**Clark University**

**Social and Behavioral Consent Form Templates**

**Revised September 2, 2020**

Unless consent requirements are waived or altered by the IRB subject to federal guidelines (45 CFR 46), all participants must give informed, written consent to participate in research projects. Consent procedures and documents specific to each project are required.

Physical, signed consent forms are not always necessary for minimal risk social and behavioral research on common (non-sensitive) topics. For example, asking participants to click on an “I approve” box within an online consent form may be acceptable, as are electronic signatures in many cases. Other approaches to documenting consent for this type of research may also be approved, depending on the project. If in doubt as to what is required for your project, please contact the IRB.

Informed consent means that subjects must understand the research project, what they are being asked to do, any risks that might be involved, how their data will be collected, used and protected, and any other information that a reasonable person would want to have before deciding whether to participate. Consent must be given freely with no coercion.

The following consent form templates are designed to provide examples for some types of projects. They are provided as illustrative examples only; each consent form should include information that is useful to participants in your project. There is no “one size fits all” or default consent form suitable for all projects. ***Other types of consent forms are acceptable, as long as they are fully consistent with both federal regulations and Clark IRB policies.*** If you have questions about the structure or content of your consent form, please contact the IRB.

**General Social and Behavioral Research Consent Form Template**

**(Begins on Next Page)**

1. When preparing your final consent form, please delete these instructions – only the final consent form itself should be in the document.
2. Instructions or notes are in red. These should be deleted from the final consent form before submission to the IRB.
3. Yellow highlighted areas should be completed with information for your project. Delete these highlights before submission.
4. This example template is provided as a starting point only and does not cover all possible research contingencies. Additional or altered components might be required for particular research projects, as dictated by Clark IRB policy and federal regulations.
5. Do not adjust the margins – these are set to allow space for the required approval stamp at the bottom of the consent form.

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**Social and Behavioral Research Consent Form**

Title of Research Study: Title

Person in Charge of the Study: Name and affiliation with Clark University

*(principal investigator)* Phone number

 Email

*(Add additional investigators if necessary.)*

Researcher Supervisor: Name and affiliation with Clark University

*(for student projects)* Phone number

 Email

By signing this form, you are giving your consent to participate in a research study on *(describe the project and* ***the purpose of the research*** *in non-technical language)*. *(Note: the IRB can waive or adapt this element if the study requires deception. In such cases, a debriefing statement should also be used to inform participants at an appropriate time after their involvement in the study.)*

**Procedures:** Your participation in this study, should you consent, will involve *(describe* ***all study procedures*** *in simple language. All procedures should be described, and any experimental procedures [interventions, manipulations, treatments] specifically noted. Mention video/audio taping, if applicable. Include types of questions that will be asked, if applicable.).*

**Duration:** Your participation will take approximately *(describe expected* ***duration*** *of participation, including the duration of individual study procedures, as applicable. Describe any follow-up contacts or participation that might be involved.).*

**Eligibility and Subjects:** *(Describe who is eligible for the study and why they have been chosen as a potential subject, along with the total number of subjects to be enrolled. This is not required for all research projects but is needed in some cases for subjects to fully understand the research and why they were chosen as a potential subject. Also if applicable, describe the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.)*

**Benefits:** The benefits you may receive from participating in this study include *(describe any* ***benefits****; if none, state as such, e.g., We do not anticipate that you will receive any direct benefits from participating in this study).* However, we cannot guarantee that you will receive any benefits *(if applicable)*. The benefits to society *(or scientific knowledge)* may include *(describe indirect benefits to society or knowledge)*. *(Or include a statement such as: We expect that this study will (describe social benefits of study).*

**Risks:** The risks *(and/or harms or discomforts)* associated with this study include *(describe* ***foreseeable risks, harms or discomforts*** *to subjects, including legal, physical, social, economic or emotional risks. Make sure to include any risks associated with loss of confidentiality, if relevant. If there are no known risks, replace this statement with: I/We do not anticipate any risks from participating in this research).*If you experience *(describe risk, harm or discomfort)*, *(describe what should be done or the treatment or therapy options that are available, including the people or groups that can be contacted and how, with contact information. A separate list of, e.g., treatment options may also be provided with the consent form. If so, reference this list here.)*.

**Voluntary Participation:** Your participation in this study is entirely voluntary. You have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to refuse to answer any question and participate in any study procedure without penalty. Your participation in this study will not affect your *(describe as appropriate, e.g., employment; medical care; grades in a class, etc.). (Provide any other details related to voluntary participation.)* *(If applicable:)* If you wish to withdraw from this study, please *(provide instructions for withdrawal)*. *(Note: If applicable, provide information on whether and how subjects can review and withdraw their data or responses once they have been provided, and the lack of penalty for doing so.) (Note: If completing particular tasks (e.g., answering certain survey or interview questions) is required for participation, you must make this condition clear to them. State that they can choose not to participate if they are uncomfortable with these conditions.)*

**Confidentiality and Data Security:** Your *(e.g., participation in, responses to, data in)* this study will be *(e.g., describe data privacy, e.g., confidential, anonymous).* Confidentiality *(or anonymity)* will be protected by **(***explain briefly, and in simple terms, how you will protect the participant’s privacy and/or confidentiality.* *Describe the extent, if any, to which confidentiality (or alternatively, anonymity) of records identifying the subject will be maintained, and primary procedures to ensure confidentiality, including measures for data coding, storage and security. Discuss de-identification of data, as applicable. Note that collection of a signed consent form is typically inconsistent with anonymity, as it enables the researcher to see who has participated and potentially link an individual to their responses).*

*Note: In general, confidentiality of the data should be the default condition. Relevant information in this section can include:*

* + *Whether you are planning not to collect any identifying information (as in anonymous surveys). If you are planning to collect identifying information, whether you will de-identify data or keep any identifying information separate from research data (e.g. signed consent forms kept separate from the survey data). If you plan to keep identifying information with the data, this should also be stated.*
	+ *Steps that will be taken to ensure security of data & research files, including physical and electronic security (e.g., password protection, encryption, access to storage devices), who will have access to the data and any identifying information, etc.*
	+ *For confidential data, include a statement that the data will not contain names or any other information allowing direct identification of individual participants; participants will be identified by code number or random pseudonyms only.*
	+ *For focus groups or other research involving group interactions, include a statement that there is an inherent risk of violation of confidentiality, due to the possibility that participants might discuss what was said outside the focus group.*
	+ *When Skype or similar technologies are used for interviews, there will be a provision for ensuring that the username will not be associated with the data.*
	+ *If applicable, include a statement that when photographs or videos are used, researchers cannot guarantee confidentiality of participant data. The consent form must describe this explicitly and request consent for these methods to be used.*
	+ *When recording interventions via Skype or similar technologies, the consent form should indicate whether only the audio portion (or both video and audio) will be retained.*
	+ *If data are not confidential, this must be stated clearly, along with any associated risks or ramifications. Justification for this must be provided in your IRB application.*
	+ *If subjects will be given the opportunity to voluntarily waive confidentiality, the consent form or statement must describe this (along with any risks and ramifications) and provide a means for subjects to indicate their agreement to such a waiver.))*

**Compensation:** You will receive *(compensation)* for participating in this study. *(Provide any other information relevant to the receipt of compensation and what must be done to receive it.)*

**Data Use and Sharing:** The results of this research study may be presented at scientific or professional meetings or published in scientific journals *(or, describe what will be done with them)*. Your individual privacy will be maintained in all published and written data resulting from the study. *(If identities will be disclosed, provide details: With your permission, your identity will be made known in written materials resulting from the study. Note: If this is done, any potential risks or harms must be described.)* The data from this study will be kept by the research team *(for X years before it is destroyed, or indefinitely. Note: federal regulations require keeping all research records for three years)*. *A statement such as the following is recommended, if applicable, to enable subsequent sharing of de-identified data:* De-identified (confidential) data from this study may be with other researchers or posted on data repositories beyond the research team, without additional consent from you. To protect your confidentiality, we will remove or code any personal information that could identify you before files are shared. *In addition, if you are collecting identifiable data or biospecimens, include one of the following:* **The de-identified data from this study might be used for future research without additional consent. -***or-* **Your identifiable information from this study might be used for future research after obtaining your consent. -***or-* **Your data from this study will not be used or distributed for future research studies.**

**Who to Contact:** If you have questions about the study, please contact *(name and contact information)*.

*(If applicable)* I give consent to be audio recorded during this study.

 \_\_\_Yes \_\_\_No

*(If applicable)* I give consent to be video recorded during this study:

 \_\_\_Yes \_\_\_No

*(If applicable)* I give consent for the *(audio or video)* recordings from this study to be used for *(describe proposed use of recordings)*:

 \_\_\_Yes \_\_\_No

*(If applicable)* I give consent to *(any other procedures that require individual consent)* during this study:

 \_\_\_Yes \_\_\_No

*(If applicable)* I give consent for my identity to be revealed in written or presented materials resulting from this study: *(Note: If this is an option, the risks and ramifications must be described above.)*

 \_\_\_Yes \_\_\_No

By signing below, I verify that I have read this consent form and agree to participate in study. I have been given a copy of this consent form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Signature) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Printed Name)

*This study has been approved by the Clark Committee for the Rights of Human Participants in Research and Training Programs (IRB). Any questions about human rights issues should be directed to the IRB Chair, Dr. Robert J. Johnston (508) 751-4619.*

*Note: If you will* ***not*** *be using oral documentation of consent, delete the following section.*

**Oral Consent Documentation:**

The study participant ID/Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has declined to sign this form. I have instead read her/him the consent statement above *(or, given him/her this form to read)*, and s/he has given consent to participate in this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Signature & Printed Name of person documenting consent)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Date)

**Confidential Interview Consent Form Example**

**(Minimal Risk & Non-Sensitive Topic)**

1. For minimal risk social and behavioral research such as interviews and surveys, simplified consent forms and procedures are often acceptable. The following is an illustrative consent form template for a minimal risk, confidential interview.
2. When preparing your final consent form, please delete these instructions – only the final consent form itself should be in the document.
3. Instructions or notes are in red. These should be deleted from the final consent form before submission to the IRB.
4. Yellow highlighted areas should be completed with information for your project. Delete these highlights before submission.
5. Do not adjust the margins – these are set to allow space for the required approval stamp at the bottom of the consent form.

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**Interview Consent Form**

Title of Research Study: Title

Person in Charge of the Study: Name and affiliation with Clark University

*(principal investigator)* Phone number

 Email

*(Add additional investigators if necessary.)*

Researcher Supervisor: Name and affiliation with Clark University

*(for student projects)* Phone number

 Email

The signing of this form constitutes consent to participate in a *(duration)* minute interview being conducted by *(researcher name)*, *(professor, student, etc.)* in *(department or unit)* at Clark University. This project is funded by *(describe funding, if applicable)*. The purpose of this study is to *(goal or purpose of study)*. The interview questions will address *(question topics)*. You are being paid $ *(or, You are not being paid)* for this interview, and your participation may *(describe impacts or benefits of the study to the person and/or society)*. The interview will be audio recorded and transcribed *(or describe how data will be collected)*.

Your participation in this study is entirely voluntary. You are free to terminate your participation in this research at any time, or to refuse to answer any questions to which you do not want to respond without penalty. Your participation in this study is confidential. Neither recordings nor interview transcripts will contain names or any other information allowing identification of individual participants; participants will be identified by code number only. If you wish to stop participating, please *(describe what they should do, e.g., inform the interviewer)*. *(Note: If applicable, provide information on whether and how subjects can review and withdraw their data or responses once they have been provided, and the lack of penalty for doing so.) (Note: If completing particular tasks (e.g., answering certain survey or interview questions) is required for participation, you must make this condition clear to them. State that they can choose not to participate if they are uncomfortable with these conditions.)*

The confidential results of this research study will be *(describe what will be done with results, how they will be presented, etc.)*. Your individual privacy will be maintained in all presentations and reports resulting from the study. *If Applicable, add:* De-identified (confidential) data from this study may be shared with other researchers, posted on data repositories or used for future research without additional consent from you. To protect your confidentiality, we will remove or code any personal information that could identify you before files are shared or posted. *(or, describe other intended procedures for data sharing, de-identification, reporting, etc.)*

Signed consent forms will be *(where consent forms will be stored and how they will be protected, e.g., stored in a locked storage area in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at Clark University, separate from audio recordings and transcripts)*. Recordings and transcripts will be stored in electronic form only, in password protected files on *(where stored, e.g., whose computer, and provide any other relevant details)*, assessable only to *(who will have access to the data)*. Recordings will be destroyed *(when, or kept indefinitely;* *federal regulations require keeping research records for three years)*. Password protected transcript files will be retained *(how long, or indefinitely)*. If you have questions or concerns about this study, you may contact *(name and contact information)*.

By signing below, I verify that I have read this consent form and agree to participate in this audio-recorded interview. I have been given a copy of this consent form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Signature) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Printed Name)

*This study has been approved by the Clark Committee for the Rights of Human Participants in Research and Training Programs (IRB). Any questions about human rights issues should be directed to the IRB Chair, Dr. Robert J. Johnston (508) 751-4619.*

**Confidential or Anonymous Online Survey Consent Form Example**

**(Minimal Risk & Non-Sensitive Topic)**

1. For minimal risk social and behavioral research such as interviews and surveys, simplified consent forms and procedures are often acceptable. The following is an illustrative consent form template for a minimal risk, confidential or anonymous online survey.
2. When preparing your final consent form, please delete these instructions – only the final consent form itself should be in the document.
3. Instructions or notes are in red. These should be deleted from the final consent form before submission to the IRB.
4. Yellow highlighted areas should be completed with information for your project. Delete these highlights before submission.
5. Do not adjust the margins – these are set to allow space for the required approval stamp at the bottom of the consent form.

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**Survey Consent Form**

Title of Research Study: Title

Person in Charge of the Study: Name and affiliation with Clark University

*(principal investigator)* Phone number

 Email

*(Add additional investigators if necessary.)*

Researcher Supervisor: Name and affiliation with Clark University

*(for student projects)* Phone number

 Email

**Purpose of the Study**

By pressing the “I Agree” button below, you consent to participate in an online survey being conducted by *(researcher name)*, *(professor, student, etc.)* in *(department or unit)* at Clark University. This project is funded by *(describe funding, if applicable)*. The purpose of this study is to *(goal or purpose of study)*. The survey questions will address *(question topics)*. You are being paid $ *(or, You are not being paid)* for completing this survey, and your participation may *(describe impacts or benefits of the study to the person and/or society)*. The survey takes most people about *(duration)* to complete. *If applicable, add:* As part of this study, you will be asked to answer *(number)* brief introductory screening questions. If you qualify to participate based on your answers to the screening questions, you will be directed to the full survey.

**Your Participation is Voluntary**

Your participation in this study is entirely voluntary. You are free to stop taking this survey at any time, or to refuse to answer any questions to which you do not want to respond without penalty. If you wish to stop participating, please *(describe what they should do, e.g., stop taking the survey and close your browser)*. *(Note: If completing particular tasks (e.g., answering certain survey or interview questions) is required for participation or compensation, you must make this condition clear to them. State that they can choose not to participate if they are uncomfortable with these conditions.)*

**Confidentiality and Data Security**

Your participation in this study is confidential *(or anonymous, if applicable)*. The survey data will not contain names or any other information allowing identification of individual participants; your survey responses will be identified by number only *(or describe how surveys will be coded and confidentiality or anonymity protected)*. *(Add any other relevant information. If applicable, add information on follow-ups and de-identification such as:* This number lets us know you have completed the survey, so that we will not send you reminders. Once we have received your completed survey, we will delete your name from all lists, so that your responses can never be traced back to you.*)* The confidential *(or anonymous)* results of this research study will be *(describe what will be done with results, how they will be presented, etc.)*. Your individual privacy *(or anonymity)* will be maintained in all presentations and reports resulting from the study.[[1]](#footnote-1) *If Applicable, add:* De-identified (confidential) *(or anonymous)* data from this study may be shared with other researchers, posted on data repositories or used for future research without additional consent from you. To protect your confidentiality, we will remove or code any personal information that could identify you before files are shared or posted. *(or, describe other intended procedures for data sharing, de-identification, reporting, etc. This is important, because it ensures that you can share and post your data without requiring additional consent from subjects. This statement is not required for anonymous data.)*

**Risks and Discomforts**

This study is minimal risk—taking this survey involves no risks other than those associated with regular day-to-day activities (such as using a computer). *(If applicable, describe any details relative to minimal discomforts and measures to reduce them, e.g., if the length or complexity of this survey causes fatigue, you may take as many breaks from survey as needed, as long as you finish the survey within X minutes.)*

**If You Have Questions**

If you have questions about this study, you may contact *(name and contact information)*.

**Approval for This Study**

This study has been approved by the Clark Committee for the Rights of Human Participants in Research and Training Programs (IRB). Any questions about human rights issues should be directed to the IRB Chair, Dr. Robert J. Johnston (508) 751-4619.

**Your Consent**

By clicking the “**I agree**” button below, I confirm that I am at least 18 years of age, I have read and understood this form, and agree to participate in all parts of the study as described above.

To participate in this survey, please click the "**I agree**" button.

If you do NOT want to participate, please click the "**I decline**" button.

Please **print or save a copy** of this form for your records before pressing one of these buttons.

**[I agree] button [I decline] button**

 *(The following is not required for many types of surveys, but may be required by the IRB in some cases, e.g., where accidental disclosure of the data would be associated with non-minimal risk:* The data from this study will be stored in electronic form only, in password protected files on *(where stored, e.g., whose computer)*, and will be assessable only to *(who will have access to the data)*. The data will be kept *(for how long before it is destroyed, or indefinitely; federal regulations require keeping research records for three years)*.*)*

**Focus Group Consent Form Example**

**(Minimal Risk, Non-Sensitive Topic, Confidential)**

1. For minimal risk social and behavioral research such as interviews and surveys, simplified consent forms and procedures are often acceptable. The following is an illustrative consent form template for a minimal risk, confidential focus group.
2. When preparing your final consent form, please delete these instructions – only the final consent form itself should be in the document.
3. Instructions or notes are in red. These should be deleted from the final consent form before submission to the IRB.
4. Yellow highlighted areas should be completed with information for your project. Delete these highlights before submission.
5. Do not adjust the margins – these are set to allow space for the required approval stamp at the bottom of the consent form.

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**Focus Group Consent Form**

Title of Research Study: Title

Person in Charge of the Study: Name and affiliation with Clark University

*(principal investigator)* Phone number

 Email

*(Add additional investigators if necessary.)*

Researcher Supervisor: Name and affiliation with Clark University

*(for student projects)* Phone number

 Email

The signing of this form constitutes consent to participate in a *(duration)* minute focus group being conducted by *(researcher name)*, *(professor, student, etc.)* in *(department or unit)* at Clark University. A focus group is a small group discussion with 6-12 participants. The purpose of this study is to *(goal or purpose of study)*. If you choose to participate, you will engage in a moderated, informal discussion about *(topic)*. This project is funded by *(describe funding, if applicable)*.

You are being paid $ *(or, You are not being paid)* for this focus group, and your participation may *(describe impacts or benefits of the study to the person and/or society)*. The focus group will be audio recorded and transcribed *(or describe how data will be collected)*.

Your participation in this study is entirely voluntary. You are free to terminate your participation in this research at any time, or to refuse to answer any questions to which you do not want to respond without penalty. Your participation in this study is confidential. Neither recordings nor transcripts will contain names or any other information allowing identification of individual participants; participants will be identified by code number only.

In any focus group, there is a possibility that other group participants might reveal what you say outside the group. To help ensure confidentiality, please do not mention your name, or the name of any other participant during the focus group. Please do not discuss the details or participants in this focus group outside of the session.

If you wish to stop participating in this focus group, please *(describe what they should do, e.g., inform the moderator)*. *(Note: If applicable, provide information on whether and how subjects can review and withdraw their data or responses once they have been provided, and the lack of penalty for doing so.) (Note: If completing particular tasks (e.g., completing the focus group) is required for participation, you must make this condition clear to them. State that they can choose not to participate if they are uncomfortable with these conditions.)*

The confidential results of this research study will be *(describe what will be done with results, how they will be presented, etc.)*. Your individual privacy will be maintained in all presentations and reports resulting from the study. *If Applicable, add:* De-identified (confidential) data from this study may be shared with other researchers, posted on data repositories or used for future research without additional consent from you. To protect your confidentiality, we will remove or code any personal information that could identify you before files are shared or posted. *(or, describe other intended procedures for data sharing, de-identification, reporting, etc.)*

Signed consent forms will be *(where consent forms will be stored and how they will be protected, e.g., stored in a locked storage area in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at Clark University, separate from audio recordings and transcripts)*. Recordings and transcripts will be stored in electronic form only, in password protected files on *(where stored, e.g., whose computer, and provide any related details)*, assessable only to *(who will have access to the data)*. Recordings will be destroyed *(when, or kept indefinitely; federal regulations require keeping research records for three years)*. Password protected transcript files will be retained *(how long, or indefinitely)*. If you have questions or concerns about this study, you may contact *(name and contact information)*.

By signing below, I verify that I have read this consent form and agree to participate in this audio-recorded focus group. I have been given a copy of this consent form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Signature) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Printed Name)

*This study has been approved by the Clark Committee for the Rights of Human Participants in Research and Training Programs (IRB). Any questions about human rights issues should be directed to the IRB Chair, Dr. Robert J. Johnston (508) 751-4619.*

1. [↑](#footnote-ref-1)