Media Organizations – Researcher involvement

Modified: September 2019

Background:

FDA has issued guidelines on the interaction between researchers and the media: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects. The guideline is meant to avoid any possible coercion to future potential study subjects and to discourage the release of research data that has not been scientifically scrutinized by the research community. The following guideline is consistent with those principles and has been agreed upon by the UF IRB, the UF General Counsel’s office and the UFHealth Privacy Office.

1. **Q: Is there a difference in interactions with the media before or after the publication of a research project?**

   Yes. Once a research effort has been published under peer review, there are no restrictions by the FDA or the IRB. However, interactions with outside media groups are still subject to applicable UF Health policies. See e.g. UF Health Shands Core Policy Number CP03.041.

2. **Q: Is there a difference in interactions with the media while you are still actively recruiting for a research project?**

   Yes. Any discussion with the media regarding a study in active recruitment, either in written format or video, must be reviewed and approved by the IRB first. If the interaction involves a non-UF media group and is a live or taped interview, guidelines for such an interview are below under item #3.

3. **Q: While the research is still “active”, what are the general guidelines regarding the interaction with any media or media publication or press release?**

   a) No claims should be made, either explicitly or implicitly, that the drug, biologic, device or procedure is:
      i) Safe or effective for the purposes under investigation, or
      ii) That the test article or procedure is known to be equivalent or superior to any other drug, biologic or device.
   
   b) Media interviews, etc. should be coordinated with the UF Health Communications department https://ufhealth.org/uf-health-communications.
      i) All interviews or media print should follow research advertisement rules:
      ii) Advertising for recruitment into investigational drug, biologic, device or procedure studies should not use terms such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.
      iii) There should be no promise of "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation.
      iv) May state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type.
      v) Should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements.
the name and address of the clinical investigator and/or research facility;
(2) the condition under study and/or the purpose of the research;
(3) in summary form, the criteria that will be used to determine eligibility for the study;
(4) a brief list of participation benefits, if any (e.g., a no-cost health examination); and risks
(5) the time or other commitment required of the subjects; and
(6) the location of the research and the person or office to contact for further information.

4. Q: Can you use current or former study subjects in the media interactions if the study is still “active”?

No. Both federal guidelines and UF guidelines do not allow the use of current or past study subjects to be involved in any media event for an active study. This includes interviews (neither video or in writing) or pictures of any such study subjects. This is considered potentially coercive and could entice others to enroll in a study they would not otherwise agree to.