Memorandum

DATE: May 6, 1998

TO: Carl Carlucci, Dan Wulff, John Delano

FROM: Anne Connolly

RE: Human Subjects Audit

Attached are the Guidelines for Obtaining Informed Consent in Human Subjects Research that are distributed by the Office for Research. Included in this packet are sample consent forms, which the projects modify for their use. This information was developed in June, 1993. The RF policy (and forms) were issued with an effective date of October, 1995. Attached are copies of the RF policy and the related forms.

A compromise solution that would merely involve modification of this "pink packet" may be simple enough to do and to administer for all involved.

The University at Albany
State University of New York

Institutional Review Board

GUIDELINES FOR OBTAINING INFORMED CONSENT IN HUMAN SUBJECTS RESEARCH

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DEFINITION OF INFORMED CONSENT

Informed consent is one of the primary ethical principles governing human subjects research; it assures that prospective human subjects will understand the nature of the research and can knowlegeably and voluntarily decide whether or not to participate.

"Informed consent" means the knowing consent of an individual, or his/her legally authorized representative, who is able to exercise free power of choice without undue inducement or any form of force, fraud, deceit, duress or other form of constraint or coercion.

THE CONSENT PROCESS

Informed consent is not a single event or just a form to be signed -- rather, it is an educational process that takes place between the investigator and the prospective subject. The basic elements of the consent process include full disclosure of the nature of the research and the subject's participation, adequate comprehension on the part of the potential subjects, and the subject's voluntary choice to participate.

Information

The federal regulations detail the following elements of information which must be provided to each subject:

1. A statement that the study involves research, an explanation of the purpose of the research, the expected duration of the subject's participation and a description of the procedures to be followed;

2. A description of any foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may be reasonably expected from the research;

4. A statement describing the extent to which confidentiality of records identifying the subject will be maintained;

5. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury;

6. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time; and

7. For research involving more than minimal risk, an explanation that the University does not have a formal plan or program to provide medical treatment or compensation for any injury which occurs as a result of the subject's participation (the subject should also be informed that this does not waive any of his/her legal rights).

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

2. An identification of any procedures which are experimental;

3. A statement that the research may involve risks to the subject which are currently unforseeable;

4. Anticipated circumstances under which the subject's participation may be terminated without regard to the subject's consent;

5. Any additional costs to the subject that may result from participation;

6. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

7. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to participate will be provided to the subject; and

8. The approximate number of subjects involved in the study.

Comprehension

Informed consent is not valid unless the consentor understands the information that has been provided. While no one can guarantee that another person has understood the information presented, it is the responsibility of the investigator to do what he/she can to enhance each prospective subject's comprehension of the information.

The investigator must consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved) in determining the appropriate way to present the information.

Factors such as age, education level, cognitive ability, and language fluency directly affect subject comprehension of information. The manner of presentation, including the specific wording of the information, must be tailored to facilitate comprehension by each individual subject.

- In most cases, technical terms and complex sentences should be avoided, even for the educated layperson. Technical terms should be replaced with ordinary language, and short sentences using active tense rather than passive tense verbs should be used.

- If English is not the subject population's primary language, the explanations and forms may need to be translated.

- For children, care must be taken to ensure that the language is appropriate to their age level. For elderly subjects, oral information may have to be presented slowly and loudly and forms printed in large type.

- When the subject population is not homogeneous, different consent procedures may be required with different populations.

The investigator should be aware that, even if the IRB has approved a consent procedure, it is his/her responsibility to ensure that each potential subject understands the information and to take whatever steps are necessary to gain that comprehension. **Individuals may not be used as research subjects unless they understand the information that has been provided.**

Voluntary Consent

Consent is a legal concept and only legally competent adults can give consent.

- In most cases, minors cannot give consent -- only parents or legal guardians can give consent for minors to participate in research. (See **"Guide to Research Involving Minors"**).

- Incompetent adults cannot give consent -- this may include the developmentally disabled, the cognitively-impaired elderly, and unconscious or inebriated individuals (the evaluation of competence must be made on a case by case basis).

- Even though children and incompetent adults cannot give consent to participate in research, their "assent" or agreement to participate should be obtained whenever possible. Assent is "knowledgeable agreement" to participate and should be used whenever the potential subject has sufficient capacity to understand what is happening and express his/her wishes. In addition, the "deliberate objection" of a subject should be construed as a veto of the consent of a parent or guardian, whether that objection is verbal or non-verbal.

In order to be valid, consent must be freely given. That means that it is free from all forms of coercion. In addition to overt coercion, the investigator needs to be sensitive to more subtle forms of coercion, such as social pressure, requests from authority figures, and undue incentive for participation. Since coercion exists when it is perceived by the subject, the investigator must attempt to view the consent process from the subject's perspective. For example, a teacher asks her class to participate in research. Even if she tells the class that participation will not affect their grades, most students will assume that they will somehow be penalized for not participating. The potential subjects perceive a coercive situation even though none exists.

A further complication exists in therapeutic and educational settings. Most individuals assume that therapists and teachers are acting in the patient's or student's best interest. Evidence has indicated that this assumption persists even if the subjects are told that the activity is research and will have no direct benefit for them. Therefore, special care must be taken in these settings to ensure that the potential subjects understand the nature of the research.

PROCEDURES FOR OBTAINING CONSENT

Unless otherwise authorized by the IRB, no investigator may involve a human being as a subject in research under the auspices of the University unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative.

General Requirements

An investigator shall seek consent only under the following circumstances:

- The potential subject has the legal and mental capacity to give consent; if not, consent must be obtained from his/her legally authorized representative;
- Sufficient opportunity is provided to the prospective subject, or his/her representative, to consider whether or not to participate;
- The possibility of coercion or undue influence is minimized;
- The information that is given to the prospective subject, or his/her representative, is in language understandable to the subject or representative; and
- The subject, or his/her representative, is not made to waive or appear to waive any of his/her legal rights, or release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

At Risk Studies

In projects where subjects are determined to be at risk:

- The actual procedure utilized in obtaining "legally effective informed consent" must be fully documented. This is accomplished by using a written consent form embodying all of the elements of information required for the project. (The IRB has prepared sample consent forms which can be found later in this document)
- The consent form must be reviewed and approved by the IRB.
- The consent form must be read by or to the subject or his/her legally authorized representative and signed by the person giving consent.
- A copy of the consent form should be given to the person signing the form and the signed form must be maintained in the investigator's files for an indefinite period of time following completion of the study.

No Risk Studies

In projects where subjects are determined to be at no more than minimal risk:

- Provision may be made for oral or written presentation and consent. Under this procedure, the subject is informed of those basic elements of consent which are applicable to low risk procedures and no signed document is necessary on the part of the subject.
- A sample copy of the presentation must be approved by the Board.
- A major exception to this policy occurs when research involves minors as subjects, in which case, written parental consent is usually required. (See below)

Research Involving Minors

Underlying IRB policy on consent in research involving minors are several assumptions. First, as in all human subjects research, the informed consent of subjects participating in research is usually required. Second, children below a certain age are incapable of giving consent. Third, when required, only parents or legal guardians are able to give consent for children to participate in research. This last assumption relates specifically to research in schools. School officials do not have the authority to give consent for children to participate in research; only parents or guardians have that authority.

Based on these assumptions, the policy of the IRB is to require parental consent whenever research involves direct intervention with children. The only exception to this policy is very innocuous research using older adolescents; i.e., juniors or seniors in high school. In that case, only the consent of the subjects is required. Research not involving direct intervention with the subjects would not normally require consent.

Documentation of parental consent depends on the nature of the research. In most cases, parental consent should be documented by a signed consent form. Parental consent forms should follow the guidelines discussed below.

For research that is very innocuous, the IRB may permit a less rigorous consent process, often waiving the requirement for a signed consent form. Where appropriate, oral consent may be obtained or parents may be informed in writing that the research is taking place without requiring signed consent. In both procedures, researchers must provide parents with the same information required in signed consent forms. In the procedure where parents are simply informed that the research is taking place, parents must additionally be provided with an opportunity to refuse permission for their child to participate.

In addition to parental consent, adequate provisions must be made for soliciting the assent of the children capable of providing such assent. Procedures for soliciting the assent of children must be appropriate for the age level, maturity and psychological state of the child. The essential information given to the child must include a description of the procedures and clear indication as to the voluntariness of his/her participation. In research conducted in schools, a clear indication must also be given that this research is not part of the child's regular school program, is not being conducted under the auspices of the school, and the child's grade will not be affected by his/her decision to participate. Of course, this information must be presented in language that is understandable to the

child. In developing language appropriate for the child in a given study, it is recommended that investigators unfamiliar with the capabilities of the population being studied consult with experts.

For additional information and sample parental consent forms and assent forms, see the document **"Guide to Research Involving Minors"** which is available in the Office for Research.

IRB Waivers

In rare cases, where these procedures will surely invalidate important objectives of the project, IRB approval of modified procedures may be sought.

In some cases, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or may entirely waive the requirement to obtain informed consent.

CONSENT FORMS

Documentation of "legally effective informed consent" usually involves the use of a written consent form containing all of the information to be disclosed and signed by the subject or the subject's legal representative. It should be emphasized that the consent form is merely the documentation of informed consent and does not, in and of itself, constitute informed consent. The fact that a subject signed a consent form does not mean that he/she understood what was being agreed to or truly gave their voluntary consent. Informed consent is a process which is documented by a signed consent form.

Consent forms should be designed to meet the needs of the particular research project where it is being used; no one form can be used in every research project. However, it is recommended that consent forms meet four criteria.

1. **Be brief, but have complete basic information.**

   Many potential subjects do not read long consent forms. The longer the form, the fewer the number of people who read it in its entirety, and the smaller the fraction of it that is read by the rest. That is, the quest to be more comprehensive by including more information may actually result in the information transmitted being less comprehensive.

   Include only the **basic information** needed by potential subjects ("basic" are the items required by federal regulations) and do not try to answer every conceivable question.

   "Non-basic information" can be given in a separate handout, perhaps in a Question-and-Answer format. One suggestion is to include a list of questions at the beginning of the handout, to permit each person to go to those questions he/she is most interested in.

2. **Be readable and understandable to most people.**

Articles in most popular magazines are at the 8th grade level. Several computer programs estimate readability by the Flesch, Flesch-Kincaid, and FOG measures. Factors that improve readability include the following:

- Technical terms should be replaced with ordinary language;
- Use active tense rather than passive tense verbs ("We did" rather than "It was done");
- Write shorter sentences in general; and
- Make clear the links of logical sequences and of cause-and-effect, even if doing so makes the sentence much longer. ("We will do this, because that happened".)

3. **Be in a format that helps people comprehend and remember the information.**

Format can help comprehend and remember complex material. Good format uses:

- headings;
- indents;
- bolded type;
- lists;
- extra spacing between sub-topics;
- repetition;
- reasonable-size type; and
- plenty of margins and empty space in general. (Think of the daunting insurance policy statements with their wall-to-wall and top-to-bottom writing in small print).

Those formats help the reader: A) to organize the information; B) to recognize, know, and remember the key points; and C) to go back later to the consent form and retrieve important information (such as telephone number of the investigator to call with questions).

4. **Serve as a script for the face-to-face discussions with the potential subjects.**

Face-to-face discussions between researcher and potential subject are the most important part of the process of informed consent. These sample forms can be the **script** for the verbal explanation by the researcher. If the verbal explanation is almost identical to the written consent form, each will reinforce the other and potential inconsistencies will be avoided.

One benefit of this approach is that the form/script prompts the researcher to use simple language for the verbal explanation. Another benefit is that the same form/script can be used for potential subjects who have difficulty reading or low literacy or who need a translation, which also should improve consistency of explanation among all subjects. I.E., researchers need develop only one form/script, not two, to permit people of all literacy levels to be potential subjects. The script could also be used in videotaping the explanation.

SAMPLE CONSENT FORMS

Explanation

To help researchers draft the forms needed for their research project, the IRB has developed several sample **Consent Forms.** The forms are for hypothetical research protocols:

1. with "greater than minimal" psychological risk;
2. a survey with "greater than minimal" social risk;
3. an innocuous experiment on normal adults; and
4. a simple questionnaire survey

The samples are good oral **scripts** and are well-formatted printed materials. For instance, the bolded headings are the key "take-home" points of the information to be transmitted. That results in two editorial benefits.

- Bolded headings attract attention and are remembered. Therefore, by having key points as headings, the key points will be remembered. (Bolded headings that are just titles or questions attract attention, but unfortunately are not intended to be remembered.)
- The length is shorter. There is little or no unnecessary verbiage.

We suggest you use the sample forms as examples, not requirements.

Do not slavishly copy these samples. (For instance, you may not want to write consent forms as scripts.) Instead, follow the principles of effective written communication discussed under the first three concerns above.

Sample Consent Form, #1

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 Academia University 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 1/2 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 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 of time. 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 ___-___-____.

Although, The NoName Clinic and Academia University do not have a plan for paying the cost of any injury or reaction from the study, they are still fully responsible for what happens and you still have your legal rights.

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

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 volunteer,** call or write

Ed Ethics:
Academia University Institutional Review Board
Office for Research
1000 Happy Ave.
Happy City, XX 12398-7654
(telephone ___-___-____)

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:*** _____***, 1993***

Witness: _____ ***Date:*** _____***, 1993***

(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 1418 words.)

Sample Consent Form, #2

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 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 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 get care by 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 will be named or identified.

You told the counselor your history already. 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 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 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 benefits to you taking part are seeing your counselor on a scheduled basis.

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

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 the counselor have already talked about things full of emotion for you. In her talk with you 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 tells anyone 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 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 questions about this study, please contact **Mary Doeswell**, phone ___-____, or in her office at the Center.

If you have questions about your rights as a volunteer, please contact
Ed Ethics:
NoName Institutional Review Board
1000 Happy Ave.
Happy City, XX 12398-7654
(telephone ___-___-____)

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 of this Consent Form is 8th grade. The text is only 978 words, yet it meets all requirements for Consent Forms for complex research that is greater than minimal social risk.)

Sample Consent Form, #3

Background: This consent form might be used for an innocuous experiment on normal adult behavior. 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 orally and/or in an instruction sheet given to the subjects.

Pattern Recognition Study

Researchers at Academia University are asking you to take part in a study on pattern recognition.

The Researchers want to know how people recognize patterns, that is how they can tell that they have seen a pattern before.

If you choose to take part, we will ask you to look at some patterns on a computer screen. You will see two patterns at a time. The patterns will be of differing colors. We will ask you to pay attention to only one of the color patterns. After you have seen all of the patterns, we will show you some more patterns and ask if you have seen any of them before.

Your responses to all of the questions will remain confidential.

We will not ask you to put your name on any of the response sheets.

Taking part is voluntary.

If you choose not to take part, there will be no penalty and you will receive the credit anyway. You may choose to stop at any time.

If you have questions about the study, please ask the experimenter or contact **Mary Doeswell** at Academia University, phone ___-____. If you have questions about your rights as a volunteer, please contact **Ed Ethics**, Chair, Academia University IRB. Call him at ___-____ or visit him at the Office for Research (AD 216) at the University.

(Note: The readability of this Consent Form is 8th. grade. The text is only 226 words and 1/2 of a page, yet it meets all requirements for Consent Forms.)

Sample Consent Form, #4

Background: This consent 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 Academia 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 questions about the survey, please contact **Mary Doeswell** at Academia University, phone ___-____. If you have questions about your rights as a volunteer, please contact **Ed Ethics**, Chair, Academia University IRB. Call him at ___-____ or visit him at the Office for Research (AD 216) at the University.

Please leave the survey form in the boxes by pharmacy, lab, or medical records.

Please take this cover sheet of explanation with you. Medical records and Mary Doeswell also have copies of the cover sheet and survey.

(Note: The readability of this Consent Form is 8th. grade. The text is only 265 words and 2/3 of a page, yet it meets all requirements for Consent Forms.)

ACKNOWLEDGMENTS

This document 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.

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)

Section: Forms
Subject: **Human Subjects**
Title: **Certification of Information Provided to Human Subjects**

Effective Date: October 16, 1995

Certification of Information Provided to Human Subjects

This form must be completed only if the aggregate payment to any one subject will be less than $600 in a calendar year, or if any one subject will not be paid for participation. If each human subject in the study will be paid $600 or more, this form does not need to be completed and each subject must sign and return the bottom portion of the confidentiality statement.

I certify that under my study, _____
(name of study)
_____,

the "Confidentiality of Information for Human Subjects" statement will be provided to each human subject participating in this study who will receive an aggregate payment during the calendar year of less than $600. For these human subjects, no payment will exceed $75 per visit and the aggregate payment for each will not be $600 or more in a calendar year.

_____ _____
Project Director's Name Date

_____
RF Account Number

Please forward form to the campus office responsible for contract and grant administration.

RF010

Note: A copy of this form that may be used for photocopying purposes follows.

Certification of Information
Provided to Human Subjects

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_____ _____
Project Director's Name Date

_____
RF Account Number

Please forward form to the campus office responsible for contract and grant administration.

Section: Forms
Subject: **Human Subjects**
Title: **Confidentiality of Information for Human Subjects**

Effective Date: October 16, 1995

Confidentiality of Information for Human Subjects

Locus of Authority for Issuing Confidentiality

The study I am about to enter is sponsored through The Research Foundation of State University of New York and is being conducted by _____ (project director).

Confidentiality and Subject Payment

All information I give will be kept confidential. Except as herein otherwise set forth, no report of any information specifically related to me will be given without my permission. In any professional communications about this research, my identity will be protected by reporting only information from a group of participants.

I understand, however, that by accepting payment(s) for participating in this study, there are audit, tax and federal reporting requirements which may require that identifying information be made available to professional auditors, the Internal Revenue Service, state tax authorities or the federal government on a confidential basis for such purposes. I understand that my permission to release the requested information is not required in such instances.

(Detach and complete the bottom section only if you will receive payments during the calendar year that total $600 or more)

Acceptance of Fee

The fee offered for _____ is $_____, which I may accept or decline.

☐ I accept payment.

My full legal name and address are:

_____

_____

_____

_____

Social Security Number _____

Signature: _____

RF011

Note: A copy of this form that may be used for photocopying purposes follows.

Confidentiality of Information for Human Subjects

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The study I am about to enter is sponsored through The Research Foundation of State University of New York and is being conducted by _____ (project director).

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(Detach and complete the bottom section only if you will receive payments during the calendar year that total $600 or more)

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☐ I accept payment.

My full legal name and address are:

_____

_____

_____

_____

Social Security Number _____

Signature: _____

Section: Administrative Procedures
Subject: **Alternate Payment Methods**
Title: **Paying Human Subjects**

Effective Date: October 16, 1995

Purpose

This document describes how payments are made to human subjects participating in sponsored projects.

Background

The Research Foundation makes payments to persons who participate in research projects as human subjects. Payments to human subjects are considered *nonemployee compensation* and as such, are subject to Internal Revenue Service requirements for miscellaneous income reporting (1099 reporting).

Confidentiality of Information Statements

Payments of $600 or More

If the total payment(s) to the subject for the calendar year is anticipated to be $600 or more, the human subject must complete, sign, and return the Confidentiality of Information for Human Subjects statement *before* participating in a study. Project directors must retain all signed statements. Refer to Document ID: PP-F-15 in the Forms section for a sample form.

Payments Less Than $600

If total payment(s) to the subject for the calendar year is anticipated to be less than $600, the project director must provide the Confidentiality of Information for Human Subjects statement to the subject. The subject is *not* required to sign and return the statement. If, however, during the study unanticipated changes occur and it is determined that payments to a subject(s) may total $600 or more, the form must be completed, signed, and *returned* to the location. Refer to Document ID: PP-F-15 in the Forms section for a sample statement.

The project director must also sign a Certification of Information Provided to Human Subjects form to indicate that the human subjects receiving less than $600 will be provided with the statement. This certification should be retained in the grants file. Refer to Document ID: PP-F-11 in the Forms section for a sample certification form.

Payment Methods

Standard Vendor Payment

A standard vendor payment can be made to a human subject for any amount. Payments exceeding $75 are normally processed this way. Standard vendor payments provide an audit trail that properly documents payments, meets sponsor and Internal Revenue Service (IRS) requirements, and complies with generally accepted accounting principles. Refer to "Processing Vendor Payments" (Document ID: PP-F-59) for more information.

Alternate Payment Methods

Alternate payment methods can be used when there is a concern about confidentiality and the payments will be $75 or less per visit. On an exception basis to meet a specific project need, this method can be used for payments exceeding $75 with the approval of the operations manager. The following two alternate methods can be used:

- the project director can establish a cash fund and make *cash* payments to subjects, or
- the project director can establish a corporate checking account with project funds and issue checks from this account.

Each method is described in the blocks that follow.

Cash Fund

The project director must submit a request to establish a cash fund. All requests must be reviewed and approved by the operations manager. Upon approval, the operating location office responsible for vendor payments issues a check to the p.d. from petty cash or the project director's account. The check must be issued using the Miscellaneous-Subject Costs budget category (6509).

The project director cashes the check and uses the funds to pay human subjects for amounts of $75 or less per visit, unless a higher limit is approved by the operations manager (see Alternate Payment Methods, page 2). As the cash reserves are expended or upon request by the project director, additional funds from the project account or from petty cash should be made available for human subject payments.

Cash Fund (cont.)

Refer to "How to Establish and Maintain Petty Cash Accounts" (Document ID: PP-A-90) and "How to Request Petty Cash Funds in Advance" (Document ID: PP-A-91) for more information on petty cash.

Corporate Checking Account

Establishing the Account

To establish a corporate checking account for human subject payments, the operations manager must submit a request to the Office of the Secretary-Treasurer. Refer to "Establishing a Bank Account" (Document ID: PP-A-56) for specific requirements. The account may only be used for the purpose for which it was established.

Bank Fees and Interest Accruals

All bank fees related to the account are the responsibility of the operating location. Bank fees may be paid from the project account if allowed by the sponsor. Interest in excess of the bank fees should be deposited to an operating location income account or project account, depending on sponsor regulations regarding income.

Issuing Checks

Based on the project director's request, a check may be issued from the project director's account out of the Miscellaneous-Subject Costs budget category (6509). The project director deposits the check into the separate corporate checking account and issues checks to human subjects from this account (payments must not exceed $75 per visit, unless a higher amount is approved by the operations manager - see Alternate Payment Methods, page 2). Funds to replenish the account may come from the project account or from petty cash.

Cash and Check Account Review Procedure

A review must be performed to maintain proper control over the cash or check payment process.

When the Review Must Be Done

For cash accounts this review must be done periodically. For checking accounts this review must be done monthly.

Cash and Check Account Review Procedure (cont.)

Review Process

The following table outlines the steps that must be taken:

Step	Action
1	Obtain documentation that indicates the ***number*** of subjects who received payment and the ***amount*** of each payment. This documentation must be signed by the project director to certify that the documentation is correct. For checking accounts, a copy of the bank statement and the bank reconciliation should also be obtained. *Note*: It is not necessary for the project director to provide the names of the human subjects.
2	Review the documentation to ensure that • subjects did not receive more than $75 per visit. • the project director signed to certify the accuracy of the documentation. • a copy of the cash or checking account reconciliation is included and approved and that the reconciliation is correct.
3	If a human subject is paid $600 or more in one calendar year, obtain the necessary payment information from the project director so that a Vendor 1099 record may be input through the Vendor 1099 Master File Addition transaction (VNDA).

Controls Over Cash and Checks

The project director must maintain proper controls over cash and checks, including security controls (such as maintaining cash and checks in a locked safe) and management controls (such as timely reconciliation of the account).

Specific duties related to cash and checking account funding, disbursing cash and checks, and account balancing should be made the

Controls Over Cash and Checks (cont.)

responsibilities of different personnel. Reconciliations of the account must be performed by project personnel other than the project director (or whoever deposits funds and authorizes disbursements).

Documentation

Cash Payments

In order to document that there has been a transfer of cash to a human subject, the office of record may obtain signed receipts. If obtained, these receipts must be retained. Other ways to document the transfer of cash to the human subject include:

- maintaining a log of interviews conducted.
- having the research program staff maintain statistical work papers.

Check Payments

Cashed checks suffice as documentation in support of payments made by check.

Office of Record for Cash and Check Payments

The office of record must retain documentation to support the number of payments made to human subjects. When payments are made to human subjects through alternate methods, the project director, with approval of the operations manager, may act as the office of record for all payment documentation. The operations manager may cancel approval at any time.

The office of record must retain records in accordance with the retention requirements for vendor payment files. Refer to Appendix F (Document ID: PP-X-F) in this Manual for Research Foundation record retention guidelines.

Reporting Requirements for Alternate Payment Methods

General Reporting

When payments are made through either alternate method, the project director must keep track of the number of subjects who receive payments and the amount of each payment. This information must be provided to the operations manager upon request.

Reporting Requirements for Alternate Payment Methods (cont.)

1099 Reporting

For each human subject paid $600 or more in a calendar year, the project director must provide the following information to the appropriate operating location business office for input to the Vendor 1099 Master File:

- name.
- Social Security Number.
- home address.
- total amount paid to the person.
- Research Foundation account number(s) from which the person was paid.

This information must be input *before* December 31.