COLUMBIA UNIVERSITY/COLUMBIA UNIVERSITY MEDICAL CENTER INSTITUTIONAL REVIEW BOARD POLICY/PROCEDURE

AUDIO/VIDEO/PHOTOGRAPHIC RECORDING OF HUMAN SUBJECTS

SCOPE OF POLICY:

This policy applies to all human research studies that involve the audio, video, photographic, or any other recording (hereafter referred to as recording) of research subjects.

EFFECTIVE DATE: APRIL 12, 2005

BACKGROUND:

Recording the voice and/or image of an individual creates a type of record that requires unique handling and storage, particularly if the content may be considered sensitive. As with all research procedures, the dignity of human subjects should be respected. Therefore, only what is necessary for the purpose of the study should be recorded. Research subjects must be informed prospectively that such recording will occur, and be provided with information about the storage, confidentiality, and future use of the resulting tape.

If a research protocol involves the recording of research subjects, the Principal Investigator must include the following elements for consideration, in his/her protocol and informed consent form for submission to and review by the IRB:

Elements for consideration:

- Type of recording that will be utilized;
- Specific identifiers that will be recorded, e.g., partial facial features, full facial features, subject's name;
- People who will have access to the recording(s);
- Mechanisms in place to protect the confidentiality of the person(s) being recorded;
- Clear indication of when the recording(s) will be destroyed or that recording(s) will be kept indefinitely;
- Use(s) of the recording(s), including educational or commercial purposes, analysis by the research team; or future unspecified use;
- Compensation, if any, to subjects for allowing themselves to be taped.

If the taping is an integral part of the research and not an optional procedure, a separate informed consent document is not required. However, documentation of the considerations listed above must be included within the body of the informed consent document for the overall study. It is important that this information be clearly stated, preferably preceded by a heading, so that it is clear to the subject that a recording will be made.

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. A separate consent signature for permission to record will be necessary. This permission can be in the form of a consent addendum (see attached sample), which includes the considerations listed above, or a separate signature line on the informed consent document labeled specifically for permission to tape. If a separate signature line is used, the considerations listed above must be included within the body of the informed consent document.

The consent addendum must be reviewed and approved by the IRB prior to implementation. This approval will be documented in accordance with Columbia University/Columbia University Medical Center approval stamp guidelines.

Attached is a sample audio/videotape addendum for consent forms.

COLUMBIA UNIVERSITY/COLUMBIA UNIVERSITY MEDICAL CENTER IRB AUDIO/VIDEOTAPE ADDENDUM TO CONSENT FORM (SAMPLE)

(This form is provided to the investigator as a guide. Instructions and sample language are denoted in boldfaced italics within the brackets []).

You have already agreed to participate in a research study entitled: [Insert Study Title] conducted by [Insert Principal Investigator]. We are asking for your permission to allow us to [include optional procedure such as audiotape (sound), videotape (picture), or both audio and videotape] as part of that research study. You do not have to agree to be recorded in order to participate in the main part of the study.

The recording(s) will be used for [include purpose of recording; e.g., sample language may include: analysis by the research team; possible use as a teaching tool to those who are

not members of the research staff (i.e. for educational purposes); commercial purposes. If the tapes will be used for commercial purposes, the consent must specifically state whether or not the subject would be compensated for this use.]

The recording(s) will include [indicate whether the subjects name or any other identifier will be recorded. If videotaping will be utilized, indicate the extent to which subject's identity would be masked (e.g., Facial features partially blocked out; recording will not include facial pictures; recording will include full facial pictures.)]

The recording(s) will be stored [include measures taken to protect subjects privacy. For example: in a locked file cabinet with no link to subjects' identity; in a locked file cabinet and linked with a code to subjects' identity; in a locked file cabinet and labeled with subjects' name or other identifiable information] and will be [indicate the length of time the recording(s) will be retained, e.g. destroyed upon completion of the study procedures; destroyed upon publication of study results; retained indefinitely.]

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

[Signature block, which should reflect the signature block on the main consent form for the study.]