# Informed Consent Template: General

Note: This consent document follows the 2018 federal regulations (effective 1/21/19) and is modelled after one developed by the University of Michigan IRB.

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 should be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level. The reading level can be higher if the target population tends to have a higher literacy rate than the general population. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age level of the child.

We recommend the use of this template to create the informed consent document(s) for your study. Please note:

1. Regulations 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. We recommend doing so for all research in which it would improve people's ability to understand what they are being asked to do. The key information should be presented first and include the following:
    a. Identification of the project as a research study and that participation is voluntary
    b. Purpose of the research, duration of participation, and a description of research procedures
    c. Foreseeable risks or discomforts, if any
    d. Expected benefits to subjects or others, if any
    e. Alternative procedures or treatments that might benefit the subject (Note: Item "e" applies primarily to clinical research)

    Many research studies have brief consent documents (2 or 3 pages) and would not necessarily benefit by having a separate "key information" section. However, if your project is complex or involves numerous research procedures, this summary is required for federally-sponsored projects and is strongly recommended for all others.

2. Text in [brackets] represents information about your study that you must add (in plain text).
3. A backslash indicates that you must make a selection depending on the procedures for your study (e.g., "will/will not" or "I/we").
4. Additional instructions or sample text are provided in boxes.
5. Before you upload your consent document to the Fairfield University online submission portal, delete this cover page, brackets, and boxes. The finished document should reflect what you will give to the subject.
6. 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 more information on plain language go to http://www.plainlanguage.gov/.

Fairfield UNIVERSITY

# Consent to be Part of a Research Study

Title of the Project:
Principal Investigator: [Name, credentials, institutional affiliation]
Co-investigator: [Name, credentials, institutional affiliation]
Faculty Advisor: [Name, credentials, institutional affiliation]
Study Sponsor: [If any]

Include Faculty Advisor information only if you are a graduate student PI. Undergraduates must have their faculty advisors serve as the principal investigator.

## 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.]. Taking part in this research project is voluntary.

## Important Information About the Research Study

Things you should know:

- The purpose of 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].
- 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.

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

For research projects that involve numerous research procedures or that are so complex that they require more than a 2-3 page consent document, provide a concise and focused presentation of key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. Organize information to facilitate comprehension.

**Delete this section if not necessary for the study (e.g., delete if consent < 2 pages).**

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

The purpose of this research study is [describe the study purpose].

If you have used the summary above, provide additional details in this section.

## What will happen if you 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.

If applicable, include a statement about whether clinically relevant research results will be shared with the subject and under what conditions. For example: "We may learn information about your health as part of the research. We will/will not share this information with you [how/why not]."

## 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 without penalty. You do not have to answer any questions or complete any tasks you do not want to. If you decide to stop before this study is completed, [provide details about disposition of data].

If applicable, explicitly note that participants will not be penalized if they do not agree to be in the study, if they skip tasks or questions, or if they quit during the study. For example, if participants are students, patients, or employees, state that doing so will not negatively affect their grade, employment status, access to specific services, or treatment, as applicable.

Describe anticipated circumstances, if any, under which the subject's participation may be terminated by the PI without the consent of the subject. For example, if the study involves multiple sessions, you might state "In order for our data to be useful, it is important that you attend every scheduled session of this 3-part study. If you miss a session and can't reschedule, we'll have to take you out of the study.]

## 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].

Financial incentives (such as money, gift cards, or chances to win a prize), or receiving course credit or extra credit are not benefits and should not be listed here. Such incentives are to be discussed under the section "How Will We Compensate You For being Part of the Study."

## 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.]. **[OR]** We don't believe there are any risks from participating in this research.

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 on "How We Will Protect Your Data." 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 and/or by stating, "Some questions may be very personal or upsetting. You can skip any questions you don't want to answer."(Be sure that is true if gathering data online)

Definition of minimal risk = the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

For research posing more than minimal risk to subjects include the following text: "Please tell the researchers if you have any injuries or other problems related to your participation in the study. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study."

## How will we protect your information?

The information you provide will be kept confidential. 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.

I/We will protect the confidentiality of your research records by [explain]. **[OR]** [Describe limitations to confidentiality, if any.]

**[If personally identifying information such as the participant's name was collected and linked with the data, state]** 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 not be included with the research data collected as part of the project.

It is possible that other people who are responsible for making sure the research is done safely and properly may need to see the information we collect about you (e.g. the Fairfield University human subjects Institutional Review Board, [the study sponsor, if any], and government offices.

*Anonymity* means that no identifying information such as name or student ID number is collected, so the privacy of participants is assured. *Confidentiality* means that the researcher will have a record of who participated but the data will be kept private.

If the subject's data is identified with a code number but there is a master list that links that code to the participant's name, email, phone number, or other identifying information, this must be made explicit to participants, and the master list must be kept secure and separately from the collected data.

Explain when the consent forms and any other identifiable data will be destroyed. Note: Federal regulations requires PIs to keep consent forms for at least 3 years after the completion of the study. You do not ever have to destroy raw data but at some reasonable point, you should destroy anyone's ability to link the participants' data to identifying information.

Issues to consider when addressing risks associated with data confidentiality and security and optional ways of addressing:

If your study involves focus groups or group interviews, state: "We ask all participants to keep everything said during the focus group/group interview confidential. However, we can't control what others say, so it is best not to share anything you don't want others to know."

If there is a risk of breach of confidentiality (the subject's data being seen by someone who shouldn't have access to it), state, "We'll store all electronic data on a password-protected, encrypted computer" or "We'll store all paper data in a locked filing cabinet in a locked office";

If there is risk of online data being hacked or intercepted, state, "The risk of online data being hacked or intercepted is the same you experience any time you provide information online. We're using a secure system to collect this data [elaborate if desired], but we can't completely eliminate this risk."

If the study is run on MTurk or a similar platform, state "Amazon could link your worker ID (and associated personal information) with your survey responses. Make sure you have read Amazon's MTurk participant and privacy agreements to understand how your personal information may be used or disclosed."

If you will collect photographs or audio or video recordings of participants, the consent form should include information as to why the recordings are needed for the research, where and how they will be stored and identified, and what will be done with them upon completion of the research (e.g., destroyed after transcription, kept indefinitely, destroyed after X years). If recording is optional, provide a space at the end of the consent document where subjects initial to consent specifically for the audio and/or video recording.

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.

If you are collecting identifiable, sensitive information and your project is NIH-funded, it will be covered by a **Certificate of Confidentiality (CoC)** –**or**– if you will apply for a CoC for non-NIH-sponsored research collecting health-related, identifiable, sensitive information, insert the following language:

"This project [is funded by the NIH and] holds a Certificate of Confidentiality (CoC) that offers additional protections for your identifiable research information, biospecimens, and records. The most important protection is that members of the research team cannot be forced to disclose or provide any of your private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your research information may only occur in limited instances. [For projects with mandatory abuse and other reporting requirements, insert the following: "For this study, I/we may share your information with appropriate authorities if I/we learn [requirements or plans for abuse or public health reporting]]." For a more detailed description of CoC protections and exceptions to those protections, please refer to Attachment A at the end of this document."

**For projects not involving a CoC**, if you are **a mandatory abuse** reporter and it seems likely you will encounter reportable events as part of the study, insert the following: "If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies."

If your project meets the definition of an **NIH clinical trial**, include the following: "A description of this study will be posted on a public website, http://ClinicalTrials.gov, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted."

If you will **register your project on ClinicalTrials.gov** voluntarily or in order to meet journal or other sponsor requirements, include the following: "A description of this study will be posted on http://ClinicalTrials.gov, and summary results of this study may be posted on this website at the conclusion of the research. No information that can identify you will be posted."

**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].

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. These data will not contain information that could directly identify you."

If you are collecting personal health information about subjects, your research may be subject to additional HIPAA regulations. See https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

## How will we compensate you 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.]

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

## 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)].

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

## Who can profit from study results?

Where a potential Conflict of Interest (COI) for a member of the study team (or Fairfield 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.
- Fairfield University may be paid licensing fees for the investigational technology, or could be paid in the future.

- When a conflict may exist, the IRB may recommend required language to be included in the consent documents.

Sample text: "[Name of conflicted individual] is a named inventor on patents or patent applications or is the creator of copyrighted material that is licensed or optioned to company name] that will be used in this research. This means [conflicted individual] could gain financially from this study."

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

## What other choices do I have if I don't take part in this study?

For clinical-type projects that involve an intervention that might treat or improve a condition or a disease, describe alternatives to participation in the research study. These could include intervention or treatment available outside the research context.

Sample text: "There may be other ways of treating your condition if you don't wish to be in this research. Check with your health care provider to discuss other options."
Instead of participating, you can [insert alternative(s)]

For projects involving students who participate to earn credit or extra credit in a course, describe an equitable alternative way to earn the credit.

Sample text: "Instead of participating, you can earn the same amount of extra credit by answering Questions 1-2 on page 394 of your textbook."
If participation is part of an established subject pool for credit or extra credit, the alternative ways to earn credit are established as part of participants enrolling in the subject pool, and therefore do not necessarily need to be addressed here.

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

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

If you have questions about this research, you may contact **[PI name, email, phone (and faculty advisor if PI is a student)].**

**The contact information for the study team should be bolded.**

For International Studies: List the name, email and phone of the local collaborator, if any, first. Be sure to include the U.S. calling code and exit number for the country of origin. The number will be in the following format: Phone: XXX+1-203-254-4000, ext. #.

## 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 concerns about this study with someone other than the researcher(s), please contact the Fairfield University IRB by contacting Susan

LaFrance, IRB Administrative Liaison for the Office of Academic Affairs, by phone (203) 254-4000 x2154 or email: slafrance@fairfield.edu

For International Studies: List information for the local IRB or Ethics Committee, if any, first. For the Fairfield IRB contact, include the U.S. calling code and exit number for the country of origin. The number will be in the following format: Phone: XXX+1-203-254-4000 x2154.

## Your Consent

Required for projects obtaining a signature only – delete this paragraph for projects that will request a waiver of documentation. The document must be dated by the person signing.

For projects involving a waiver of documentation, include the following statement:

Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records [or you can print a copy of the document for your records]. If you have any questions about the study later, you can contact the study team using the information provided above.

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.*

_____
Printed Subject Name

_____
Signature Date

## 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 may be required. Contact the IRB Chair for more information.

If using this document for a parent to give permission for his or her child to participate in research, in places where it says "you" referring to the research subject, replace with "your child" throughout the document, as appropriate.

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

**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 de-identified 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

***Note 1:*** *If your research holds a CoC, include Attachment A as the last page of the consent document. If there is no CoC for this research, delete Attachment A from the consent document.*

***Note 2:*** *Text in [brackets] is instructional and is not meant to be a part of the Attachment A language. The brackets and text within should be deleted from the final version.* ***Delete Notes from the final version of document.***

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**Attachment A**
**Certificate of Confidentiality (CoC)**

This research holds a Certificate of Confidentiality from the National Institutes of Health.

***What is a Certificate of Confidentiality?***
With this Certificate, the researchers may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

***When are the researchers allowed by the CoC policy to disclose my information?***

- If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).
- If you have consented to the disclosure, including for your medical treatment. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

- If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

***When may the researchers disclose my research information for this study?***

- [Use the following language as applicable; edit as necessary, e.g., if the research is federally funded but isn't subject to the requirements of the FDA, do not include the second phrase.] If the [name of federal or state agency], the agency funding this research, requests information to audit or evaluate our procedures; or if we must disclose information in order to meet the requirements of the federal Food and Drug Administration (FDA).

- [*Use the following language if you intend to disclose information covered by a Certificate, such as with potential child abuse, or intent to hurt self or others, in response to specific federal, state, or local laws.*] The CoC will not be used to prevent disclosure of [*list what will be reported, such as child abuse and neglect, or harm to self or others*], as required by federal, state, or local law. [OR, for non-mandatory reporters] If the researchers learn about child abuse or anything that leads them to think you might harm yourself or others, we may report this to the appropriate authorities.

- [*Use the following language if you intend to disclose information covered by a Certificate, with the consent of research participants.*] The CoC will not be used to prevent disclosure for any purpose you have consented to, as described in this informed consent document. This includes [*restate what will be disclosed, such as including research data in the medical record*].