

***Informed Consent Form Template***  
*Updated 10/22/2018*

Notes to Researchers:

Any researcher who intends to work with human subjects should seek legally effective "informed consent from each prospective subject or the subject's legally authorized representative." Under federal regulations, this is mandatory rather than an optional matter because informed consent is "one of the primary ethical requirements underpinning research with human subjects," reflecting the principle of respect for persons.

Below you will find details on how to prepare an informed consent form. Once you have completed it, you will submit it along with your application and any other required documents.

### **Preparing an Informed Consent Document**

In reviewing your application, the IRB reader will look for an informed consent document. . The informed consent document consists of two parts: the information sheet and the consent certificate. The documents should contain all of the following information:

1. The document describes, briefly and simply, **what the research is about**.
2. It tells the subjects **what they will be asked** to do and for how long.
3. It explains any **risks and benefits**. If there is no direct benefit to the subject, the document should explain what the study hopes to discover and why.
4. If you promise to **protect your subjects' identity**, you must describe how you will do this. If it is impossible for you or anyone else to link the data you collect to a specific person, then you may promise to guarantee the subjects' anonymity. However, in most cases it will be possible to use your records to identify a subject. In that case, the most you can promise is to keep the subjects' personal information private to the extent allowed by law.
5. The document describes any **compensation** the subject will receive and conditions under which no payment or partial payment will be made.
6. The document makes it clear that **participation is voluntary**.
7. It tells subjects that they may skip questions or withdraw from the study at any point **without penalty**.
8. It gives the subjects the names, addresses, and telephone numbers or e-mail addresses of **persons to contact** if they have questions or concerns about the study. The IRB asks that name, address, and telephone number or e-mail address be included for the investigator and his or her faculty advisor (if the investigator is a student).

9. It tells subjects that if they have questions or concerns, they may also **contact the IRB chair**, c/o the Office of the Associate Dean of the college (see examples below).
10. It does not contain "**exculpatory language**." Subjects must not be asked to waive (or appear to waive) any of their legal rights, nor may they be asked to release the investigator, any funding organization, or Anoka-Ramsey Community College from liability for negligence. By signing the consent document, the subject is not "signing away" any rights. Their signature merely indicates that the subject has read the document or has had it read to him/her, has had a chance to discuss it with the investigator, and understands it.

Information in the consent document should be presented to prospective subjects "**in a language they can understand**." The reading level of the consent form should match the reading level and background of the subjects. In some cases the document may need to be translated into another language. It is best to use simple declarative sentences and avoid abstract, academic words and phrases. It is best to construct the consent form **using "you"** rather than "I" because it may be unclear whether "I" refers to the investigator or to the subject.

If the prospective subject uses a language that the investigator does not speak, it might be necessary to have a **translator** present who will go over the document point-by-point with the subject. If the prospective subject speaks English but does not read it, the investigator may be the one to go over the document orally with the subject.

The federal regulations emphasize that an investigator should get **signed consent**. If a subject is a *minor* (a person under age 18 in Minnesota, or below the age of majority in the state or country where he/she lives), the signed consent of a parent or legal guardian is required. Ordinarily the investigator should give one (signed) copy of the consent form for the subject to keep, and retain another (signed) copy with the project records.

In unusual circumstances, the IRB may waive some points that are usually covered in the consent document. In some cases the IRB may determine that your research is "exempt" under Federal Guidelines, which may mean that you will not need to employ a consent form. It is in your interest to submit a consent form anyway to avoid unnecessary delays in reviewing your application.

TEMPLATE ON FOLLOWING PAGE



## ANOKA-RAMSEY COMMUNITY COLLEGE

[Informed Consent Form for \_\_\_\_\_]

Name the group of individuals for whom this consent is written and the project.

*(Example: This informed consent form is for students at X college who we are inviting to participate in research Y, titled "The Community Response to Malaria Project".)*

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principle Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Project and Version]

**This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

**You will be given a copy of the full Informed Consent Form**

### **Part I: Information Sheet**

#### **Introduction**

Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at anytime.

#### **Purpose of the research**

Explain the research question in lay terms which will clarify rather than confuse. Use simplified words rather than scientific terms and professional jargon. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by the Institutional Review Board.

#### **Type of Research Intervention**

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves an interview, a questionnaire, or something else.

*(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one hour interview).*

#### **Participant Selection**

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

*(Example: You are being invited to take part in this research because we feel that your experience as a student (or as a community member) can contribute much to our understanding and knowledge of local education practices.)*

## **Voluntary Participation**

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate.

*(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Institution will continue and nothing will change.*

*OR*

*The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)*

## **Procedures**

A. Provide a brief introduction to the format of the research study.

*(Example: We are asking you to help us learn more about education in your community. We are inviting you to take part in this research project. If you accept, you will be asked to.....:)*

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

*Example (for interviews)*

*During the interview, I or another interviewer will sit down with you in a comfortable place at the College. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after \_\_\_\_\_number of days/weeks.*

*Example for questionnaire surveys)*

*You will be asked to fill out a survey which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys].OR You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down.*

*If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)*

## **Duration**

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

*(Example: The research takes place over \_\_\_ (number of) days/ or \_\_\_ (number of) months in total. During that time, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)*

## **Risks**

Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

*(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview")*

*OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)*

### **Benefits**

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

*(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community).*

### **Reimbursements**

State clearly what you will provide the participants with as a result of their participation. The college does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These may include, for example, travel costs and reimbursement for time lost. The amount should be small enough that it would not be seen as coercive in the consent process.

*Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).*

### **Confidentiality**

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

*(We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, etc])*

### **The following applies to focus groups:**

Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

*(Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)*

### **Right to Refuse or Withdraw**

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

*(Example: You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)*

### **Whom to Contact**

Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted. State also the name (and contact details) of the local IRB that has approved the proposal.

*(Example: If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]*

*This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact \_\_\_\_\_.)*

**This proposal has been reviewed and approved by the Anoka-Ramsey Community College Institutional Review Board, which is a committee tasked with ensuring that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, phone number.]).**

You can ask me any more questions about any part of the research study, if you wish to.  
Do you have any questions?

**Part II: Certificate of Consent**

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this.

**(This section is mandatory)**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study**

**Print Name of Participant** \_\_\_\_\_

**Signature of Participant** \_\_\_\_\_

**Date** \_\_\_\_\_  
Day/month/year

*If subject is a minor <sup>1</sup>*

**Print name of Parent/Guardian** \_\_\_\_\_

**Signature of Parent/Guardian** \_\_\_\_\_

**Date** \_\_\_\_\_  
Day/month/year

**Statement by the researcher/person taking consent**

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this ICF has been provided to the participant.**

**Print Name of Researcher/person taking the consent** \_\_\_\_\_

**Signature of Researcher /person taking the consent** \_\_\_\_\_

**Date** \_\_\_\_\_  
Day/month/year

\_\_\_\_\_