

TEMPLATE INSTRUCTIONS
ADULT INFORMED CONSENT TO PARTICIPATE IN RESEARCH

The following instructions and examples are provided to assist in developing a consent form. Additional templates and information are available on the IRB [website](#). **Please Note: Only unprotected documents can be stamped by the IRB.**

Before submitting the consent form for IRB approval, delete this page and all instructions, boxes, examples, and non-applicable language.

The following should be considered when developing the consent form:

- Consent forms must include clear identification of the responsible institution (Chapman University letterhead as shown above or department-specific letterhead can be used).
- All forms should be submitted suitable for reproduction (printed single-sided or available electronically) using a minimum 12-point font and 1-inch margins.
- Each page of the consent form should be full without blank sections or inappropriate divisions. Sections can be split (some on one page, some on another page) so that large blank areas do not exist.
- All consent forms must include page numbers at the bottom of each page.
- The informed consent form must be written in the second person (i.e., “you”). When combined with conditional language, use of the second person personalizes the consent form and reflects the existence of voluntary decision-making on the part of the prospective participant. If this form is being used to obtain parental permission for a child to participate in research, please change “you” to “your child” throughout the document.
- The information in the informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the prospective participant focus on each individual element of consent, thereby increasing the validity of the consent process.
- The consent form must be written in simple enough language so that it is understood by the least educated of the participants who will participate. Normally, the highest level of language in the consent form should be at an eighth-grade level. Scientific terms should be avoided when possible. If scientific terms will be included, the lay term or definition should be provided.
- Please remember, the age of majority in California is 18 years old. Anyone younger than 18 requires parental permission and [child assent](#), with few exceptions based on state law, or a waiver of parental permission that must be approved by the IRB.

- Refer to the ‘[Additional Elements of Consent](#)’ document for other information that may be useful to include in your consent form.

ADULT INFORMED CONSENT TO PARTICIPATE IN RESEARCH**Title of Study**

List the title exactly as it appears on the IRB application.

Members of the Research Team

List the name and contact information for the principal investigator. For greater than minimal risk studies, consider including a personal phone number. Other members of the research team do not need to be included on the consent form but may be listed as

Principal Investigator: Jane Doe, Ph.D.

Office: (714) 123-4568

Key Information

The 2018 changes to the Common Rule (45 CFR 46) require that consent forms “must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding

You are being asked to take part in a research study. Research studies include only people who choose to take part. You should take your time deciding whether you want to participate.

If you agree to participate in this study, this research will involve:

- Individuals who are 18 years or older [add any other characteristics that may describe participants]
- Procedures will include [summary of X procedures]
- [X number of] visit(s) that will take [X] total hours
- Risks that [exceed or do not exceed] what would typically be encountered in daily life
- \$X for your participation

Invitation

Invite the prospective participant to participate in the study using the following standard invitation.

You are invited to take part in this research study. The information in this form is meant to help you decide whether to participate. If you have any questions, please ask.

Why are you being asked to be in this research study?

Explain succinctly why the prospective participant is eligible to participate. As appropriate, major eligibility criteria may be included in this section.

You are being asked to be in this study because [describe relevant characteristics of the participants].

What is the reason for doing this research study?

This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential participant understand why the research is being done. The information should be delivered in simple language.

This research seeks to [describe what the study purpose is or what research questions will be asked].

If this research is funded by an external organization such as the National Institutes of Health, indicate so here.

This research is funded by [XX organization].

What will be done during this research study?

Describe the procedures and their duration chronologically using simple language, short sentences, or short paragraphs. The use of subheadings may help organize this section and increase readability for studies with many procedures.

You will be asked to complete [describe the research procedures]. Each session will take [X hours] in [XX] setting.

How will my data be used?

If the research involves collecting or sharing data/biospecimens/images with other researchers, include the following statements as applicable. Please also see the [Additional Elements of Consent](#) document for further guidance.

Your data [biospecimens/images] will not be used in future research studies or shared with other

If the research involves collecting or sharing de-identified data/biospecimens/images with other researchers, include the following statement.

Your data [describe which data, e.g., biospecimens/images/survey or interview results] will be made available to researchers outside of Chapman University or made publicly available on [indicate where the data will be accessed from e.g., website, repository, etc.] for [explain why the data are being sent outside Chapman University]. Although your data [biospecimens/images/survey or interview results] will initially be collected with identifying information, all personal identifiers will be removed from the data [biospecimens/images/survey or interview results] before being shared outside of the research team.

If the research involves collecting or sharing identifiable data/biospecimens/images with other researchers, include the following statement.

Your data [describe which data, e.g., biospecimens/images/survey or interview results] will be made available to researchers outside of Chapman University or made publicly available on [indicate where the data will be accessed from e.g., website, repository, etc.]. With your permission, the data will be sent to other researchers containing identifiable information, including [describe the identifiable information that will be associated with the data]. Identifiable information is being sent to other researchers because [explain the purpose of sending identifiable data to researchers outside Chapman University].

What are the possible risks of being in this research study?

Identify each procedure with a subheading and then state the associated risk(s) using simple language. If warranted, the most serious and common risks should be addressed first, followed by disclosure of uncommon and less serious risks in a separate paragraph. Risks common to social science and behavioral research may include loss

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Other risks in this research include possible emotional and/or psychological distress because the surveys involve sensitive questions about your work habits. [Add other risks as necessary.]

Conclude with the following standard clause.

It is possible that other rare side effects could occur that are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

Alternately, if there are no known risks, use the below standard clause.

There are no known risks to you for being in this research study.

What are the possible benefits to you?

If direct benefits can reasonably be anticipated as a result of participating in the study, then describe these possible benefits. Conclude with the following standard clause.

[Describe benefits]. However, you may not get any benefit from being in this research study.

If direct benefits are NOT anticipated, use the following standard clause.

You are not expected to get any direct benefit from being in this study.

What are the possible benefits to other people?

State the possible benefits to society in terms of advancement of knowledge and/or ultimate possible benefits to other people.

The benefits to science or society may include a better understanding of [include what knowledge may be gained].

What are the alternatives to being in this research study?

Describe in reasonable detail alternatives the prospective participant may have available. If there are no alternatives, this section does not need to be included.

Instead of being in this research study, you can [X] or choose not to participate.

What will participating in this research study cost you?

This section should state the financial obligations the participant may incur as a result of participating in the study. If there are no financial obligations to the participant, use the following standard clause.



There is no cost to you to be in this research study.

Will you be compensated for being in this research study?

If participants will receive compensation for participating in the research (either money or research credit), state the amount of compensation and conditions for payment. A prorated payment system should be used when appropriate and

You will receive \$X for your participation in this study.

You will receive research credit for an eligible course through the [XX] Subject Pool. You will receive a ½ unit of research credit for each ½ hour of participation in this study. The total amount of credit you may earn is [XX].

If the participant will be compensated for multiple sessions.

You will receive [indicate type of compensation and amount/value] after each study visit. There are [# of study sessions]. Total compensation for participation in this study is [\$XX]. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed.

If participant will receive payments over \$600 per calendar year, the Internal Revenue Service (IRS) requires that Chapman report payments on Form 1099-Misc.

If you receive compensation over \$600 per calendar year, your name and social security number will be collected and released to the Office of Accounting to process the Form 1099-Misc for Internal Revenue Service (IRS) tax reporting purposes.

Alternately, if there is no compensation, use the following standard clause.

You will not be compensated for your participation in this research study.

What should you do if you have a problem during this research study?

Your estimation of risk determines what additional information you will include in this section. For studies classified as minimal risk, use the following standard clause.

Your welfare is the primary concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the

people listed at the beginning of this consent form.

For studies classified as greater than minimal risk, use the following standard clause.

If you have a problem or experience harm as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form. If needed, seek immediate emergency care for this problem. It is important for you to understand that Chapman University will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. That cost will be your responsibility. Agreeing to this does not mean you have given up any of your legal rights.

Think about also providing resources to participants dependent on the project parameters. For example, provide them with student health or wellness contact information.

How will information about you be protected?

Begin with the following standard clause.

Reasonable steps will be taken to protect your privacy and the confidentiality of your study data.

Next, if the research requires collecting sensitive information (social, financial, legal, or otherwise) from the prospective participant, provide a brief description of the precautions used to protect the data.

Use this standard clause and edit as needed for projects that collect paper records.

The data will be stored in a locked cabinet in [location] and will only be seen by the research team during the study and for [XX] years after the study is complete.

For projects that collect electronic records, use this standard clause and edit as needed. Describe the security in detail so the participant can understand what protections are in place.

The data will be stored electronically in [location] and will only be seen by the research team during the study and for [XX] years after the study is complete.

For all protocols, include the following standard clause and edit as needed.



The only people who will have access to your research records are the research team members, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. Information from this study may be published in scientific journals or presented at scientific meetings, but the data will be reported as a group or summarized data, and your identity will be kept strictly confidential. We cannot guarantee total privacy.

If applicable, discuss required reporting of child abuse (for more information, see Chapman's [policy](#) on mandated reporting).

Please note that all Chapman University employees are required to report any known or suspected abuse of children or minors to appropriate authorities.

What are your rights as a research participant?

Use the following standard clause.

You may ask any questions about this research and have those questions answered before agreeing to participate in the study or during the study.

For study-related questions, please contact the investigator(s) listed at the beginning of this form.

For questions concerning your rights or complaints about the research, contact the Institutional Review Board (IRB) at (714) 628-2833 or irb@chapman.edu.

What will happen if you decide not to be in this research study or decide to stop participating once you start?

Use the following standard clause.

You can decide not to be in this research study, or you can stop being in this research study (i.e., “withdraw”) at any time before, during, or after the research begins for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator or with Chapman University [list others as applicable]. You will not lose any benefits to which you are entitled.

Documentation of informed consent

Use the following standard clause if you are obtaining signed consent.

You are voluntarily deciding whether to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered, and (4) you have decided to be in the research study. You will be given a copy of this consent form to keep.

If the consent process is taking place electronically, replace the last sentence above with the following sentence.

You may print or save this consent form if you would like a copy to keep.

Printed Name of Participant or Legal Guardian

Signature of Participant or Legal Guardian

Date

If using audio or video recording, include the boxes below and describe the recording procedures in the section above called “What will be done during this research study?” Otherwise, delete.

AUDIO RECORDING:

I have received an adequate description of the purpose and procedures for audio recording sessions during the course of the proposed research. I give my consent to allow myself to be audio recorded during participation in this study, and for those records to be reviewed by persons involved in the study, as well as for other professional purposes as described to me.

_____ **Yes**, I agree to allow the research team to **audio record** my interview(s).

_____ **No**, I do not wish to have my interview(s) **audio recorded**.

Signature of Participant or Legal
Guardian

Date

VIDEO RECORDING:

I have received an adequate description of the purpose and procedures for video recording sessions during the course of the proposed research. I give my consent to allow myself to be video recorded during participation in this study, and for those records to be reviewed by persons involved in the study, as well as for other professional purposes as described to me.

_____ **Yes**, I agree to allow the research team to **video record** my participation.

_____ **No**, I do not wish to have my participation **video recorded**.

Signature of Participant or Legal
Guardian

Date

If the research involves collecting or sharing identifiable data/biospecimens/ images with other researchers, include the following statement.

SHARING IDENTIFIED INFORMATION PUBLICALLY:

I have received an adequate description of the purpose and procedures for sharing identifiable data and making the data available outside the research team. I give my consent to allow the researchers to share my identifiable data, in the manner that has been described to me.

_____ **Yes**, I agree to allow the research team to **share my identifiable data**.

_____ **No**, I do not consent to share my **identifiable data**.

Signature of Participant or Legal
Guardian

Date

For greater than minimal risk studies, include the following investigator certification clause.

Investigator certification

My signature certifies that all elements of informed consent described on this consent form have been explained fully to the participant. In my judgment, the participant possesses the capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person Obtaining Consent

Date

The California Protection of Human Subjects in Medical Experimentation Act requires that participants in medical experiments be provided a written “Experimental Subject's Bill of Rights” in addition to the informed consent form. If your study involves a medical experiment or procedure, the use of a device, the use of ingestible substances other than food, applying hot or cold to participants, or electromagnetic radiation,