CFR 46.116