

Institutional Review Board for the Protection of Human Subjects

Informed Consent General Template for HSR

General instructions – *delete before uploading to IRB application*

Informed consent is required to provide potential subjects or their legally authorized representatives with the information necessary for them to make a decision about participating in research.

Information in the consent document must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age level of the child.

Using this template for your study guide you to help ensure that you include all required elements of informed consent as outlined below-

* Regulations now require that federally-sponsored research projects contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. The key information must be presented first and must include the following:
	+ Identification of the project as a research study and that participation is voluntary
	+ Purpose of the research, duration of participation, and a description of research procedures
* Foreseeable risks or discomforts, if any
	+ Expected benefits to subjects or others, if any
	+ Alternative procedures or treatments that might benefit the subject (applies primarily to clinical research)

How to use the template:

* Text in [brackets] represents information about your study that you must add.
* A backslash indicates that you must make a selection depending on the procedures for your study (e.g., “will/will not” or “I/we”).
* Additional guidance that may/may not apply to your study is provided in boxes.
* Before you upload your consent document to the IRB portal application, delete this cover page, brackets, and boxes. The finished document should reflect what you will give to the subject.
* Use a file name for each consent document that it clearly identifies type of consent and for which subjects it is intended (e.g. child assent, parental permission, adult consent, etc.).

For questions about informed consent, please contact the IRB 315-792-3122 or irb@utica.edu

**Consent to be Part of a Research Study**

Title of the Project:

Principal Investigator: [Name, credentials, institutional affiliation]

Faculty Advisor: [Name, credentials, institutional affiliation]

**Invitation to be Part of a Research Study**

You are invited to participate in a research study. In order to participate, you must be [eligibility criteria; e.g., age, gender, language, etc.]

This study is being led by: [*Name, Credentials, Department]* at Utica University.

The co-investigator(s) for this study: *[Name, Credentials, Department]* at Utica University

TheFaculty Advisor for this study is:*[Name, Credentials, Department]* at Utica University*.*

We will describe this study to you and answer any of your questions.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

**Important Information about the Research Study**

Things you should know about this study:

* What is the study about? The study is to [briefly describe study purpose]. If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].
* What are the risks? Risks or discomforts from this research include [briefly describe].
* The study will [description of potential direct benefits to subjects – or no benefits].
* Taking part in this research project is voluntary. You don’t have to participate and you can stop at any time without penalty.

**What is the study about and why are we doing it?**

The purpose of the study is [describe the study purpose in detail, including why you are doing it].

**What will happen if you agree take part in this study?**

If you agree to take part in this study, you will be asked to [provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how)]. We expect this to take about [duration, number of interactions]. [Indicate if information collected will be linked to other data (e.g., research data, protected health information, or administrative data such as US Census data).]

For projects involving the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the type of questions that will be asked or describe the sensitive topic areas that are involved and what action can be taken to minimize discomfort – i.e. refuse to answer a question, stop participation, etc.

If applicable, include a statement about whether research results will be shared with the subject and under what conditions.

**How could you benefit from this study?**

Although you will not directly benefit from being in this study, others might benefit because [insert details]. **[OR]** You might benefit from being in this study because [insert details].

Describe any probable benefits of participation. Be sure to distinguish between a likely direct benefit (e.g., from therapeutic or intervention research) and a possible indirect benefit (e.g., reflecting on an experience may lead to a better understanding of oneself). If there are no direct benefits, indicate that there are none.

Describe the expected benefits to society or scientific knowledge: e.g., “…information from this study may benefit other people now or in the future…” or “…we hope to learn more about \_\_\_\_\_\_\_ …”

Note: Compensation, financial incentives, learning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participantare not “benefits” and should not be listed here.

**How will you be compensated for being part of the study?**

You will receive [nature and total amount of incentive/compensation] for your participation in this study. [Describe how compensation will be determined if the subject withdraws from the research before the end of the study.]

 **[OR]**

You will not receive any incentive or compensation for you participation in this study.

Indicate whether the participant will receive compensation or extra credit for being in the study. If participants will not receive any compensation, state this. If students will receive course credit for participation, ways of earning credit without participating in the research should be mentioned here.

**What risks might result from being in this study?**

There are some risks you might experience from being in this study. They are [describe specific risks, and indicate what the study team will do to minimize those risks.]

In simple, non-scientific language, describe any reasonably foreseeable risks or discomforts.

Primary risks include physical, psychological, or informational risks. For informational risks (e.g., those involving breach of confidentiality), describe what you will do to protect the data during collection, while stored or during transmission of the data in the section below.

Psychological risks (e.g., those associated with the completion of a particularly sensitive survey or interview) could be mitigated by providing subjects with contact information for counseling resources.

If there are no known risks, state: I/We do not anticipate any risks from participating in this research.

**What will be done with the results of the study?**

I/We plan to publish the results of this study. To protect your privacy, I/we will/will not include any information that could directly identify you.

If you wish to use identifying information in a publication or presentation, including photographs, audio or video recordings, include the following, as appropriate:

The results of this study may be published or presented at a scientific meeting. The researchers will ask for separate written permission to include your name [or pictures, recordings] or other information that could identify you.

I/We will protect the confidentiality of your research records by [explain]. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**. [OR]** [Describe limitations to confidentiality, if any.]

It is possible that other people may need to see the information we collect about you. These people work for Utica University, [the study sponsor, if any], and government offices that are responsible for making sure the research is done safely and properly.

**How will your privacy, confidentiality and data security be protected?**

I/We plan to publish the results of this study. To protect your privacy, I/we will/will not include any information that could directly identify you.

Explain briefly, and in lay terms, how you will protect the participant’s privacy and/or confidentiality, including:

-De-identification of data

-If you will de-identify data with identifiers, or keep identifying information separate from research data ( e.g. signed consent forms kept separate from the survey data and the two will not be connected)

-If you plan to keep identifying information with the data, state this here

-If you are not planning to collect any identifying information at all (as in anonymous surveys).

-Physical security of data/research files

-Who will have access to identifying information

-How will sensitive data be kept secure in an electronic environment

-When will data be destroyed/deleted (i.e. within three years following completing of the study)

*If using a survey vendor to administer online surveys, include the following statement:*

Please note that the survey(s) [is/are] being conducted with the help of [company name], a company not affiliated with Utica University and with its own privacy and security policies that you can find at its website. We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

*When the research involves e-mail communication, include the following statement:*

Please note that email communication is neither private nor secure. Though [I am/we are] taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

*For sensitive research data with identifiers, stored in the cloud or on servers, or transmitted via the internet, consider including the following statement:*

Data may exist on backups and server logs beyond the timeframe of this research project.

***[OR]***

Your confidentiality will be kept to the degree permitted by the technology being used. We cannot guarantee against interception of data sent via the internet by third parties.

**What will happen to the information we collect about you after the study is over?**

I/We will/will not keep your research data to use for [future research or other purpose]. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

**[OR]**

Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

I/We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. [If data must or will be deposited in a public or other repository, briefly describe.]

**[OR]**

[We will not share your research data with other investigators.]

Sample text:

Data collected as part of this research will be provided to the XXX repository for future use by other researchers. This data will not contain information that could directly identify you.

Sharing De-identified Data Collected in this Research

(If you may share data without identifiers: We strongly recommend that you include this section in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.)

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Future use of Identifiable Data or Specimens Collected in this Research

In addition to the recommended data sharing language, above, if you are collecting identifiable data or identifiable biospecimens, you must include one of the following:

Identifiers might be removed and the de-identified information or biospecimens used for future research without additional consent.

[OR]

Identifiable information might be used for future research with obtaining your consent.

[OR]

Your information or biospecimens will not be used or distributed for future research studies.

**What are the costs to you to be part of the study?**

To participate in the research, you will need to pay for [Indicate what costs, if any, subjects will have to pay (such as parking)].

**[OR]**

Add a statement indicating ‘Other than your time, there are no costs to you to participate in this study.”

**Who can profit from study results?**

Where a potential Conflict of Interest (COI) for a member of the study team (or Utica University) has been identified, subjects must be informed about the nature of the conflict. Examples include:

* Investigators have an ownership, consulting, or similar financial relationship with a sponsor.
* A company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study whose product is being studied, particularly if the company/organization is also the sponsor of the study or has a financial interest with the investigators.

**Delete this section if not applicable to the study.**

**Your Participation in this Study is Voluntary**

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, [provide details about disposition of data]. [Describe anticipated circumstances, if any, under which the subject’s participation may be terminated by the PI without the consent of the subject].

**Contact Information for the Study Team and Questions about the Research**

You may ask any questions that you have now. If you have questions later, you may contact

**[PI name, email, phone]**

**[Faculty advisor name, email, phone]**

**Contact Information for Questions about Your Rights as a Research Participant**

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Utica University

Maria DeGiglio, IRB Chair

Phone (315) 792-3122

Email irb@utica.edu

**Consent**

 *(For online studies, asking participants to click on an “I approve” box is usually sufficient).*

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study and understand that I can ask questions at any time.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your name (printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person obtaining consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent Date

This consent form will be kept by the researcher for three years beyond the end of the study.

**Parent or Legally Authorized Representative Permission**

**Delete this section if not applicable to the study.**

For more than minimal risk research involving children, signature by two parents/legal guardians may be required.

By signing this document, you are agreeing to [your child’s **OR** the person’s named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child* ***OR*** *the person named below] to take part in this study.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Subject Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Parent/Legally Authorized Representative Name and Relationship to Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Parent Name and Relationship to Subject (when 2 signatures are required)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

You may also need to obtain dated consent for specific activities when those activities are ***optional*.** Whether an activity is required or optional must be clearly described in the main body of the consent above. Some common optional research activities are included below:

**Consent to be Audio/video Recorded**

*I agree to be audio/video recorded.*

***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

If you will take photographs or make audio, video, or other recordings that you want to use for activities beyond research analysis (publications, presentations, other promotional purposes), include a section that:

•Informs the participant that you are making a [type(s) of media used] recording in which

 the person’s name, likeness, image, and/or voice will be included;

•Asks the participant to grant you the right to make, use and publish recordings in whole

 or in part in media forms now known (such as film, slides, and digital audio) or

developed in the future. This includes the right to edit or duplicate any

images/recordings;

•Explains the limitations on reproduction, distribution, performance, or display of

images/recordings;

•Explains that the participant does not have rights to inspect or approve the finished

product or printed/published matter that uses the images/recordings or versions of the

images/recordings; and

•Explains that the participant will not receive any financial compensation for commercial

and/or non-commercial (as appropriate) uses of the images/recordings.

**Consent to Use Data for Future Research**

*I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information.* (Note: This separate consent is not necessary if you will only store and share deidentified data.)

***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**Consent to be Contacted for Participation in Future Research**

*I give the researchers permission to keep my contact information and to contact me for future research projects.*

***YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date