IRB approval is required to make audio/video recordings or take photographs of research subjects. These procedures must be described in the HawkIRB application and in the Informed Consent Document (ICD). If the audio/video/photos will be used for non-research purposes, such as educational, classroom, training, demonstration, advertising, promotion, or publication, researchers document the agreement for this on a separate release form from the UI Office of the General Counsel and UI Health Care Marketing and Communications.

HawkIRB

Describe plans to make audio/video recordings and take photographs of research subjects in the following sections of the HawkIRB application:

Plans to Make Audio/Video/Photos

**VII.E.5** Does this project involve creating any audiotapes, videotapes, or photographs?
- Yes
- No

“Yes” populates language in the ICD to describe the recording(s) to subjects.

Procedures for Audio/Video/Photos

**VII.E.6** Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

**DESCRIBE:**
- What subjects will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- The time commitment for the subject for individual visits/procedures
- Long-term followup and how it occurs

The IRB application and ICD should be specific about:

- **What** recordings/images will be collected and
- **How** they will be used
- Whether audio/video/photos are **optional or mandatory**. If optional, how the research team will honor the wishes of the subjects who decline to be recorded or photographed.
• If audio/video/photos will be used for non-research purposes, **describe procedures** for presenting subjects with a separate release form (See “Non-Research Use of Audio/Video/Photos” below).

• When applicable, **describe procedures** for informing non-subjects who might be captured during audio and video recording or photographs of enrolled subjects.

**Privacy Protections**

What are you doing to protect the privacy interests of the subjects?

Privacy protections protect the person from or about whom information, recordings or images are taken. Researchers protect subject privacy by limiting the amount and type of recordings/images to what is necessary to answer the research question. The following are some examples of privacy protections for these materials:

1) In video recordings, mask identifying facial features or other identifiers that are not necessary for the research analysis.

2) Allow subjects a choice about audio and video taping and photographs for research purposes.

3) Implement plans to protect people not enrolled in the study who might be incidentally captured in research audio/video/photo.

**Confidentiality Protections**

How will information/data be collected and stored for this study (check all that apply):

- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.)
  Describe the security methods that will be used when hard copy records are being transported, transferred, or stored and the specific location for storage of these records.

- Electronic records (computer files, electronic databases, etc.)
  Describe in detail the methods/systems used to collect and store these data and the security methods that will be used when electronic records are being transported, transferred or stored. This should include both logical (IT) and physical protections in place for any computer systems used.

Confidentiality protections protect the data once it is gathered. For paper and electronic records related to the audio/video/photos, describe:

- Where/how transcripts, images and recordings will be stored and protected.
- Plans to label them with an ID code, mask identifying features, and/or destroy them after transcription or data analysis.
  - Destroying audio/video/photos immediately following transcription is one way to protect confidentiality, but it is not required by the IRB if the application (Section XII) and ICD describe storage of recordings/photos for future research use.
• If the researcher describes destroying the recordings/photos as a confidentiality protection, then the researcher must follow through with those plans or obtain and document subject permission for storage and future use.

Researchers might also need privacy and confidentiality protections for people who are not enrolled subjects but are captured in the audio/video/photos. These protections should be specifically described in Section X.1 and Section X.4.

Future Use of Audio/Video/Photos

If contribution is mandatory,

• State this in the ICD. Subject signature indicates agreement to mandatory audio/video/photos. Delete optional agreement boxes from the ICD template.

If contribution is optional,

• Include the optional agreement (Yes/No) box in the ICD for the subject to indicate agreement or decline this storage for future use.

Informed Consent Document (ICD) Template

The ICD template in HawkIRB is a “smart document.” The way a researcher answers certain questions in HawkIRB adds template language to the ICD template. A “Yes” response to Section VII.E.5 adds the following template language:

Audio Recording/Video Recording/Photographs

One aspect of this study involves making [audio recordings / video recordings/photographs] of you. [Then describe why the recordings/photos are being made, who has access to them, and if or when they will be destroyed. If audio recording or video recording or photo is optional, (i.e., you would still enroll the subject in the study if s/he refused that aspect of the study), explain that the subject can still be in the study without being recorded or photographed, and add this statement:]

[ ] Yes [ ] No I give you permission to make [audio recordings/ video recordings/ photographs] of me during this study.

• Edit the content of the sections that are in bold and brackets to describe the procedures for the research study.
• If there is only audio recording, remove references to video recording and photographs
• Determine if the recordings or photos are necessary for the conduct of the study (for example, the researcher needs to transcribe a recorded interview)
  o If they are mandatory, delete the optional agreement boxes.
  o If subjects have a choice, keep the Yes/No optional agreement boxes.

Non-Research Use of Audio/Video/Photos
The signature on a research study ICD documents agreement from the subject to participate in research procedures. This document should not be used to grant permission for non-research activities. If a researcher wants to use audiotapes, videotapes or photographs for a non-research purpose (such as in a classroom for educational purposes, in promotional materials for a department or program, or in a professional publication or poster), they must document subject agreement on a separate release template. Request the appropriate template from the Human Subjects Office (irb@uiowa.edu or 319-335-6564) or directly from the University of Iowa Office of the General Counsel or from UI Health Care (UIHC) Marketing and Communications.

*Additional guidance on privacy and confidentiality can be found on the Data Security, Storage and Transmission Handout.