

CONSENT DOCUMENTS

There are four basic types of consent documents:

1. Subject consent form: This is used when you have contact with subjects; subjects need to sign the form.
2. Parental/guardian consent form: This contains the same content as the subject consent form but it is written from the perspective of the parent/guardian and has subject assent lines. Often, it is not signed in the presence of the researcher.
3. Assent form: This is a simplified version of the subject consent form used with children and subjects with impaired cognitive abilities. It is written with simplified language and with simplified headings. It does not contain all of the information in a consent form.
4. Recruitment/consent e-mail and letter: This contains the same content as the subject consent form but it is presented in a letter format. It is used for surveys when there is no contact with subjects (e.g. on-line survey). No subject signature is needed as consent is implied by completion of the survey.

If your study has multiple phases and there is no contact with subjects in one phase (e.g., on-line survey) but there is contact with subjects in another phase (e.g., interview), you will need two consent documents (e.g., a recruitment/consent e-mail for an on-line survey and a subject consent form for an interview). If all phases involve contact with subjects, but performance in an initial phase determines participation in a later phase, you will need a consent form for each phase. If your study has one phase or multiple phases in which you expect subjects to participate in all phases, you only need one consent document.

Depending on the types of subjects and your specific methodology, you may need to provide separate consent documents for each type of subject. You should think about your design to determine if you can cover all types of subjects in one consent document. If this is not possible or it would be cumbersome/confusing to do so, you should use multiple consent documents. If you are studying subjects in the late teen years, it is important to consider if some of your subjects will be under age 18 and some will be over age 18. In this case, include a subject consent form for those over the age 18 and parental/guardian consent form for those under the age of 18. If your subjects include those who are cognitively impaired, you should use an adapted version of the assent form rather than a consent form.

The following pages contain information about creating each type of consent document. The information for each type contains examples for each paragraph of the document. These examples DO NOT contain every possible variation that may be needed. Be sure to follow the guidelines of what should be included in each paragraph rather than cutting and pasting the example paragraph. The information in red should be included on the consent document.

SUBJECT CONSENT FORM

The top of the consent form should have the title of your project (centered). The title should be the same as the one listed in section 1 of the IRB application. One exception is when an experimental method necessitates the true nature of the study not be revealed before participation. In this case, create a research question that is plausible given your title and methodology.

The first paragraph should state that they have been invited to participate in a study about the research question you described in number 6, section A. This should be very brief and general. Identify any cooperating agency/organization(s) listed in number 5, section A, subsection I. If your project is funded by a federal grant (number 4, section A, subsection I) or other source (number 8, section A subsection Ib), it should be disclosed here.

The next sentence should state why they were selected as a possible subject by listing the selection criteria provided in number 6 section B subsection IV. The last sentence should inform them that they should read the form and ask any questions they have before agreeing to participate in the study.

Example: You are invited to participate in a research study on the effect of frequent organizational restructure on employee perceptions. You were selected as a possible subject because you've experienced an organizational restructure a minimum of two times within the past eighteen months. Please read this form and ask any questions you may have before agreeing to participate in the study.

The second paragraph should state who is conducting the study. Include you (principal investigator) and co-investigator (if relevant—number 3, section B). In addition, indicate that the research is being conducted with the help of a research assistant (if relevant—number 3, section C)) and include the person's name. Identify the cooperating agency/organization (if relevant—number 5, section A subsection I). If the principal investigator, co-investigator, or research assistant have a relationship with a cooperating agency/organization (number 5, section A subsection II) and/or have a close relationship to potential subjects (number 9, section D, subsection I), it will need to be disclosed here. If your project is funded by a Federal grant (number 4, section A, subsection I) or another external source (number 8, section A, subsection Ib), it should be disclosed here. If you are student, you should list information about your advisor including your advisor's name, degree (e.g., Ph.D., Ed.D.), title (Adjunct Professor, Assistant Professor, Associate Professor, or Professor), and department. If a graduate student, you should indicate your degree program.

Example: This study is being conducted by me, Jane Doe, as part of the degree requirements for obtaining a Masters Degree in Social Work at Augsburg College and in cooperation with the Minnesota Department of Transportation at which I am currently an intern. My advisor is John Smith, Ph.D. an Associate Professor in the Social Work department.

The third paragraph should be titled **PROCEDURES** (left justified and in a line by itself) followed by a paragraph that describes what subjects will be asked to do. This information was provided in number 6, section B, subsections II, IV, Vb, and Vc. In addition, if you plan to record an interview, you will need to include that and be sure to indicate that the recording only will occur if granted permission.

Example: If you agree to be in this study, I will ask you and your close friend to participate in two interviews each. The first interview is a two-hour, one-on-one interview with me. (I will interview your friend separately). The second interview will be a two-hour interview with both you and your friend. If granted permission I will audiotape both interviews.

The fourth paragraph should be titled **MONETARY COMPENSATION** (left justified and in a line by itself). If not providing monetary compensation state that. If providing monetary compensation that should be stated (number 8, section A, subsection Ia). If monetary compensation is not being provided, state that.

Example: Subjects will be given a \$25 gift card to Target as a thank you gift for participating in the study. OR Subjects will receive no monetary compensation for participating in this this study.

The fifth paragraph should be titled **RISKS AND BENEFITS OF PARTICIPATING IN THIS STUDY** (left justified and in a line by itself) followed by a paragraph that describes the risk and benefits associated with participation in the study. Be sure to list the direct benefits(number 8, section B, minor subsection I, subsection ai) and indirect benefits (number 8, section B, subsection II). If there are no direct benefits, you need to state that. Be sure to include all the risks checked in number 8, section C, minor subsection I, subsection a (except inability to guarantee absolute anonymity and the use of deception). If your study could cause physical injury or psychological distress, you need to provide the referral information listed on the IRB application. If the service is free be sure to indicate that and if it is not be sure to indicate that it is the responsibility of the subject (or parents of the subject) or a third party payer to pay for the service.

*Example: **The risks to participation are** the following: possible invasion of privacy of subject or family, and probing for personal or sensitive information. There are no **direct benefits** for participating in this study. **Indirect benefits are:** Fairview Mental Health Unit may be able to use the information gathered to advocate for improved services and programs for young adults with mental illness.*

Example referral information statement: In the event that this research activity results in distress, you may contact Jane Doe, Ph.D., L.P. at 651-123-4567, ext. 555 for counseling and follow-up care as needed. Payment for treatment is the responsibility of the subject or a third party payer (e.g., personal health insurance).

The sixth paragraph should be titled **CONFIDENTIALITY** (left justified and in a line by itself) followed by a paragraph that describes the ways in which you will maintain confidentiality. This includes information from number 8, section E about “other” precautions (if they relate to confidentiality). The risk from number 8, section C minor subsection I, subsection a about the inability to guarantee absolute anonymity due to the reason listed (if relevant). As well as all of the information provided in number 10, sections A (subsection I), B (subsections Ia, II, and IIIa), and C. As well as number 8, section D, minor subsection II, subsection ai . The paragraph should begin with a sentence indicating that the records of the study will be kept confidential, unless required by law.

*Example for a study using recordings: **The records of this study will be kept confidential, unless required by law.** All data will be kept in a locked file and only the researcher and her advisor, Dr. Smith, will have access to the data. The results will be disseminated in a final paper and presented to the faculty in the Education department at Augsburg College. The paper will be placed in the Lindell Library and a copy will be given to the John Doe, the superintendent of the Rochester Public School District. The results also may be published in a professional journal or at local, regional, national, or international conferences via a poster or oral presentation. In any form of dissemination, I will not include any information that will make it possible to identify you. If granted permission, direct quotes may be used, but a pseudonym, rather than your actual name will be used. All other identifying information will be changed to protect your identity. Despite these precautions, absolute anonymity cannot be guaranteed due to the small number to be interviewed. I will be transcribing the audio*

recordings. Transcriptions and audio recordings will be kept in a locked file and only my advisor and I will have access to them.

Example for a study not using recordings and the data contain no identifying information: *The records of this study will be kept confidential, unless required by law.* Only the researcher and his advisor, Dr. Smith, will have access to the data. The results will be disseminated in a final paper and presented to the faculty in the Psychology department for departmental honors. The results also may be published in a professional journal or at local, regional, national, or international conferences via a poster or oral presentation. In any form of dissemination, I will not include any information that will make it possible to identify you because the data contain no identifying information.

Example for a study not using recordings and the data contain identifying information: *The records of this study will be kept confidential, unless required by law.* All data will be kept in a locked file and only the researcher and her advisor, Dr. Smith, will have access to the data. The results will be disseminated in a final paper and presentation to the Undergraduate Research and Graduate Opportunities Office. The results also may be published in a professional journal or at local, regional, national, or international conferences via a poster or oral presentation. In any form of dissemination, I will not include any information that will make it possible to identify you.

The seventh paragraph should be titled **VOLUNTARY NATURE OF THE STUDY** (left justified and in a line by itself). This should be followed by a paragraph indicating that the subject's decision about whether or not to participate will not affect their future or current relations with Augsburg College, the researcher (or researchers if there is a co-investigator), research assistants (if relevant) or the cooperating agency/organization (if relevant). Include the information about the required precautions to minimize risk provided in number 8, section D, subsection I and "other" precautions (number 8, section E) if they relate to the voluntary nature of the study.

Example: *Your decision about whether or not to participate in this study will not affect your current or future relations with Augsburg College, the researcher, or the Brian Coyle Center. If you decide to participate, you are free to skip questions in the interview or withdraw at any time without affecting those relationships.*

The eighth paragraph should be titled **CONTACTS AND QUESTIONS** (left justified and in a line by itself) followed by a paragraph that begins by informing subjects that may ask any questions they have now. Provide the contact information of the principal investigator, co-investigator (if relevant), and advisor (if relevant) if they have questions later. Provide both e-mail (must be an Augsburg e-mail) and phone contact information. Do not use home telephone numbers; use work or cell phone numbers. Include information about contacting the IRB (at IRB@augsborg.edu) if they have concerns/questions about their rights as a research subject or want to report problems/complaints about the research study and reference the IRB approval number (once the approval number is assigned). On a separate line, include a sentence indicating they will be given a copy of the form for their records.

Example: *You may ask any questions you have now. If you have questions later, you may contact me, Jane Doe, at 612-123-4567 or doe@augsborg.edu. You may also contact my advisor, John Smith, at 612-330-5555 or smith@augsborg.edu. If you have questions about your rights as a research subject or want to discuss problems/complaints about the research study, send an e-mail to IRB@augsborg.edu.*

You will be given a copy of this form to keep for your records.

The ninth paragraph should be titled **STATEMENT OF CONSENT** (left justified and in a line by itself) followed by consent statements to (1) participate in the study, (2) be audio or video taped (if relevant), and (3) use direct quotes (if relevant). Each consent statement should include a signature line for the subject. For the consent statement to participate in the study, you will need to include (1) a line for the subject to print their name, (2) a line for the date after the subject signature line, (3) a line for the investigator to print their name, and (4) a signature and data line for the investigator.

Example: I have read the above information or have had it read to me. I have received answers to questions asked. I consent to participate in the study.

Subject Printed Name _____

Subject Signature _____ *Date* _____

Investigator Printed Name _____

Investigator Signature _____ *Date* _____

I consent to be audio-taped

Subject Signature _____ *Date* _____

I consent to allow use of my direct quotations

Subject Signature _____ *Date* _____

PARENTAL/GUARDIAN CONSENT FORM

The content of a parental/guardian consent form is identical to that of a subject consent form. Therefore, in general, you should follow the guidelines for a subject consent form when creating one. The exceptions to the general guidelines are that parental/guardian consent forms should be written from the perspective of the parent/guardian. If the subject is capable of understanding the language in a subject consent form, you should include an assent printed name and signatures lines. If not capable of understanding the language, do not include the assent information and create an assent form.

The parent/guardian perspective in the writing is relevant in the following places on the consent form (there may be other places so be sure the perspective is maintained throughout the document):

The first paragraph

Example: You child is invited to participate in a research study about..... Your child was selected as a possible subject because.....

In many situations in which parental/guardian consent is obtained the child is bringing the consent form to their parents for permission to participate. If this is the case, the last sentence should be altered to indicate that contact information is available at the bottom of the form.

Please read this form and ask any questions you may have before agreeing to have your child participate in the study (contact information is available near the bottom of this form)

The third paragraph titled **PROCEDURES**

Example: If you agree to have your child participate in this study, I will ask your child to...

The sixth paragraph titled **CONFIDENTIALITY**

Example:In any publication or conference presentation, I will not include any information that will make it possible to identify your child. Direct quotes may be used, but a pseudonym, rather than your child's actual name will be used. All other identifying information will be changed to protect your child's identity.....

The seventh paragraph titled **VOLUNTARY NATURE OF THE STUDY**

Example: Your decision about whether or not to allow your child to participate in this study will not affect..... If you decide to allow your child to participate, they are free to skip questions in the interview or withdraw.....

If the study is taking place over a protracted time period (across days, weeks, months, or years), add the following line: *You also are free to withdraw your child from the study at any time by contacting the researcher (see contact information below).*

The eighth paragraph titled **CONTACTS AND QUESTIONS**. If you will not be present when the parent is signing the consent form, indicate that the contact information provided is for questions they have now or later.

Example: If you have any questions now or later, you may contact.....

The ninth paragraph titled **STATEMENT OF CONSENT**. If the minor is capable of understanding the information in the consent form, include assent printed name and signature lines. If the child is incapable of understanding the information in the subject consent form, create an assent form.

Example: I have read the above information or have had it read to me. I have received answers to questions asked. I consent to have my child participate in the study.

Parent/Guardian Printed Name _____

Parent/Guardian Signature _____ *Date* _____

Subject Printed Name _____

Subject Assent Signature _____ *Date* _____

Investigator Printed Name _____

Signature of investigator _____ *Date* _____

I consent to have my child audio-taped

Parent/Guardian Signature _____

Subject Assent Signature _____

I consent to allow use of my child's direct quotations

Parent/Guardian Signature _____

Subject Assent Signature _____

ASSENT FORM

The wording of the assent form may be adapted based on the age and/or ability of the subjects.

The top of the assent form should have the title of your project (centered).

In the first paragraph, you should introduce yourself and state that you are doing a research study. The next sentence should explain what a research study is, followed by your specific research question described in section 6/A of the IRB application. This should be very brief and general. The last sentence should tell them that you would like them to participate in the study.

Example: My name is John Doe and I am doing a research study. A research study is a special way to learn about something. I am doing this research in order to understand how a place, like a garden, shapes how children think about each other and the earth. I would like you to be in this research study.

The second paragraph should be titled **Why am I being asked to be in this research study?** (left justified and on a line by itself) followed by a paragraph explaining why they are being asked to participate in the study.

Example: You are being asked to be in this research study because you are in Miss Smith's kindergarten class.

The third paragraph should be titled **What will happen during this research study?** (left justified and on a line by itself) followed by a paragraph explaining what the subjects will be asked to do (if the minor will be asked to do multiple things, it is helpful to use lists), where it will take place, and how long it should last.

Example: I want to tell you about some things that will happen if you are in the study. This study will take place right after school is over. I think it will last 20 minutes.

If you want to be in this study, here are the things that I will ask you to do:

- 1. Tell me about the things you do at recess*
- 2. Draw a picture of you and your friends during recess*

The fourth paragraph should be titled **Are there any bad things that might happen during the research study?** (left justified and on a line by itself) followed by a paragraph about the risks of participating in the study.

Example: Sometimes bad things happen to people who are in research studies. These bad things are called "risks." The risks of being in this study might be that you may get sad or angry talking about your brother or sister who is sick. This may not happen to you. If it does, I will make sure that you get help to deal with those bad feelings.

The fifth paragraph should be titled **Are there any good things that might happen during the research study?** (left justified and on a line by itself) followed by a paragraph about the benefits of participating in the study.

Example: Sometimes good things happen to people who are in research studies. These good things are called “benefits.” The benefit of being in this study is that we will give you a toy dinosaur after we are done to thank you for answering my questions. Also, we hope to help other teachers learn how to teach students about dinosaurs.

The sixth paragraph should be titled **Who can I ask if I have any questions?** (left justified and on a line by itself) followed by a paragraph about who they should contact if they have questions.

Example: If you have any questions about this study, you can ask me. Also, if you have any questions that you didn't think of now, you can ask later. You can call me at 612-330-1234 or ask your parents (or guardians) to call me.

The seventh paragraph should be titled **What if I don't want to be in the study?** (left justified and on a line by itself) followed by a paragraph about the voluntary nature of the study.

Example: If you don't want to be in this study, you don't have to. It's up to you. If you say you want to be in it and then change your mind, that's OK. All you have to do is tell me that you don't want to be in it anymore. No one will be mad at you or upset with you if you don't want to be in it.

The eighth paragraph should be titled **My choice:** (left justified and on a line by itself) followed by a consent statement, subject's printed name line (an adult should print the name), subject signature line with date, investigator's (or person obtaining assent) printed name line, and signature of investigator line with date.

Example: If I write my name on the line below, it means that I want to be in this research study.

Subject's printed name _____

Signature of Subject _____ Date _____

Investigator's (or person obtaining assent) Printed Name _____

Signature of investigator (or person obtaining assent) _____ Date _____

RECRUITMENT/CONSENT LETTERS AND E-MAILS FOR SURVEYS WITH NO SUBJECT CONTACT

When utilizing a survey methodology in which the researcher has no direct contact with the subject, consent letters or e-mails are used. The communication serves as both recruitment and consent. Therefore, the content is identical to the subject consent form. However, it is written in a letter format and this leads to some changes in the order of the information.

You should begin with an opening salutation (e.g., Dear _____).

In the first paragraph, you should introduce yourself and your affiliation with Augsburg College (e.g., graduate student in social work, undergraduate student in psychology, faculty member in the business department). Include the co-investigator (if relevant—number 3, section B). Indicate that the research is being conducted with the help of a research assistant (if relevant—number 3, section C) and include the person's name. Identify the cooperating agency/organization (if relevant—number 5, section A, subsection I). If the principal investigator, co-investigator, or research assistant have a relationship with a cooperating agency/organization (number 5, section A, subsection II) and/or have a close relationship to potential subjects (number 9, section D, subsection I), it will need to be disclosed here. If you are student, you should list information about your advisor including your advisor's name, degree (e.g., Ph.D., Ed.D.), title (Adjunct Professor, Assistant Professor, Associate Professor, or Professor), and department.

Example: Hello, my name is John Doe. I am a graduate student in the Social Work Department at Augsburg College and I am interning at the Minnesota Human Services HIV/AIDS unit who is a cooperating with me to conduct this study. My advisor is Jane Smith, Ph.D., an Associate Professor in the Social Work Department.

In the second paragraph, you should invite them to be in a study about the research question you described in number 6, section A. This should be very brief and general. If your project is funded by a Federal grant (number 4, section A, subsection I) or another external source (number 8, section A subsection Ib), it should be disclosed here. The next sentence should state why they were selected as a possible subject by listing the selection criteria provided in number 6, section B, subsection IV. The last sentence should ask them to read the entire e-mail or letter before completing the survey. You should inform them how to contact you (co-investigator and advisor, if relevant), before completing the survey. Provide both phone (not a home phone number) and Augsburg e-mail contact information. Include information about contacting the IRB (at IRB@augsborg.edu) if they have concerns/questions about their rights as a research subject or want to report problems/complaints about the research study and reference the IRB approval number (once the approval number is assigned).

Example: You are invited to participate in a research study about the communication modes (email, face-to-face meetings, instant messaging, phone calls, and teleconferences) used in a health-related business environment. This project is funded by the National Healthcare Association. You were selected as a possible subject because you are a member of the Health Management division at Unity HealthCare and report to John Doe. Please read this entire e-mail before completing the survey. If you have any questions now or later, you may contact me, Jane Doe, at 612-123-4567 or doe@augsborg.edu. You also may contact my advisor, John Smith, at 612-330-5555 or

smith@augsborg.edu. *If you have questions about your rights as a research subject or want to discuss problems/complaints about the research study, send an e-mail to IRB@augsborg.edu.*

The third paragraph should inform the subjects about what they will be asked to do if they choose to participate (number 6, section B, subsections I, IV, and V, if relevant).

Example: If you agree to be in this study, I will ask you to click on the link below and complete a 25-item survey about how St. Lawrence Church is meeting your needs as a parishioner. The first 20 items are multiple choice and the last 5 are open-ended. It should take approximately 25 minutes to complete.

The fourth paragraph should describe the risks and benefits associated with participation in the study. Be sure to list the direct benefits (number 8, section B, subsection I) and indirect benefits (number 8, section B, subsection II). If there are no direct benefits, state that. If providing monetary compensation (number 8 section A subsection Ia) that needs to be stated and worded as a thank you gift for participating in the study. If not providing monetary compensation state that. Be sure to include all the risks checked in number 8 section C subsection Ia (except inability to guarantee anonymity and the use of deception). If your study could cause psychological distress or physical injury provide the referral information. If the service is free indicate that and if it is not free be sure to indicate that it is the responsibility of the subject or third-party payer (e.g., personal health insurance) to pay for the service.

Example: The risks to participation are the following: possible invasion of privacy of subject or family. There are no direct benefits to participating in this study. The indirect benefits are that the Minnesota Veteran Association may be able to use the results to advocate for improved services and programs for veterans. There will be no monetary compensation for participating in the study.

Example referral information statement: In the event that this research activity results in psychological distress, you may contact Jane Doe, Ph.D., L.P. at 651-123-4567, ext. 555 for counseling and follow-up care as needed. However, payment for treatment is the responsibility of the subject or a third party payer (e.g., personal health insurance).

The fifth paragraph should describe the ways in which you will maintain confidentiality. This includes information from number 8, section E about “other” precautions (if they relate to confidentiality), the risks from number 8, section C subsection Ia about the inability to guarantee absolute anonymity due to the stated reason (if relevant), as well as the information provided in number 10, sections A, B, and C and all subsections within A, B, and C. The paragraph you should begin with a sentence indicating that the records of the study will be kept confidential, unless required by law.

Example: The records of this study will be kept confidential, unless required by law. The results of this study will be disseminated in a final paper and presented to the faculty in the Education department at Augsburg College. The final paper will be placed in the Lindell Library. The results also may be published in a professional journal or at local, regional, national, or international conferences via a poster or oral presentation. In any publication or conference presentation, I will not include any information that will make it possible to identify you. All data will be kept in a locked file and only my advisor and I will have access to it.

The sixth paragraph should indicate that the subjects' decision about whether or not to participate will not affect their future or current relations with Augsburg College, the researcher (or researchers if there is a co-investigator), research assistants (if relevant) or the cooperating agency/organization (if relevant). Include the information about the required precautions to minimize risk from number 8, section D, subsection I but eliminate the information about withdrawing from the study. In this situation, withdrawal is equivalent to not returning the survey so there is no need to include information about it. However, you will need to include information about skipping questions. Also, include "other" precautions to minimize risk listed in number 8, section E if they relate to the voluntary nature of the study.

Example: Your decision about whether or not to participate in this study will not affect your current or future relations with Augsburg College, the researcher, or Tubman Center. If you decide to participate, you are free to skip questions on the survey without affecting those relationships.

The sixth paragraph is about consent. Subjects will not be signing a consent form but consent is implied by completion of the survey. You should include a consent statement and indicate the action that is indicative of implied consent. End with a statement indicating they may keep the e-mail or letter for their records.

Examples:

On-line survey: I have read the above information or have had it read to me. I have received answers to questions asked. Consent to participate in this study is implied by clicking on the link below and completing the survey. You may keep this e-mail for your records.

Mail survey: I have read the above information or have had it read to me. I have received answers to questions asked. Consent to participate in this study is implied by completing the attached survey and returning it to me in the self-addressed and stamped envelope. You may keep this letter for your records.

Survey delivery method of a publically available survey: I have read the above information or have had it read to me. I have received answers to questions asked. Consent is implied by completing the attached survey and placing it in the locked survey response box located on the table. You may keep a copy of this letter for your records. If you do not wish to participate, please leave this information on the table.