

Informed Consent for Exempt Studies

Purpose:

The information in this guidance is intended to aid Principal Investigators (PIs) in the development of meaningful consent information for exempt studies. This document also contains illustrative examples of informed consent forms for various types of exempt research.

In this document:

[Applicability](#)

[Informing Participants](#)

[Information to Provide](#)

[Process of Informing](#)

[Exempt Consent Examples:](#)

[Use of Coursework for Research](#)

[Benign Online Survey](#)

[Sensitive Online Survey](#)

[Online Survey using Amazon's MTurk](#)

[Interviews with Adults](#)

[Focus Groups with Adults](#)

[Minor Deception](#)

[Incomplete Disclosure](#)

[Additional Information](#)

Applicability:

Information in this document only applies to studies meeting the criteria for exempt review.¹

Informing Participants:

Informed consent is a cornerstone principal of ethical human subjects research. Researchers must ensure prospective participants receive information about the study, sufficiently detailed to facilitate a truly informed choice, in a manner that facilitates *voluntary* consideration of whether to participate. This ethical obligation exists for all research—exempt and non-exempt. Federal regulations outline formal informed consent requirements for non-exempt research. Research confirmed as meeting the criteria for exempt review (i.e. “exempt research”) is not subject to those formal requirements, allowing PIs flexibility in how informed consent is obtained.

¹ PIs for studies not meeting the criteria for exempt review (i.e., non-exempt research (expedited review or full committee review)) are encouraged to review [Informed Consent information](#) including guidance regarding the elements of consent required within the regulations, a checklist for informed consent, and form templates.

Information to Provide

While the use of a formal informed consent form containing all the elements of consent is not required for research under exempt review; the Iowa State University IRB expects researchers to provide information about the research to prospective participants (and their parent/legal guardian, when applicable) prior to their enrollment in the study. At minimum, this information should include:

- a statement that the project involves *research*;
- a general description of study procedures and time commitment;
- any potential discomfort or risk related to participation (e.g., discomfort responding to sensitive or personal questions, privacy concerns, disclosure risks);
- indication that participation is voluntary and that they may skip any questions they do not feel comfortable answering in an interview or survey;
- how their privacy and confidentiality will be protected;
- an outline of plans for data-sharing or future research use of their information.

When applicable, PIs should also describe:

- any use of information about participants obtained from records (e.g., student coursework, medical information, data from a prior study);
- plans to audio/video record or photograph participants and how recordings/images will be used and retained;
- information about participants' use of software or apps, including any privacy issues, incurred costs, etc.;
- any plans for capturing information via screen-recording, key-stroke-logging, etc.;
- If deception about the purpose or nature of the study is planned, prospective subjects must be informed that they will be unaware of, or misled about, the nature or purposes of the research, and agree to proceed.

As with nonexempt research, the decision to participate in a research study belongs entirely to the potential participant. This choice must be voluntary and free from any undue influence – real or perceived. If a study necessitates inclusion of persons in subordinate positions (e.g., students, employees) PIs should take steps to ensure that individuals do not experience (or perceive) pressure to participate. Inclusion of language within the informed consent (for example, explaining that the decision to participate will not impact a course grade or their relationship with the PI) may be one way to address and mitigate this concern.

Process of Informing

As indicated above, use of a formal, signed consent form is not required by the IRB for studies under exempt review. For many benign surveys, a few simple paragraphs preceding the survey sufficiently meets the spirit of this ethical tenet.

When establishing a consent procedure for online surveys, researchers are cautioned to consider privacy and confidentiality implications of the process. For example, requiring participants to “*type their name to agree*” at the

beginning of the survey will, unless the survey has been carefully configured, embed participant names into the dataset. Having a record of participant names is not a requirement of the IRB and may violate the privacy and confidentiality provisions under which the IRB granted exemption for the study.² A simple “*check to agree*” or “*proceeding to the survey indicates your consent*” is often sufficient.

Consent processes for exempt studies that involve interviews could take the form of a short email or a bulleted information sheet with the degree of formality mirroring that of the study. Because signed documentation is not an IRB requirement for studies undergoing exempt review, a simple process of: providing the information (for example, emailing consent information ahead of the interview, or providing an information sheet at the time of the interview) with verbal confirmation that the participant understands and wishes to proceed is often appropriate.

While federal regulations do not require signed informed consent for participation in research under exempt review, researchers must be aware of other regulatory or policies that *may* require documented/signed informed consent. Research involving educational records or the use of student coursework/grades is likely subject to the Family Educational Rights and Privacy Act (FERPA). FERPA regulations typically *do* require that students (or parent/guardian) provide written consent for use of records or coursework for research regardless of the level of IRB review.

Other regulations such as the Health Insurance Portability and Accountability Act (HIPAA)³ and the General Data Protection Regulation (GDPR)⁴ may have additional consent, documentation, and/or notification requirements beyond those required by the IRB.

Exempt Consent Examples

The following are examples of informed consent forms for exempt research intended as illustrations only. Individual study details vary greatly. Please do not copy these examples verbatim, as informed consent forms should accurately account for study-specific nuances.

Use of Coursework for research

You are asked to take part in a research study about the effectiveness of remote classroom collaboration activities. The study is being conducted by Dr. Soma Teacher at Iowa State University. Participation in this study is voluntary.

If you agree to be a part of the study, we will contact you approximately 2 weeks after the end of the semester with a short (5 minute) online survey about your experiences in the class with remote learning. You may skip any questions in the survey that you do not want to answer.

In addition to the post-semester survey, we are also asking for permission to analyze your peer writing assignments for research. **These assignments are required coursework for the class**; however, your choice to allow our research use is voluntary and will have no impact on your standing in the course or your relationship with the instructor. Dr.

² Collection of names or other identifiers may violate the Terms of Service for some platforms (e.g. [Amazon MTurk's Participation Agreement](#) prohibits collection of Worker PII)

³ HIPAA may apply to research involving medical records/information

⁴ GDPR privacy regulations may apply to research conducted with persons located in the European Union

Teacher will not look to see which students have provided permission to use their coursework until after final grades have been submitted.

When we report our findings from the study we will not use your name and will change any details (e.g., majors, course names) that could indirectly identify you or others. Study data, including portions of your peer writing assignments, which have been stripped of any information that could identify you (de-identified) may be made public or used for future research purposes.

- I agree to be contacted for the post-semester survey

- I agree to the use of my **peer writing assignments** for research.

X

Participant Name / Date

Benign Online Survey:

We are asking you to take part in a research study conducted by Stu Dent and Dr. Cokie Kolla at Iowa State University. Participation in this study is voluntary. If you choose to take part, you will complete an online survey that will help us learn more about soft-drink consumption habits of young adults. You have been asked to take part because you are an adult aged 18-25 who may consume soft-drinks. The survey will take about 6 minutes to complete. You may skip questions that you do not want to answer or stop at any time. Any identifiers collected as part of this survey (i.e., IP addresses) will be promptly deleted. Study data that have been stripped of any information that could identify you (de-identified) may be made public or used for future research purposes.

Questions? Please contact Stu Dent at student@xxxxx or Dr. Kolla at kolladrinks@xxxxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

If you want to participate in this study, click the [*Agree, Accept, Next, Start*] button to start the survey.

Sensitive Online Survey:

We are asking you to take part in a research study conducted by Dr. Emo at Iowa State University. You must be 18 or older to participate. Participation in this study is voluntary. If you choose to take part, you will complete a survey that will help us learn more about how personality traits influence romantic relationships. The survey will take about 25 minutes to complete and includes questions that you may find sensitive, uncomfortable, or difficult to answer. You may skip questions or stop at any time.

Any identifiers collected as part of this survey (i.e., IP addresses) will be promptly deleted. Study data that have been stripped of any information that could identify you (de-identified) may be made public or used for future research purposes.

In appreciation of your time completing this survey, we will send \$5 Starbucks gift card to you via email. To facilitate payment, you will be asked to enter your email address following completion of the survey. Your email address is entered into a separate dataset and is never linked to your survey responses.

Questions? Please contact Dr. Emo at (515) 294-xxxx, emo@xxxxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

If you want to participate in this study, click the [*Agree, Accept, Next, Start*] button to start the survey.

MTurk Online Survey:

We are asking you to take part in a research study conducted by Dr. Felicia Pants at Iowa State University. You must be 18 or over to participate. Participation in this study is voluntary. If you choose to take part, you will link to an external survey site (Qualtrics). Your responses to this short (~6 minute) survey will help us learn more about lounge ware preferences of young adults. You may skip questions that you do not want to answer or stop at any time.

You will be compensated (\$xx) through MTurk. Upon completion of the survey, you will receive a code to enter into MTurk in order to receive your compensation. While your MTurk worker ID will be temporarily collected for payment, we will delete this identifier promptly following compensation.

If applicable: [Please note that this survey contains checks to make sure that participants are finishing the tasks honestly and completely. If you read the instructions and complete the tasks, your HIT will be approved. If you fail these checks, we may reject your HIT meaning that you will not receive compensation.]

Information you provide in the survey may be made public or used for future research purposes. We will take steps to ensure that your identity remains confidential before the data are shared. MTurk worker IDs will never be included in data that are shared.

Questions? Please contact Dr. Felicia Pants at felicpants@xxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

If you want to participate in this study, click the [*Agree, Accept, Next, Start*] button to start the survey.

Interviews with Adults

We are asking you to take part in a research study conducted by Stu Dent and Dr. Teachafar at Iowa State University. If you agree to take part in this voluntary study, we will contact you to schedule an interview conducted via Zoom. The brief (20-30 minute) interview will help us learn more about remote learning experiences of young adults. You have been asked to take part because you are an adult aged 18-25 who may be learning remotely. You can skip questions that you do not want to answer or stop at any time.

The interview will be audio and video recorded to allow us to accurately record your responses. The audio/video *recordings* will be destroyed promptly following transcription of the interview and will never be shared with others or used beyond this project. We may share or use the *text transcript* of your interview for future research purposes; however, we will take steps to remove any information that may identify you before the transcript is shared. When we write-up our findings from the study, we will replace your name with a pseudonym (fake name) and will take care to change details (majors, course names) that could indirectly identify you or others.

Questions? Please contact student@xxxxxx or Professor Teachafar at teachafar@xxxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

Focus Groups with Adults

We are asking you to take part in a research study conducted by Dr. Resha Earch at Iowa State University. You must be 18 or older to participate. If you agree to take part in this voluntary study, you will be asked to engage in an audio recorded focus group discussion about napping habits. The discussion will last approximately one-hour and will be held at [location]. You may skip questions that you do not want to answer or stop participating in the discussion at any time.

The recording will be kept secure following transcription of the discussion and will not be shared with other researchers. However, we may use the recording for additional analysis. Written transcripts may be shared with other researchers and/or used for future research.

When we report our findings from the study we will not use your name and will take care to change any details that could indirectly identify you or others. Please know that while we are taking steps to protect your confidentiality, we cannot control what others in the group divulge to others. Please be mindful of these limits to confidentiality when participating. We ask all participants to respect other's privacy and not disclose who was present or what was said during this discussion.

Questions? Please contact reshaearch@xxxxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

Minor Deception Regarding Study Purpose

We are asking you to take part in a research study about short-term memory retention conducted by Dr. Amy G. Dala at Iowa State University. You must be 18 or older to participate. Participation in this study is voluntary. If you choose to take part in this study, you will read some fictional news stories, perform problem-solving tasks (e.g., puzzles, math problems), and complete a survey. The readings, tasks, and survey questions are similar to those encountered in a classroom setting. You may skip questions or stop at any time. For scientific reasons, we may misrepresent certain aspects of the study; however, at the end of the study we will give you more information and the option to remove your data from the research.

The study will take about 25 minutes to complete. You will be compensated 1 SONA research credit. Your course syllabus includes alternative opportunities for earning research credit. Information that could identify you (e.g., name, email address) will be promptly separated from your responses. When we report study findings, we will make sure you cannot be identified. Study data that has been stripped of any information that could identify you (de-identified) may be made public or used for future research purposes.

Questions? Please contact Dr. Dala at (515) 294-xxxx, amygdala@xxxxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

If you want to participate in this study, click the [*Agree, Accept, Next, Start*] button to start.

Debriefing

Thank you for participating our study "*Detail Retention Study*." In order to obtain your unbiased, natural reaction, we misled you regarding the purpose of the study. In truth, our research focuses on how reading positively vs. negatively framed news stories may impact behavior and problem-solving persistency. Our hypothesis is that participants reading positively framed stories will persist at the problem-solving tasks longer than those reading stories framed negatively. You may have responded unnaturally had you been aware of our true study purpose. To help ensure that other participants also have unbiased responses, we ask that you do not share information about this research project with others.

Although you have already completed your participation in the study, your involvement in the research is still voluntary. Now that you are aware of the true nature of our study, you may choose to have your data removed without penalty or loss of compensation. Your choice to remove your data will not impact your relationship with Dr. Dala or Iowa State University. Because we work quickly to de-identify the study data, you must make your removal request at this time.

Questions? Please contact Dr. Dala at (515) 294-xxxx, amygdala@xxxxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

Deception/Incomplete Disclosure of Study Purpose

We are asking you to take part in a research study conducted by Sierra Bellum and Dr. Amy G. Dala at Iowa State University. You must be 18 or older to participate. Participation in this study is voluntary. We are interested in learning about memory. For scientific reasons, we cannot provide specific details about the research question being tested; however, we will give you more information and the opportunity to reconsider your consent at the end of the study.

If you choose to take part in this online study, you will read some watch two short videos, perform cognitive tasks (e.g., puzzles, word scrambles), and complete a brief survey. The videos, tasks, and survey questions are similar to those encountered in a classroom setting. You may skip questions or stop at any time.

The study will take about 25 minutes to complete. Information that could identify you (e.g., name, email address) will be promptly separated from your responses. When we report study findings, we will make sure you cannot be identified. Study data that has been stripped of any information that could identify you (de-identified) may be made public or used for future research purposes.

Questions? Please contact Sierra Bellum, (515) 294-xxxx or Dr. Dala at (515) 294-xxxx, amygdala@xxxxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

If you want to participate in this study, click the [*Agree, Accept, Next, Start*] button to start.

Debriefing

Thank you for participating our study, "*Learning and Memory*." To obtain your unbiased, natural reaction we did not inform you regarding the purpose of the study. Our research focuses on how viewing the videos with slow or fast frame rates impact ability to retain small details. You may have responded unnaturally had you been aware of our true study purpose. To help ensure that other participants also have unbiased responses, we ask that you do not share information about this research project with others.

Although you have already completed your participation in the study, your involvement in the research is still voluntary. Now that you are aware of the true nature of our study, you may choose to have your data removed without penalty. Your choice to remove your data will no negative affect your relationship with Dr. Dala or Iowa State University. Because we work quickly to de-identify the study data, you must make your removal request at this time.

Questions? Please contact Dr. Dala at (515) 294-xxxx, amygdala@xxxxxx. If you have questions or concerns about your rights as a research participant, you can contact the Iowa State IRB at (515) 294-4566, IRB@iastate.edu

Additional Information:

Exempt Research

[Information about Exempt Research](#)

Iowa State University | IRB | Policies and Guidance

[Informed Consent for non-exempt studies \(i.e. expedited or full committee\)](#)

[Checklist for Easy-to-Read Informed Consent Documents](#)

Iowa State University | IRB | Informed Consent Templates

[Consent Process](#)

Iowa State University | IRB | Policies and Guidance

[Elements of Informed Consent](#)

Iowa State University | IRB | Policies and Guidance

[Informed Consent Templates](#)

Iowa State University | IRB | Informed Consent Templates

Document History

Created/Approved: 2/2/2021
