Recruitment Guidelines for Using Participant Testimonials

OVERVIEW

It is becoming more common for researchers and study sponsors to use testimonials from persons who are currently participating in or have previously participated in a research study involving humans for recruiting purposes. Participant testimonials may be presented in person, such as during a health fair, posted online, and/or distributed on TV and radio.

When using testimonials for recruitment purposes, accurate information must be provided to the targeted audience for potential participants to decide whether to obtain additional information about the research study. The content, tone, and format of the testimonials are all important considerations. The testimonial must be informative, explanatory, and contain useful information about the study.

The following is provided as a guide as to what is required, what to include in, and what to exclude from the testimonial document(s) submitted to the IRB.

BACKGROUND

The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of humans participating in research.

Regulatory bodies consider direct advertising for study participants to be the start of the informed consent and participant selection process. USC requires all direct recruitment tools intended to be seen or heard by prospective participants to be approved by the IRB **prior** to use for non-exempt (expedited and full board) applications. A script of the audio or video presentation must be provided to the IRB.

Decisions on whether the final taped audio/video recruitment materials require review by the IRB will be made on a case-by-case basis.

Prior to releasing testimonials, USC's Media Relations should be consulted. The contact information for USC's Media Relations office is at the end of this document.

If Protected Health Information (PHI) is accessed/utilized for participant testimonials, compliance with the Health Insurance Portability and Accountability Act (HIPAA) may be required. Investigators should contact the Office of Culture, Ethics and Compliance (OCE&C) for guidance. The contact information for OCE&C is at the end of this document.

Recruitment of participants to give testimonials and recruitment of potential participants must be equitable and include racial, ethnic, educational, socioeconomic and gender identity diversity appropriate to the condition that is studied. All recruitment methods must respect rights to privacy and confidentiality of all prospective participants. Only USC email addresses can be used in recruitment tools.

NOTE: Regardless of the risk determination or approval type all recruitment guidelines should be adhered to.

The radio/television/video recruitment script must be informative, explanatory, and contain useful information about the study. The language in the recruitment tool should reflect the language in the approved protocol and Informed Consent Form or Information Sheet and may include the following:

- Name and contact information of the investigator and facility
  - Including university affiliation and/or department
  - USC email address must be utilized
- Accurate description of the research purpose
- A statement that participation in the study is voluntary
- Condition under study and/or purpose of the research
- Eligibility criteria
- Basic overview of study procedures, including the time commitments required
- Location of the research
- Compensation (should not stand out from the surrounding text)

USE OF PARTICIPANTS IN RECRUITMENT

Asking research participants to engage in testimonials requires careful consideration by the researcher due to the power dynamic that exists between researchers and participants. Participants may feel obligated to provide testimony because of their study participation and belief that they owe something to the researcher.

The testimonial must be informative, explanatory, and contain useful information about the study. The language in the recruitment tool should reflect the language in the approved protocol and Informed Consent Form or Information Sheet.

The recruitment section of the study protocol document must clearly describe the testimonial including:

- Description of attestants (participants, actors, etc.)
  - Criteria for identifying potential attestants
  - If research participant, instructions for withdrawal of testimony
  - When the invitation to attestants will be presented to them
- Instructions for attestant(s), including language restrictions
- Anticipated length of testimony
- Whether/which research data will be shared with event holders
- Website address where the testimonial will be placed, if applicable
- Description of the event/organizer, if applicable

The consent document(s) must:

- Fully describe the use of testimonies, including
  - A description of event/organizer/platform
  - The anticipated length of testimony
- Indicate whether research data will be shared with event holders
- Include a statement that participation in testimonies is voluntary and participation in the study is not contingent on providing testimonials
- Include a statement that participants can change their mind at any time
- Include instructions of what can and cannot be said
- Include instructions for withdrawing testimony
- Include two checkboxes in the signature section
  - I agree to participate in the testimony
  - I do not agree to participate in the testimony

Media Relations Contact

Emily Gersema
Executive Director
Media Relations
Email: gersema@usc.edu
Phone: 213 712 3168

Office of Culture, Ethics and Compliance Contact

Phone: 213 740 8258
Email: compliance@usc.edu

Credits

University of Kentucky
University of Virginia
FDA
OHRP