

Model Volunteer Consent Form, #3

Background survey has

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 exempt from IRB 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.

A first planning step for any researcher doing "greater than minimal social risk" research is to outline fully all the potential social and physical risks. In this kind of research, risks often include:

- loss of confidentiality about the identity of the volunteers;*
- loss of confidentiality about the information given by the volunteers;*
- triggering internal conflicts within volunteer-respondents, e.g., emotional reactions or needs;*
- triggering external conflicts of social, stigmatizing, or physical damage against volunteers, e.g., assault by abusing partners or legal action by authorities, if study participation in the study became known. In some research (e.g., about fetal alcohol syndrome), the people at risk include not only the subjects of the research but third-parties (e.g., the mothers) as well.*

The next step is to ensure that the research methods minimize the risks to the volunteers and any others. The researcher must try to ensure confidentiality; we suggest relying on anonymity whenever possible. To minimize emotional risks triggered by the research itself, the interview time must include extended listening, ventilating, discussing, and referral to counseling services. (Cooperation of counseling services must be obtained before approving the research.) If the research concerns illegal behavior, e.g., a study of HIV and risk factors among prostitutes, the researcher may need to have the cooperation of local legal authorities. If there is a risk of triggering violence by abusing partners, the researcher must ensure that nothing given can identify a person as a respondent. Risk to the community must be minimized, often by researchers and community agreeing about publication, e.g., whether to identify the community.

Researchers should also maximize benefits of the research to each volunteer and community. They must ensure availability of services to the volunteers. For a survey of fetal alcohol syndrome, for instance, researchers should link to established, or help establish, treatment.

Research involving emotionally-vulnerable subjects should avoid institutional pressure by caregivers: any patients who are dependent on caregivers' help may feel that refusing to take part will lead to loss of the care they need, in spite of the written "non-coercion disclaimer" in consent forms. One way to avoid the problem is to emphasize repeatedly the freedom to refuse. Another is to have at least the consent, and sometimes the research as well, done by people other than the caregivers. (In this hypothetical project, the researchers did not want to introduce a stranger into the relationship, due to extreme vulnerability of victims of domestic battering; thus, they felt that the counselors should be the people to solicit consent and do the follow-up research. But both the counselors doing the verbal explanation and the consent form repeatedly emphasized the freedom to choose.) In an actual project similar to this hypothetical research, several women did refuse to take part, indicating true freedom.

Please note a specific aspects of the hypothetical research and model Volunteer Consent Form. The

need for a Certificate of Confidentiality depends on: 1] the questions asked; and 2] if the Federal Privacy Act applies. In this hypothetical case, 1] the survey includes legally sensitive answers about the subject and third-parties, and the survey retains identifiers for the longitudinal survey; and 2] the Family Shelter is not a federal facility. Thus, the researchers got a Certificate. The explanation about the Certificate should be short and understandable, not long and in legalese.

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. An IHS 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 record.

No reports about the survey will contain your name or the name 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 IHS 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 care or services from the Family Crisis Center, IHS, or anything 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 a **complaint, grievance, or other concern** please contact Jane Goodlawyer She is a staff attorney for the NoName Legal Defense Office (NLDO), and is a member of the NoName IRB. Call her at ___-___ or visit her at NLDO. You may use a Clinic phone to make the calls.

Thank you for helping build a better NoName community for all families.

We will report the results of this study at the NoName Nation's Annual Meeting, in May 1994. A summary will be available at the Center shortly before the meeting. You can also discuss the results with any Center counselor.

I agree to take part in the NoName Family Crisis Center study about violence in the home. My questions have been answered, I receive help by the Center, I refuse to answer questions about programs and people, and their telephone numbers.

[Note: The readability of this Consent Form is 8th grade. The text is only 1033 requirements for Consent Forms for complex research that is greater than minimal social risk.]