MULTIMEDIA RECORDINGS

Definitions

These guidelines apply to human research studies that involve the audio, video, photographic, or any other recording of research subjects.

Description

Using multimedia tools to record the image and/or voice of an individual creates a record that requires careful handling and storage, particularly if the content of media or the purpose of the research may be considered sensitive.

As with all research procedures, the dignity of human subjects must be respected, and the wishes of the subject must govern. Therefore, only what is necessary for the purpose of the study should be recorded, and participants should be given the option to decline being recorded (i.e., through alternate recording procedures, by refusing to participate in the research, etc.).

Research subjects must be informed prospectively that such recording will occur, and be provided with information about the purposes, procedures, storage, confidentiality, security, and future use of the resulting record.

There are several points that should be considered during the design phase of the study when you intend to use multimedia recordings. Some of these points include:

- The type of recording that will be utilized;
- Specific identifiers that will be recorded (e.g., partial facial features, full facial features, participant's name, participant's medical information, participant's voice, etc.);
- The purpose(s) of the media and how the media relates to the achievement of the study objectives;
- Whether compensation will be offered to the participants for allowing themselves to be recorded for research purposes, and if so, whether the compensation may be considered coercive;
- Which members of the study team will have access to the recording(s), and at what level of identifiability the recording will be when the investigator is given access;
- Mechanisms in place to respect the privacy of the person(s) being recorded;
- A clear description of where the recordings will be stored, duration of storage, and when/how they will be destroyed, or that recording(s) will be kept indefinitely;
- Procedures for controlling access to, and use of the media;
- Future use(s) of the recording(s), including public, educational, and/or commercial purposes, analysis by the research team, or future unspecified use;

Details about these points should be outlined in the New Study Application, and clearly stated in the Consent Document.

Non-Optional Recording

If the multimedia is an essential part of the research study and not an optional procedure, a separate informed consent document is not required. A sub-section may be included in the consent document addressing the above points which states that if the participant does not want to be recorded, he/she should not participate in the research.

Optional Recording

If the recording is optional (based on participant preference), a specific statement must be included stating that participation in the research is not contingent upon the agreement to be recorded. A set of checkboxes/initial lines should be included to allow the participant to indicate their choice, or a separate signature line on the informed consent document labeled specifically for permission to record should also be included.

Identifiability
If the contents of the media are identifiable (e.g. faces, voices, etc.), participants in the conversation or situation must give their explicit consent for any public use of tapes or photos (e.g. use in the classroom, use in a public presentation of research results, etc.). The informed consent document or a separate release form must be used to obtain a participant's explicit consent for the public use of his/her media. If measures will be taken to prevent identifiability (e.g. blurred faces, voice distortion, etc.), these measures must be described.

Third Parties
Measures should be taken to ensure that third parties who are not the focus of the research are not included in the recordings. If inclusion of these parties cannot be avoided, they should be informed of the basics of the research (purpose, procedures, etc.) and should give their consent to be recorded, with the understanding that their dialogue will not be transcribed or used for the research. This process may be conducted somewhat informally, but should be documented in the research file, and the consent process must be outlined in the application. The IRB may not necessarily require formal consent if their data will not be used for the research, but this will be determined on a case-by-case basis.

Patient Photography
The use of patient photography, videotaping, digital imaging, and other visual recordings during patient care has become commonplace. For example, scopes and surgical equipment allow for the recording of surgical procedures. HIPAA requires patient authorization for the release of protected health information, including patient photography, for purposes beyond treatment, payment, and healthcare operations. Therefore, if patient photographs, videotapes, digital or other images, are used in the research, the IRB must approve the collection, use and/or release of patient photography. As part of the Authorization for Use of Your Protected Health Information section, the investigator should list (as applicable) photographs, videos, digital or other images.

VA Research
The VA Directive 1200.05 states that informed consent for research must include information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how the recordings will be used for the research, and whether the recordings will be disclosed outside of the VA. Informed consent to take a photograph, video, and/or audio recording cannot be waived by the IRB. HIPAA Authorization is necessary if the images/recordings will be disclosed outside the VA.

Points to Address

New Study Application:	1. **Data Monitoring Plan page (5), question 3:** Answer the question, "Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?" If yes, describe the recordings and what the plan is after the recordings are made.
Consent Document:	1. The informed consent should must include information describing any photographs, video, and/or audio recordings that will be used for the research. 2. If patient photographs, video, and/or audio recordings are used in the research, the authorization section should describe the use and disclosure of the recordings.

References & Links

VA Directive 1200.05 *https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171*