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Recruitment Material

The DHHS regulation 45 CFR 46.109(b) requires IRBs to ensure that information given to subjects as part of the informed consent process meets the requirements specified in the regulations 45 CFR 46.116. Recruitment materials are often the earliest component of the informed consent process and therefore need to be approved by the IRB.

University Hospitals IRB requires the approval of all television, radio, videotape, print advertisements (posters, flyers, and handouts) e-mail solicitations, Internet websites, and other recruitment methods and materials intended for the recruitment of prospective research subjects PRIOR to their use.

Print advertisements may only be posted in designated approved on-campus and off-campus areas. Such locations **DO NOT** include restrooms or elevators. Please ensure that when submitting recruitment materials, a description of how the material will be used, distributed, and/or posted is included. In addition, all print materials must possess the IRB Advertisement Approval Stamp. Please contact the [Office of Research Compliance](#) for assistance.

Privacy versus Confidentiality

In approving protocols, the IRB are required to ensure that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (45 CFR 46.111(7)). The Federal regulations distinguish the terms privacy and confidentiality, and thus understanding the definition is important to ensure that these regulatory requirements are appropriately addressed in the research protocol. Privacy relates to people, whereas confidentiality relates to data.

Privacy pertains to an individual's wish to control the access of information about them to others, i.e., having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. The research protocol should describe the strategies to be used to protect a subject's privacy including how information about a person will be accessed and who it will be shared with.

Confidentiality pertains to the methods used to ensure that information obtained from researchers about subjects is not improperly divulged. The research protocol should describe the strategies used to maintain the confidentiality of data. Routine practices should include: substituting codes for identifiers; removing face sheets and other documents that may contain identifiers; limiting access to identified data; impressing on research staff the importance of confidentiality; and storing research records in locked cabinets.

Helpful Tip: Who can be a Principal Investigator?

Teaching is a significant part of the UHCMC mission. The responsible conduct of research is an important part of this teaching process. Often, students, residents, fellows, and other trainees must conduct research as a part of their training. It is important to note that research conducted by trainees can and should identify the trainee as the principal investigators for a protocol if s/he is the primary individual responsible for the conduct of the research. When an individual trainee is not a full time member of the UH medical staff or does not have a faculty appointment at Case, then a responsible investigator with such credentials must be identified in order to utilize a Case / UH affiliated IRB. Both the principal investigator and responsible investigator must be certified in Human Subjects' Protections.