**SCOPE:** This guidance applies to all human subject’s research studies which propose to include the audio, video, photographic, digital or any other recording(s) (hereafter referred to as recording) of human subjects.

**BACKGROUND:**

Massachusetts law pertaining to recording requires consent to the use of any recording devices (e.g., microphone, video recorder, camera, or telephone, etc.). Although the Office of Human Research Protections (OHRP) regulations do not specifically address recording, the recording of an individual’s voice or image may create an identifiable record, which requires unique handling and storage, especially if the recorded content could be considered sensitive. Only recordings which are essential for the purpose of the study should be recorded. Subjects must be informed, prospectively, of planned recordings and be provided with information about the storage, confidentiality, future use of the recorded result, and potential risks (e.g., breach of confidentiality, damage to reputation, legal ramifications).

**ELEMENTS FOR CONSIDERATION:**

If a research protocol proposes to include the recording of human subjects, within the proposal and informed consent form, the Principal Investigator must address the following elements for consideration:

- Identify the type of recording that will be utilized, (i.e.: audio/video/photographic/digital).
- Identify the specific identifiers to be recorded, (i.e.: partial or full facial features, subject’s name, etc.).
- Identify the people who will have access to the saved recording(s).
- Detail the mechanisms in place to protect the privacy/confidentiality of the person(s) being recorded.
- Clarify when the recording(s) will be destroyed or if recording(s) will be kept indefinitely.
- Detail the study’s planned use(s) of the recording(s) and analysis(es) to be completed by the research team:
  - Archiving Recordings for Future Research must include a justification for the indefinite archival and provide participants with the option and instructions to withdraw recorded data.
  - Archiving Recordings for Secondary Data Analysis (SDA) must clarify what potential secondary analyses may involve. Note, SDA’s must be submitted as an amendment or as a new protocol depending on the scope. Analyses which differ significantly from the purpose of the original study or which place participants at an increased risk are subject to the IRB requirement that informed consent obtained from participants for the SDA.
  - Educational Use(s) must clarify how recording will be used and with what population.
  - Commercial Use(s) must clarify if compensation will be offered for recording.
- Clarify if compensation will be offered to subjects for allowing themselves to be recorded.
- Clarify if recording(s) is required or optional:
  - If the recording is an integral part of the research and not an optional procedure, documentation of the considerations listed above, must be included within the informed consent form.
  - If the recording is not required as part of the research procedures, then the consent document must include a specific statement indicating that participation in the research study is not contingent upon agreeing to be recorded. The consent form should include a separate section after the statement of consent, labeled specifically for permission to be recorded, address considerations listed above, and an additional corresponding signature line. Alternatively, a consent addendum can be generated for use (see attached sample).

**NOTE:** All consent forms must be reviewed and approved by the IRB prior to implementation.

Adapted with gratitude from the following references:


**IRB SAMPLE ADDENDUM CONSENT FORM FOR OPTIONAL RECORDING**

**UMASS DARTMOUTH IRB GUIDANCE ON RECORDINGS**

**EFFECTIVE DATE:** June 30th, 2023.