TEMPLATE INSTRUCTIONS

**ADULT INFORMED CONSENT TO PARTICIPATE IN RESEARCH**

The following instructions and examples are provided to assist in development of a Consent Form. Additional templates and information are available on the IRB [website](https://www.chapman.edu/research/integrity/irb/forms-and-instructions.aspx).

**Please Note**: Only unprotected PDF 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 departmental specific letterhead can be used).
* All forms should be submitted suitable for reproduction (printed single sided or available electronically) using at minimum 12-point font and 1-inch margins.
* Each page of the consent form should be full without inappropriate divisions. Sections can be split (some on one page, some on another page) so that large blank areas do not exist.
* All pages must include page numbers at the bottom.
* 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 subject. 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 subject 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 subjects 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, age of majority in California is 18 years old. Anyone younger than 18 requires parental consent and [child assent](https://www.chapman.edu/research/_files/_files-sponsored/irb-files/child-assent-template.docx), with few exceptions based on state law, or a waiver of parental consent that must be approved by the IRB.
* Refer to the ‘[Additional Elements of Consent](https://www.chapman.edu/research/_files/_files-sponsored/irb-files/informed-consent-additional-elements.doc)’ 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 by name those members of the research team authorized to document consent as listed in the IRB application. This may include lead researchers, student researchers, and other researchers. For greater than minimal risk studies, consider including night/home phone numbers and/or other direct contact mechanism. List other study personnel and contact information as appropriate.***

Student Researcher: John Smith, MA Office: (714) 123-4567

Lead Researcher: 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 subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.”***

You are being asked to take part in a research study. Research studies include only people who choose to take part. A member of the research team will explain the study to you and will answer any questions you might have. You should take your time in deciding whether or not you want to participate.

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

* [Males/Females] between the ages of [age range]
* Procedures will include [summary of X procedures]
* There are [X] number of visits
* These visits will take [X] amount of hours total
* There [are/are not] risks associated with this study that exceed what would typically be encountered in daily life
* You will be paid [X] amount for your participation
* You will be provided a copy of this consent form

**Invitation**

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

You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.

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

***Explain succinctly and simply why the prospective subject 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 you are either an employee or a supervisor working a night shift. You must be 18 years of age or older to participate.

**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 subject understand why the research is being done. The information should be provided in simple language without reference to the subject.***

People who work at night employ different strategies for staying awake during their shifts. These methods are likely to be different between employees and supervisors, because of their different levels of responsibility. This research is designed to (1) better understand these strategies and (2) determine whether ‘supervisor strategies’ could be successfully used by employees.

**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 a large number of procedures.***

You will be asked to complete 5 surveys using an internet-based questionnaire that ask question about [X]. Each survey will take 1-2 hours to complete and you may complete them from your home computer, one each week for 5 weeks.

**How will my [data/samples/images] be used?**

***If the research involves collection and/or sharing of data/biospecimens/images to other researchers, include the following statements as applicable. Please also see the***

[***Additional Elements of Consent***](https://www.chapman.edu/research/_files/_files-sponsored/irb-files/informed-consent-additional-elements.doc) ***document for further language guidance.***

***If the research involves collection and/or sharing of de-identified data/biospecimens/images to other researchers include the following statement.***

Your [data/samples/images] will be sent to researchers outside of Chapman University for [explain why the samples are being sent outside Chapman University]. Any personal information that could identify you will be removed before the [data/samples/images] are shared.

***If the research involves collection and/or sharing of identifiable data/samples/images to other researchers include the following statement.***

Your [data/samples/images] will be sent to researchers outside of Chapman University for [explain why the samples are being sent outside Chapman University]. The [data/samples/images] that are sent to these researchers will contain identifiable information including [describe the identifiable information that will be associated with the data]. Identifiable information is being sent to these 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. The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress.***

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 subject 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 subject benefits are NOT anticipated, then 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 persons in the prospective subjects’ position.***

The benefits to science and/or society may include better understanding of how to help others working night shifts and their coping strategies.

**What are the alternatives to being in this research study?**

***Describe in reasonable detail, alternatives the prospective subject 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 subject may incur as a result of participating in the study. If there are no financial obligations to the subject, then 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 the subject will receive compensation for participating in the research (either money or course credit), state the amount of compensation and conditions for payment. A prorated payment system should be used when appropriate and commensurate with the degree of participation required.***

You will receive $5.00 for each survey you complete in this study.

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

***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 major 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 collection of sensitive information (social, financial, legal or otherwise) from the prospective subject, provide a brief description of the precautions that will be used to protect the data.***

***For projects that collect paper records, use this standard clause and edit as needed.***

The data will be stored in a locked cabinet in the investigator’s office 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 through a secure server 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 members of the research team, 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 group or summarized data and your identity will be kept strictly confidential.

***If applicable, discuss required reporting of child abuse (for more information, see Chapman’s*** [***policy***](https://mywindow.chapman.edu/depts/hr/Documents/Mandated%20Reporter%20Policy%20June%202015%20FINAL.pdf) ***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 subject?**

***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/written consent***

You are voluntarily deciding whether or not 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.

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 Printed Name of Participant or Legal Guardian

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

 Signature of Participant or Legal Guardian Date

***If using audio or video recording, include the boxes below. 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 |

**Investigator certification:**

***If applicable, include the following investigator certification clause. (Generally used for greater than minimal risk studies).***

*My signature certifies that all elements of informed consent described on this consent form have been explained fully to the subject. 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