ANTIOCH UNIVERSITY

**INSTITUTIONAL REVIEW BOARD**

## SAMPLE CONSENT, ASSENT & PERMISSION FORMS

The following templates and samples are provided for investigators who are designing consent, assent, or permission forms for research with human participants.

Theses forms are not intended as boilerplate text. Revise bracketed and example-specific text in the forms as appropriate to your project, keeping in mind best practices for informed consent.

**All forms must include the required elements described in the *AU Investigator's Handbook for the Protection of Human Participants in Research*.**

**Sample Forms** **Page**



This material was based, in part, on information from the following sources:

- The IRB Guidebook, Prepared by The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (2014).
- Levine, Robert J. Ethics and Regulation of Clinical Research, Urban & Schwarzenberg, Baltimore-Munich (1981).
- Sample Volunteer Consent Forms. Prepared by the Indian Health Service (William L. Freeman, MD, MPH, Chair, National IHS IRB, 2000).

## CONSENT FORM TEMPLATE #1

Project Title:_____
Project Investigator:_____
Dissertation Chair:_____

1. I understand that this study is of a research nature. It may offer no direct benefit to me.
2. Participation in this study is voluntary. I may refuse to enter it or may withdraw at any time without creating any harmful consequences to myself. I understand also that the investigator may drop me at any time from the study.
3. The purpose of this study is:_____ (to be filled in by investigator).
4. As a participant in the study, I will be asked to take part in the following procedures:
   [to be filled in by investigator]

   Participants in the study will take _____ of my time and will take place in _____.

5. The risks, discomforts and inconveniences of the above procedures might be:

   (to be filled in by investigator)

6. The possible benefits of the procedure might be:
   a. Direct benefit to me:
   b. Benefits to others:

7. Information about the study was discussed with me by _____. If I have further questions, I can call him/her at _____.
8. Though the purpose of this study is primarily to fulfill my requirement to complete a formal research project as a dissertation at Antioch University, I also intend to include the data and results of the study in future scholarly publications and presentations. Our confidentiality agreement, as articulated above, will be effective in all cases of data sharing"

If you have any questions about the study, you may contact [Dr. P. Investigator], at telephone # (XXX-XXX-XXXX) or via email at [insert email address here]. (Note: we do not recommend that investigators provide their home phone number here. A campus office phone number is more appropriate.)

If you have any questions about your rights as a research participant, you may contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

Date:_____ Signed:_____

## CONSENT FORM TEMPLATE #2

This informed consent form is for [BRIEF DESCRIPTION OF WHY THE PARTICIPANTS ARE] who we are inviting to participate in a research project titled "[TITLE OF RESEARCH]".

Name of Principle Investigator:
Name of Organization: Antioch University, PhD in Leadership and Change Program
Name of Project: [NAME]

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

Introduction
I am [NAME], a student in [NAME OF DEGREE PROGRAM]. As part of this degree, I am completing a project to [SHORT DESCRIPTION OF PURPOSE OF THE PROJECT]. I am going to give you information about the study and invite you to be part of this research. You may talk to anyone you feel comfortable talking with about the research, and take time to reflect on whether you want to participate or not. You may ask questions at any time.

Purpose of the research
The purpose of this project is to [SHORT DESCRIPTION OF PURPOSE OF THE PROJECT]. This information will may us to better understand [SHORT IDENTIFICATION OF POTENTIAL VALUE – AVOIDING OVERSTATEMENT THAT COULD BE SEEN AS COERCIVE].

Type of Research Intervention
This research will involve your participation in a [NAME ALL TYPES OF PARTICIPATION], where your [SHORT DESCRIPTION OF PURPOSE OF THE INTERVIEW]. Each of these interviews will be tape recorded solely for research purposes, but all of the participants' contributions will be de-identified prior to publication or the sharing of the research results. These recordings, and any other information that may connect you to the study, will be kept in a locked, secure location.

Participant Selection
You are being invited to take part in this research because [NAME INCLUSION CRITERIA]. You should not consider participation in this research if [NAME EXCLUSION CRITERIA].

Voluntary Participation
Your participation in this study is completely voluntary. You may choose not to participate. You will not be penalized for your decision not to participate or for anything of your contributions during the study. IF THIS IS WORKPLACE RESEARCH INCLUDE THIS NEXT SENTENCE: Your position in the [NAME WORKPLACE OR SCHOOL DISTRICT] will not be affected by this decision or your participation. You may withdraw from this study at any time. If an interview has already taken place, the information you provided will not be used in the research study.

Risks
No study is completely risk free. However, I do not anticipate that you will be harmed or distressed during this study. You may stop being in the study at any time if you become uncomfortable If you

experience any discomfort as a result of your participation, employee assistance counselors will be available to you as a resource.

Benefits
There will be no direct benefit to you, but your participation may help others in the future.

Reimbursements
You will not be provided any monetary incentive to take part in this research project.
OR [USE ONE OR THE OTHER STATEMENT AND DELETE THE OTHER]
You will be provided [IDENTIFY COMPENSATION]

Confidentiality
All information will be de-identified, so that it cannot be connected back to you. Your real name will be replaced with a pseudonym in the write-up of this project, and only the primary researcher will have access to the list connecting your name to the pseudonym. This list, along with tape recordings of the discussion sessions, will be kept in a secure, locked location.

Limits of Privacy Confidentiality
Generally speaking, I can assure you that I will keep everything you tell me or do for the study private. Yet there are times where I cannot keep things private (confidential). The researcher cannot keep things private (confidential) when:

- The researcher finds out that a child or vulnerable adult has been abused
- The researcher finds out that that a person plans to hurt him or herself, such as commit suicide,
- The researcher finds out that a person plans to hurt someone else,

There are laws that require many professionals to take action if they think a person is at risk for self-harm or are self-harming, harming another or if a child or adult is being abused. In addition, there are guidelines that researchers must follow to make sure all people are treated with respect and kept safe. In most states, there is a government agency that must be told if someone is being abused or plans to self-harm or harm another person. Please ask any questions you may have about this issue before agreeing to be in the study. It is important that you do not feel betrayed if it turns out that the researcher cannot keep some things private.

Future Publication
The primary researcher, [YOUR NAME] reserves the right to include any results of this study in future scholarly presentations and/or publications. All information will be de-identified prior to publication.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so, and you may withdraw from the study at any time without your job being affected.

Who to Contact
If you have any questions, you may ask them now or later. If you have questions later, you may contact [YOUR NAME AND ANTIOCH EMAIL ADDRESS]

If you have any questions about your rights as a research participant, you may contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

This proposal has been reviewed and approved by the Antioch International Review Board (IRB), which is a committee whose task it is to make sure that research participants are protected. If you wish to find out more about the IRB, contact Dr. Lisa Kreeger.

DO YOU WISH TO BE N THIS STUDY?
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

DO YOU WISH TO BE AUDIOTAPED IN THIS STUDY? [IF AUDIOTAPING KEEP THIS IN. DELETE IF NOT]
I voluntarily agree to let the researcher audiotape me for this study. I agree to allow the use of my recordings as described in this form.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

*To be filled out by the researcher or the 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 Informed Consent Form 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

## ANONYMOUS NON-SENSITIVE SURVEY OF ADULTS

*Background: This form might be used for an anonymous survey of adults in which no sensitive information is sought. Thus, the research would be no more than minimal risk. Even though a signed consent form is not required in this type of research, the subjects must still be given the same information that they would receive in a consent form. This information should be presented in an instruction sheet attached to survey.*

**Health Care Research Study**

Researchers at Antioch University are asking you to fill out a survey about what services NoName Clinic patients need.

The Researchers want to know what Clinic patients think about the health care services they are receiving and what other services they might need. We will use the results of the survey to plan for better health care services for everyone. We are asking all adult patients seen by the NoName Clinic, and parents of children, to fill out the form. There are no risks to you in taking part, because we are not asking for any names and no one can know who filled out a form. It takes about 10 minutes to finish.

Taking part is voluntary.

If you choose not to fill out the survey, there will be no penalty and it will not affect any services or other benefits you might receive from NoName Clinic. If you do fill out the survey, you may leave any question blank, but we ask you to answer as many questions as you can.

If you have any questions about the study, you may contact [Dr. P. Investigator], at telephone # (XXX-XXX-XXXX) or via email at [insert email address here]. (Note: we do not recommend that investigators provide their home phone number here. A campus office phone number is more appropriate.)

If you have any questions about your rights as a research participant, you may contact Dr. [insert name and of local IRB Chair], Chair of the Antioch University [insert local campus name] IRB, [insert telephone number of IRB Chair] or [Insert name of local campus chief academic officer, title, and telephone number].

## INTERNET SURVEY

Dear [describe participant],
This is a survey about [short description of what the research is about]. This survey will give you an opportunity to [short description of benefits – if any – should not be overstated].

Your responses will [short description of purpose of research].

There are minimal, if any, risks from participating. Your identity will be anonymous and confidential. You will not be asked for your name and all demographic data being collected will be reported as aggregated information. No personally identifiable information will be associated with your responses to any reports of these data. The survey will take approximately [time in minutes]to complete.

This survey is part of my dissertation research at Antioch University in the PhD in Leadership and Change Program. he study results may be included in future presentations and publications.

Your participation is voluntary and you may elect to discontinue your participation at any time. If you have any questions about the survey or the research study, please contact me at:
[your contact information]

This project has been approved by the Institutional Review Board at Antioch University. If you have any questions about your rights as a research participant, please contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

I have read and understood the above information. By clicking "Next" below, I am indicating that I have read and understood this consent form and agree to participate in this research study.

Please print a copy of this page for your records.

Thank you for your participation!

## PARENTAL PERMISSION #1

Date
Dear
This year I am enrolled in a Master's of Education program at Antioch University New England. Part of my required coursework includes a Master's Project. My project is focused on…
This work will contribute to my work and the experience of the students by…

I will be reading books and articles, attending workshops and seeking other resources to inform myself about… (the topic). I will collect information from activities in the classroom and conversations with students. The project will include… (surveys, interviews, observations, etc.). These activities will not interfere with classroom time, or involve any risk. The project will help to inform my practice, my knowledge about learning processes, and the students.

The results of this project may be used for classroom discussion in my graduate work, professional presentations, articles, and other purposes related to teacher education. Primarily it will be used for my own professional development.

In all written materials and presentations the names of students will not be used. Pseudonyms will be substituted for all names. Every effort will be made to protect the anonymity of participants. Photos (or videos) taken in the course of this project will be used to illustrate general aspects of the project not to identify individual students and will be destroyed or erased at the end of the project.

I plan to discuss this project with the students. I would be happy to discuss any aspect of the project with you. Your child's participation is completely voluntary. You do not have to allow your child to be part of this project. If at any time, or for any reason, you wish not to have your child involved in the project please let me know.

If you have any questions about the study, you may contact [Dr. P. Investigator], at telephone # (XXX-XXX-XXXX) or via email at [insert email address here]. (Note: we do not recommend that investigators provide their home phone number here. A campus office phone number is more appropriate.)

If you have any questions about your rights as a research participant, you may contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

Sincerely,

Print Child's Name _____

Print Parent or Guardian's Name _____

Parent or Guardian Signature _____ Date _____

## PARENTAL PERMISSION #2

Student's Name_____Grade: ___

Dear Parent:
Researchers at Antioch University New England are asking permission for your child to be in a research study on reading.

The study compares children reading below grade level with those reading at or above grade level on various measures of learning and memory.

We selected your child based on the testing you agreed to when your child started school. With your permission, s/he will work with a person from the University on six occasions for approximately 20-30 minutes each time. During each session, s/he will be working on a variety of tasks designed to measure learning, memory and other things related to reading. The tasks are not difficult and in most instances the children find them quite enjoyable.

We will see each child on a one-to-one basis and arrange scheduling with his/her teacher to make sure that s/he does not miss important classroom activities. This study has the approval and support of your child's school.

Your child's responses will remain confidential.

No reports about the study will contain your child's name. We will not release any information about your child without your permission.

Taking part is voluntary.

If you choose not to have your child take part, neither you nor your child will be penalized.

We will also ask your child to participate and only children who want to will take part in the study. Your child may choose to stop at any time.

If you have any questions about the study, you may contact [Dr. P. Investigator], at telephone # (XXX-XXX-XXXX) or via email at [insert email address here]. (Note: we do not recommend that investigators provide their home phone number here. A campus office phone number is more appropriate.)

If you have any questions about your rights as a research participant, you may contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

Attached is a form for you to sign. Please indicate whether or not you agree to have your child be in the study and have him/her return the form to school tomorrow. We would greatly appreciate your cooperation in this research.

READING STUDY PERMISSION FORM

I have read and understood the information provided to me about the research study on reading being conducted in my child's classroom by researchers from Academia University.

_____ I give

_____ I do not give permission to have my child (Child's Name) included in the study.

_____ _____

(Parent's Signature) Date

## PASSIVE" PARENTAL PERMISSION

Dear Parent:
Researchers at Antioch University are asking permission for your child to be in a research study on teaching math.

During the next week, researchers from Antioch University will be conducting a research study in your child's classroom. The study compares different methods of teaching mathematical concepts. We will not interact directly with your child. His/her teacher will simply be presenting the material in two different ways to separate classes.

Both teaching methods are acceptable methods for teaching these concepts and your child will receive adequate instruction in both classes. The only measure of performance will be a standard math test. This test will not be a part of your child's record and will not affect his/her grade in any way.

Your child's responses will remain confidential.

No reports about the study will contain your child's name. We will not release any information about your child without your permission.

Taking part is voluntary.

All students in the class will take the test. If you do not wish your child to be in this study, which will mean that we won't include his/her test results in the data, please fill out the form at the bottom of this letter and return it to me. In addition, please instruct your child to hand in a blank test sheet so that we will not include him/her in the research. We will also ask the children to participate and tell them to hand in a blank test sheet if they do not want to be included. Your child may choose to stop at any time.

If you have any questions about the study, you may contact [Dr. P. Investigator], at telephone # (XXX-XXX-XXXX) or via email at [insert email address here]. (Note: we do not recommend that investigators provide their home phone number here. A campus office phone number is more appropriate.)

If you have any questions about your rights as a research participant, you may contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

I do not wish my child _____to be in the research study on teaching math being conducted in his/her classroom.

_____
(Parent's Signature)

## ASSENT FORM SAMPLE

Student's Name_____
School _____

**RESEARCH STUDY ON READING**

Do you remember the permission slip you took home for your parents to sign a few days ago?

The people I work with and I are interested in learning about reading in children. We are asking you and a lot of other kids to work with us to find out about it.

If you agree to do this, I will ask you to take a reading test and solve some puzzles. Most kids think this is fun to do.

This is not a test like you usually have in school. You won't be graded on anything you do and the results will not affect your school grade. All you have to do is try as hard as you can to do the things I ask, and you will do fine.

Your teachers and parents and the other children will not know how you do. It will be just between you and me and the people I work with.

Of course, you don't have to do this if you don't want to, even if your parents gave their permission. If you do not want to do this or your parents asked you not to do this, just tell me and you can go back to your classroom. It is OK with me if you don't want to be in the study and no one else, not even your teacher, will know.

Do you have any questions?
[The Experimenter should answer any question the child might have]

Again, this will not affect your grades even if you choose not to be in the study. If you agree to do this, I would like you to sign this paper.
[If necessary, the Experimenter reads assent statement to the child.]

The study on reading has been explained to me and any questions I had have been answered. I would like to take part in the study.

_____ _____
Student's Signature Date

## ASSENT FORM TEMPLATE

Study Title:
Researcher:
Email Address and Telephone Number:
Research Supervisor:
Email Address:

You are invited to be part of a research study. The researcher is a doctoral learner at [INSERT SCHOOL HERE]. The information in this form is provided to help you decide if you want to participate. The form describes what you will have to do during the study and the risks and benefits of the study.

If you have any questions about or do not understand something in this form, you should ask the researcher. Do not sign this form unless the researcher has answered your questions and you decide that you want to be part of this study.

WHAT IS THIS STUDY ABOUT?
The researcher wants to learn about [RESEARCH TOPIC SUMMARY HERE].

WHY AM I BEING ASKED TO BE IN THE STUDY?
You are invited to be in the study because you are:

- [INSERT INCLUSION CRITERIA]
- [INSERT INCLUSION CRITERIA]

All participants will be between [INSERT AGE RANGE HERE].
If you do not meet the description above, you are not able to be in the study.

HOW MANY PEOPLE WILL BE IN THIS STUDY?
About [INSERT NUMBER OF PARTICIPANTS] participants will be in this study.

WHO IS PAYING FOR THIS STUDY?
The researcher is not receiving funds to conduct this study.
OR
The researcher is employed at [INSERT NAME OF RESEARCH SITE], but is not receiving funds to conduct this study. The researcher will not be paid for conducting the study. [Use this space to disclose other potential conflicts of interest, such as financial considerations]

WILL IT COST ANYTHING TO BE IN THIS STUDY?
Your parent/guardian does not have to pay to be in the study.

WHAT WILL HAPPEN DURING THIS STUDY?
If you decide to be in this study and if you sign this form, you will do the following things:
[SELECT ONE OR MORE OF THE FOLLOWING ACTIVITIES. OMIT ACTIVITIES WHICH WILL NOT BE PART OF THE STUDY]

- give personal information about yourself, such as your age, gender, occupation, and education level.

- answer questions during an interview about [INSERT STUDY INFORMATION HERE].
- answer questions during a focus group about [INSERT STUDY INFORMATION HERE].
- complete a survey about [INSERT STUDY INFORMATION HERE].
- allow a researcher to observe you while you [DESCRIBE ACTIVITY HERE].
- allow a researcher to look at your records [DESCRIBE RECORDS].

While you are in the study, you will be expected to:
- Follow the instructions you are given.
- Tell the researcher if you want to stop being in the study at any time.

WILL I BE RECORDED?
The researcher will audiotape your [describe what will be recorded – i.e. interview, focus group, XXX activity]. The researcher will use the audiotape in order to [INSERT DESCRIPTION HERE]
The researcher will only use the recordings of you for the purposes you read about in this form. They will not use the recordings for any other reasons without your permission unless you sign another consent form. The recordings will be kept for seven years and they will be kept confidential. The recordings will be destroyed after seven years.

WILL BEING IN THIS STUDY HELP ME?
Being in this study will not help you. Information from this study might help researchers help others in the future.

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?
No study is completely risk-free. However, we don't anticipate that you will be harmed or distressed during this study. You may stop being in the study at any time if you become uncomfortable.
OR:
As part of the study you may [describe risks, including the likelihood and magnitude of risk. Disclose all risks (social, financial, psychological, or possible physical risks) and they must be told under what conditions their participation in the study can be terminated by the researcher.]

WILL I GET PAID?
If you participate, you will be paid [ENTER AMOUNT HERE]
OR:
If you participate, you will receive a [ENTER AMOUNT HERE] gift card to [ENTER NAME HERE]
OR:
You will not receive anything for being in the study.

DO I HAVE TO BE IN THIS STUDY?
Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you. If you want to stop being in the study, tell the researcher.
Your parent(s)/guardian(s) have also said that you may participate in this study.

The researcher can remove you from the study at any time. This could happen if:

- The researcher believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- You no longer meet the inclusion criteria to participate

WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS STUDY?
Any information you provide in this study that could identify you such as your name, age, or other personal information will be kept confidential. [EXPLAIN HERE HOW INFORMATION WILL BE KEPT CONFIDENTIAL]. In any written reports or publications, no one will be able to identify you.

The researcher will keep the information you provide in a [PASSWORD PROTECTED COMPUTER AND/OR A LOCKED FILE CABINET] in [LOCATION] and only the researcher, research supervisor, and [LIST OTHER INDIVIDUALS] will be able to review this information.

[IF TAPE RECORDINGS ARE MADE, EXPLAIN WHO WILL HAVE ACCESS TO THEM]
Even if you leave the study early, the researcher may still be able to use your data. [DESCRIBE UNDER WHICH CIRCUMSTANCES THEIR DATA COULD STILL BE USED]

Limits of Privacy Confidentiality
Generally speaking, I can assure you that I will keep everything you tell me or do for the study private. Yet there are times where I cannot keep things private (confidential). The researcher cannot keep things private (confidential) when:

- The researcher finds out that a child or vulnerable adult has been abused
- The researcher finds out that that a person plans to hurt him or herself, such as commit suicide,
- The researcher finds out that a person plans to hurt someone else,

There are laws that require many professionals to take action if they think a person is at risk for self-harm or are self-harming, harming another or if a child or adult is being abused. In addition, there are guidelines that researchers must follow to make sure all people are treated with respect and kept safe. In most states, there is a government agency that must be told if someone is being abused or plans to self-harm or harm another person. Please ask any questions you may have about this issue before agreeing to be in the study. It is important that you do not feel betrayed if it turns out that the researcher cannot keep some things private.

Future Publication
The primary researcher, [YOUR NAME] reserves the right to include any results of this study in future scholarly presentations and/or publications. All information will be de-identified prior to publication.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so, and you may withdraw from the study at any time without your job being affected.

Who to Contact

If you have any questions, you may ask them now or later. If you have questions later, you may contact [YOUR NAME AND ANTIOCH EMAIL ADDRESS]

If you have any questions about your rights you may contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

DO YOU WANT TO BE IN THIS STUDY?

I have read this form, and I have been able to ask questions about this study. The researcher has talked with me about this study. The researcher has answered all my questions. I voluntarily agree to be in this study. I agree to allow the use and sharing of my study-related records as described above.

By signing this form, I have not given up any of my legal rights as a research participant. I will get a signed copy of this consent form for my records.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____

Printed Name of Researcher

_____ _____

Signature of Researcher Date

**********

DO YOU WISH TO BE AUDIOTAPED IN THIS STUDY?

I voluntarily agree to let the researcher audiotape me for this study. I agree to allow the use of my recordings as described in this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

**********

DO YOU WISH TO BE VIDEOTAPED IN THIS STUDY?

I voluntarily agree to let the researcher audiotape me for this study. I agree to allow the use of my recordings as described in this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

## GREATER THAN MINIMAL PSYCHOLOGICAL RISK

*Background: This consent form is for a study of psychological treatment of a disorder. Thus, the study has greater than minimal psychological risk. The hypothetical research is about a non-drug treatment for high blood pressure. The study has several phases and subjects must be informed about the risks and procedures for all of the phases. It is possible, in a multi-phase study, to break up the consent procedure, but the subjects need to know what the overall study involves before they agree to participate in the first phase.*

**Blood Pressure Research Study**

We are asking you to take part in a research study on high blood pressure.

The NoName Biopsychology Clinic and Antioch University New England are doing this research to study the psychological treatment of high blood pressure.

The study will consist of several parts.

The first part involves several physical and psychological tests to find out more about your high blood pressure. The second part involves the psychological treatment of high blood pressure. In the third part, the follow-up phase, people who participated will be seen every 3 months for up to a year for some short tests. After one year, they will have a complete physical and psychological examination.

The psychological treatment being studied in this research is called "biofeedback."

With "biofeedback" people learn to control their blood pressure without drugs by controlling the temperature of their fingertips and feet.

If you do not volunteer to be in this study you could have your high blood pressure treated with drugs or with some other form of therapy.

If you volunteer for this study, you will not receive any medication for your high blood pressure, which is what most people receive as treatment for this condition. So, you could go to a doctor and receive medication or some other form of therapy for your blood pressure if you chose not to participate in this study.

If you volunteer to take part in the first part of the study, you will receive a thorough psychological and physical examination to learn more about your high blood pressure.

We will interview you briefly about your medical history and your state of mind, give you several psychological tests to learn more about your personality and state of mind, and give you a physical examination to learn more about your condition.

We will draw one tube of blood three different times and ask you for two urine samples.

If you volunteer to take part, a skilled lab tech will draw one tube of blood (about two teaspoonfuls). We will draw the blood during the examination, at one month, and in one year. To draw the blood from you, we will ask you to come back to the NoName Clinic in 1 month and 1 year. We will take the urine samples at the NoName Medical Center during the physical examination and 1 year later. We use the blood tests and the urine samples to find out more about your condition.

We will also do some other tests to learn more about your high blood pressure.

If you volunteer, we will attach you to a machine to measure your physical reactions. This machine, which is harmless and painless, is similar to the kind of "lie detector" you see in movies or on TV, but we will not be using it for that; rather, we will be using it to see how you react to different things. While you are attached, we will ask you to do a number of activities:

- We will ask you to try and relax and to try and control certain responses;
- We will ask you to perform some arithmetic in your head and to imagine some things which may be related to your high blood pressure; and
- We will ask you to hold your hand in a mixture of ice and water for 1 ½ minutes.

If you volunteer, we will ask you to keep track of your blood pressure every day and to keep track of your practice of what you have learned.

During the first part of the study, we will ask you to keep daily records of your blood pressure and return them promptly to the clinic. You will be given a blood pressure gauge to do this.

If you are eligible and choose to participate in the treatment part of the study, you will receive psychological treatment for your blood pressure.

We will see you for 16 sessions over an 8-week period. During these sessions, we will teach you how to control the temperature in your fingers and feet. You will be expected to continue to keep daily records of your blood pressure and practice what you have learned and keep records of it. At the end of the training, you will have another set of physical and psychological examinations, similar to the first part of the study.

If you continue with the follow-up part of the study, you will be tested for up to a year.

You will have a brief examination every 3 months and a thorough examination at the end of 1 year.

There are no major risks in being in this study.

In the physical and psychological examinations and laboratory tests there are no risks greater than those usually associated with this sort of examination.

There are no risks in keeping the daily blood pressure and practice records. In the ice water test, you will experience temporary pain and cold. Your blood pressure will also go up. You can stop this test at any point. There are no major risks with the treatment part of the study. You may feel some temporary strange sensations as you become deeply relaxed, which make you concerned or you may feel frustrated at not being able to control your bodily responses. These are normal reactions; however, you should inform the researcher if either of these occur.

There are small risks with your not being on blood pressure medication and your blood pressure being high (above 90 mm) during the 14-16 weeks of treatment. These risks include the possibility of heart attack, stroke, or rupture of major blood vessels. The risk of one of these events happening is about 12 chances in 1,000 if you receive no treatment for your high blood pressure. Based on our previous research, this risk is reduced with

treatment to about 4 chances in 1,000. If you did not enter the study but remained on medication, your risk for one of these events is about 1 chance in 1,000.

The study may benefit those who participate.

If you participate you may get some benefit from the experience. In the first part of the study, you may learn more about yourself and your condition. You may also become eligible for the treatment part of the study. Although we cannot be sure, by participating in the treatment part of the study you may learn how to reduce your blood pressure and decrease your need for medication.

We will guard your confidentiality.

We protect all information about you and your taking part in this study as much as we can. We have trained all staff not to tell anyone outside the study any information about a participant.

We may end your participation for a number of reasons:

1. Your blood pressure rises to dangerous levels;
2. Other physical or psychological problems arise which would interfere with the study;
3. You do not keep accurate records of your blood pressure and practice;
4. You fail to keep appointments and fail to make up missed appointments; or
5. If we feel it is in your best interests for your health.

In case of injury or reactions, call Dr. Ida H. Service at ___-___-____.
If you have an injury or reaction that may be caused by your being in this study, please call Dr. Service immediately. Her telephone number is ___-___-____.

If you have questions about the research, call Dr. Service at ___-___-____, or write her at:

NoName Clinic
1000 Named Street
NoName City, XX 12345-6789

You have rights as a research volunteer.

- Taking part in this study is voluntary. If you do not take part, you will have no penalty and lose no benefits.
- You may stop taking part in this study at any time. You may stop taking part at any time, with no penalty or loss of any benefits to which you are otherwise entitled.
- If you have any questions about your rights as a research participant, you may contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

Consent Statement:
I have read and understood the information above. The researchers have answered all the questions I had to my satisfaction. They gave me a copy of this form. I consent to take part in the Blood Pressure Research Study.

Signature: _____Date: _____

Witness: _____Date: _____

*(Note: The readability of this Consent Form is 8th grade. There are 72 sentences with an average length of 20 words and only 11% are in the passive voice. The text is 1398 words.)*

## GREATER THAN MINIMAL SOCIAL RISK

*Background: This consent form is for a survey of sensitive and risky information. Thus, the survey has greater than minimal social risk. The hypothetical research is about domestic violence. Research about stigmatized, incurable, genetic, or sexual diseases, or illegal behavior such as substance abuse or prostitution, all have similar risks.*

*This hypothetical research is conducted in, and by, a hypothetical Family Crisis Center, serving battered women in a rural reservation community. It provides drop-in counseling services; shelter is provided by a network of "Safe Homes." The research is in two phases: (1) use the existing data of the initial care interview by the counselor; and (2) do follow-up interviews at 1 and 6 months. If the data in the first phase were anonymous, the phase could be reviewed under expedited review by "using existing data anonymously."*

*However, the researchers want to reinforce the empowerment of the women. Thus, they chose to ask for consent to use even that existing data. The benefits, risks, and management of risks for participating in the research for the potential volunteer are primarily the same as those for the woman going to the Center for help, and had been covered extensively in the discussion between counselor and woman.*

**Volunteer Consent to a Study about Domestic Violence**

The NoName Family Crisis Center asks you to take part in a research study about violence in the homes in the NoName community.

> The study will help us understand the type and severity of violence that occurs in NoName homes. The Crisis Center will use the study to plan better programs to prevent domestic violence, and to treat the family victims of violence including children. We are asking to interview all women seen by the Center. Please understand that you will always receive care from the Family Crisis Center whether or not you agree to take part!

If you agree to take part, your counselor will put some of your story into the research. Neither you nor anyone involved will be named or identified.

> You have already told the counselor your history. If you agree, she will use the facts of your history for the study. She may ask a few more questions to complete your history. A doctor will also review your chart for injuries you have had that may be related to problems with your partner.

She will also want to talk with you in 1 month and 6 months.

> She will ask you how you are doing. You can tell her then what you thought about the Crisis Center, and what should be done to help you and other women, families, and children. She knows that your partner may be angry if he found out that you talked with us. So, she will ask you what is the best way to contact you to set up a time to talk. She will contact you only by the way you want. The Family Crisis Center is a safe place to come and talk.

The benefit to you in taking part in this study is in seeing your counselor on a

scheduled basis.

She will help you think through your situation, as she did today. You can both discuss your needs when you meet; she may suggest programs or people that can help you further.

If you take part, however, the main benefit is to the community.

The Crisis Center will use the results of the survey to improve programs to help families, women, children, and partners in need. You and your family are not alone! More than 1 out of every 5 NoName families have suffered violence.

You may experience discomfort by taking part. The Family Crisis Center has tried to prevent any risk to you.

You and your counselor have already talked about issues full of emotion for you. When you meet in 1 and 6 months, she will listen and spend as much time with you as you want. Most women feel better after talking like that.

No one in the Center will tell anyone about who has come here to talk or for help. If your partner finds out from others that you were here and asks you what you did, you can say that we gave you help about "women's issues". They included child care and transportation to Clinic.

We will give a list of services and people to call for help about violence in the home. To avoid making any woman's partner angry, that list contains other numbers and programs as well. In fact, it is a list of every social program in the NoName community. There is no sign that the list is related to violence in the home.

You do not have to sign a volunteer consent form to take part.

You can agree to take part just by telling us, if you want. You can take a copy of this volunteer consent form with you, but we suggest you do not, to avoid triggering violence by your partner.

The Family Crisis Center has tried to make sure no one else can know what you say.

Your name is not on the study form with your answers. Only a special code number is there. Your counselor will keep your code number and name locked up with the Center's records.

For even more protection, the Crisis Center also has a Certificate of Confidentiality from the federal government. It was made to protect all information from disclosure, even that ordered by a court, without your written consent. That is, it was made to keep the information private or confidential, like your medical records.

No reports about the survey will contain your name or the name of any volunteer in the study. If you tell the counselor that someone, you or your children, is in danger of great physical harm, she will tell the Clinic to provide protection. The same thing would happen if you gave the same information to a doctor, nurse, or counselor in the Clinic.

Taking part is voluntary.

If you do not take part, you will lose no benefits or services from the Family Crisis Center, or anyone else. The Crisis Center will continue to give you help. You may refuse to answer any question, but we hope you answer as many questions as you can. You may also refuse to take part in the interviews at 1 month and 6 months from now, but we hope you will take part then.

If you have any questions about the study, you may contact [Dr. P. Investigator], at telephone # (XXX-XXX-XXXX) or via email at [insert email address here]. (Note: we do not recommend that investigators provide their home phone number here. A campus office phone number is more appropriate.)

If you have any questions about your rights as a research participant, you may contact [insert name and office phone number of local IRB Chair] or [Insert name of local Provost, title, and office phone number].

Thank you for helping build a better NoName community for all families.
I agree to take part in the NoName Family Crisis Center study about violence in the home. My questions have been answered. I will continue to receive help by the Center whether I agree to take part or not. I may refuse to answer any question I want. I have received a list of helping programs and people, and their telephone numbers.

*(Note: The readability level of this Consent Form is 8th grade. The text is only 995 words, yet it meets all requirements for Consent Forms for complex research that is greater than minimal social risk.).*