Guidance for Audio/Videotaping and Photographs of Research Subjects

Institutional Review Board and Human Subjects Office

Table of Contents 1

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.

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

Indicate in Section VII.E.4 what type(s) of recordings will be made.

VII.E.4 Does this project involve creating any audiotapes, videotapes, or photographs?

- ☐ Audio
- ☑ Video
- ☐ Photograph
- ☐ None of the above

Procedures for Audio/Video/Photos

The information in Section VII.E.6 in 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.

VII.E.6 Provide a detailed description in sequential order of the study procedures *following the consent process*.

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

DO NOT cut and paste from the Consent Document. Information in this section should be in lay language. Details in this section must be consistent with the informed consent materials, other sections of the IRB application, and/or the protocol (when applicable).

Privacy Protections

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.

In section X.1, selecting yes means that the investigator is agreeing to collecting minimal information and conducting procedures in a way that protects participant privacy.

X.1 Are you implementing the following measures to protect subjects' privacy:

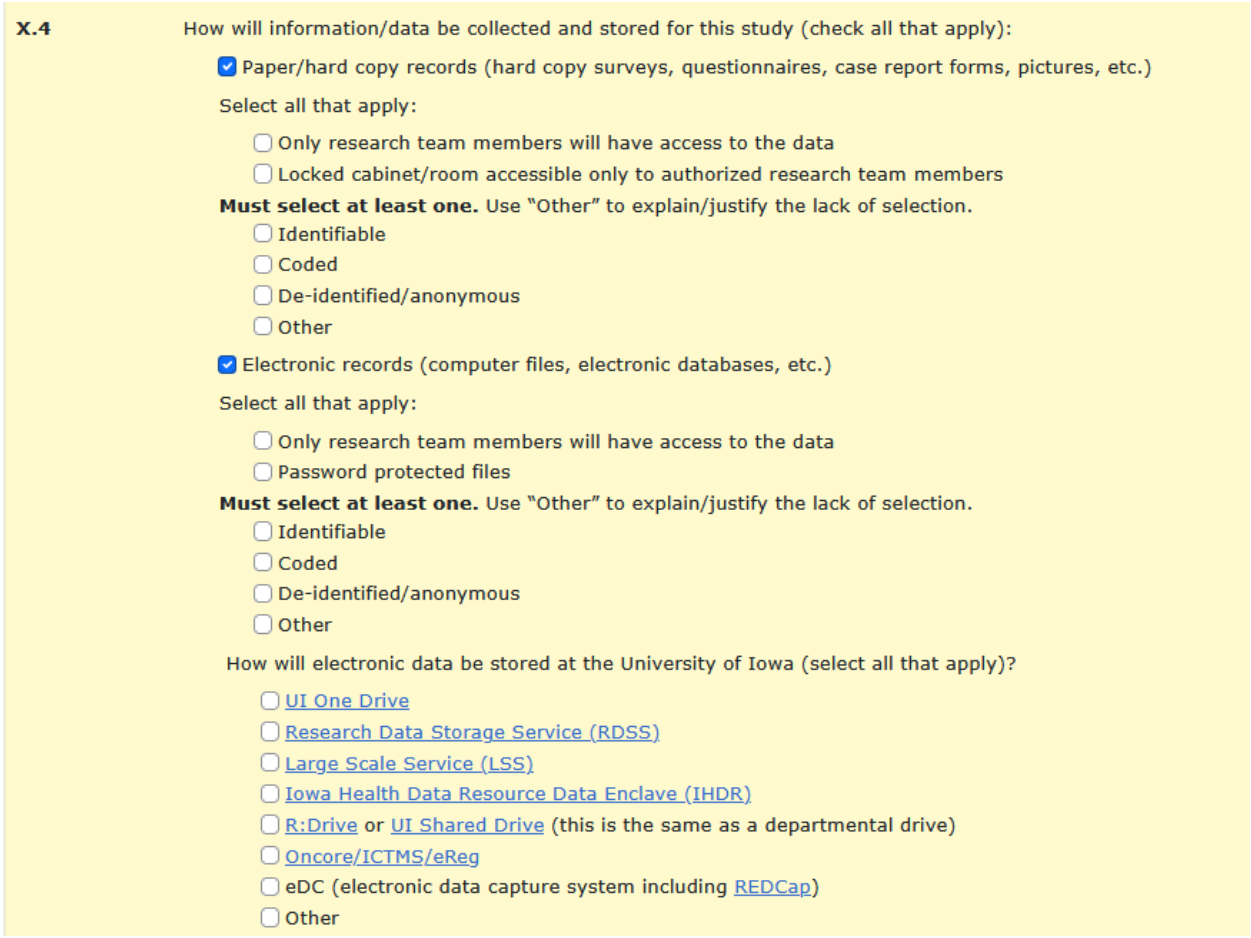
- Collecting minimal information necessary to meet the aims of the study.
- Conducting the informed consent process in a private location.
- Conduct procedures in private setting when applicable.

(●) Yes
( ) No

Confidentiality Protections

Confidentiality protections protect the data once it is gathered. Information about the steps to take to protect the confidentiality of data is provided in HawkIRB section X.4. For paper and electronic records related to the audio/video/photos, describe:

- Who will have access (i.e., research team members only).
- How the data will be secured (i.e., locked filing cabinet/office/password protected).
- If data will be identifiable, coded, deidentified/anonymous, or other (describe).
- If the data is electronic, the investigator must indicate how the electronic data is stored.



X.4 How will information/data be collected and stored for this study (check all that apply):

- [x] Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.)

Select all that apply:

- [ ] Only research team members will have access to the data
- [ ] Locked cabinet/room accessible only to authorized research team members

Must select at least one. Use "Other" to explain/justify the lack of selection.

- [ ] Identifiable
- [ ] Coded
- [ ] De-identified/anonymous
- [ ] Other

- [x] Electronic records (computer files, electronic databases, etc.)

Select all that apply:

- [ ] Only research team members will have access to the data
- [ ] Password protected files

Must select at least one. Use "Other" to explain/justify the lack of selection.

- [ ] Identifiable
- [ ] Coded
- [ ] De-identified/anonymous
- [ ] Other

How will electronic data be stored at the University of Iowa (select all that apply)?

- [ ] UI One Drive
- [ ] Research Data Storage Service (RDSS)
- [ ] Large Scale Service (LSS)
- [ ] Iowa Health Data Resource Data Enclave (IHDR)
- [ ] R:Drive or UI Shared Drive (this is the same as a departmental drive)
- [ ] Oncore/ICTMS/eReg
- [ ] eDC (electronic data capture system including REDCap)
- [ ] Other

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 VII.E.6 outlining study procedures.

VII.E.6 Provide a detailed description in sequential order of the study procedures *following the consent process*. 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
- Describe study populations separately if they will be participating in different procedures – include CONTROL population if applicable.

DO NOT cut and paste from the Consent Document. Information in this section should be in lay language. Details in this section must be consistent with the informed consent materials, other sections of the IRB application, and/or the protocol (when applicable).

Future Use of Audio/Video/Photos

Whether contribution of the audio/photo/video data for future use is mandatory or optional for future use should be Indicated in section XII.1.

XII.1 Does this project involve storing any data, tissues, or specimens for future research or data management and sharing requirements?

- (●) Yes - contribution(s) for future use is mandatory for participation in the study
- ( ) Yes - contribution(s) for future use is optional
- ( ) Yes - contribution(s) that are both mandatory and optional
- ( ) No

- Mandatory contribution should be stated in the ICD, Delete optional agreement boxes from the ICD template.
- Optional contribution will include the optional agreement (Yes/No) box in the ICD for the subject to indicate agreement or decline this storage for future use.
- Indicate in questions XII.2 through XII.4 the additional information about data storage.

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)
    - If they are mandatory, delete the optional agreement boxes.
    - 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.