IRB Appendix

Model Volunteer Consent Documents for the Indian Health Service - *2nd Ed*

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Explanation

To help investigators draft the documents needed for their projects, the IHS IRBs developed the attached 10 model volunteer documents for different hypothetical situations. The situations include 7 research protocols typically seen in IHS, a protocol typical in tertiary-care (#5), and 2 EPI-AID protocols (#9, #10). The protocols, and thus the documents or sheets, range from complex (#1, #3, #5, #8) to simple (#4, #9). The specific hypothetical situations are:

1] a randomized, double-blind, placebo-controlled, Phase III clinical trial of an Investigational New Drug vaccine, *i.e.*, with "greater than minimal" biomedical risk;
2] a screening by lab testing of a population for diabetes;
3] a survey about domestic violence, *i.e.*, with "greater than minimal" social risk;
4] a simple questionnaire survey of users of a clinic for health service research;
5] a generic open-label single arm protocol to use and assess ribavirin for hantavirus;
6] a "youth risk behavior survey" (YRBS);
7] community-based participatory research, using qualitative research methods, on the highly sensitive, emotionally-distressing, topic of miscarriage;
8] genetic research into a complex syndrome of colon and ovarian cancers, HNPCC; and
9], 10] *information sheets* for investigations of simple (7) and complex (8) epidemics.

The last page lists those elements in consent documents required by regulations 45 CFR 46 (marked by **@**), or needed by only some protocols (unmarked). The regulation's section for each element is cited. The list is from a larger checklist used by IHS Area and National IRBs.

I wrote the 8 model Volunteer Consent Documents and 2 information sheets to be understandable by most people. The National Adult Literacy Survey (NALS), whose results were released in early September, 1993, guided they the documents were written.* Let me describe the NALS briefly, and show how it is relevant to consent documents.

In 1992, NALS tested a valid sample of 13,600 US adults for 3 types of applied literacy:
- *prose* literacy, using new stories, articles about health, etc.;
- *document* literacy, using payroll forms, transportation schedules, maps, etc.; and
- *quantitative* literacy, asking them to balance a checkbook, complete an order form, etc.

The results of testing applied *prose* literacy were relevant to developing consent documents.

NALS divided the results into 5 "Levels" of prose literacy.
- 1: unable to read; or "read a relatively short text to locate a single piece of information."
- 2: "integrate two or more pieces of information to compare and contrast easily identifiable information"; locate a single piece of information but the passage had several "distractors" ("plausible but incorrect pieces of information").
- 3: "make matches that require low-level inferences"; "integrate information from dense or lengthy text that contains no organizational aids such as heading."
- 4: "integrate or synthesize information from complex or lengthy passages"; "[c]onditional information is frequently present."
- 5: "search for information in dense text which contains a number of plausible distractors": readers must "use specialized background knowledge" to understand part of the text.

Levels 4 and 5 describe many consent documents we have all seen, and written! How many US adults could be expected to understand Level 4 or 5 consent documents? See the graph below.
Apparently only 20% of US adults would understand the dense and complex consent documents we are familiar with. How can consent documents be made understandable to more people?

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* Kirsch IS, Jungeblut A, Jenkins L, Kolstad A. *Adult literacy in America: a first look at the results of the National Adult Literacy Survey.* Washington, DC: National Center for Education Statistics, US Dept. Education; 1993.

One possible approach would reverse or omit those factors that contributed to decreased comprehension in the texts used by NALS. Those factors included the following.

Factors that decrease comprehension of prose material used by NALS

1.	Increase in **number of items** or categories of information
2.	Decrease in the **closeness of relationship** of the text to the information being tested
3.	Increase in **length** and **density** of the text
4.	Increase in **amount of background information needed** by reader to understand the text
5.	Increase in **number of distractors** (information apparently similar to, but actually different from, the information being tested)
6.	Decrease in the **organization aids** of the format of the text.

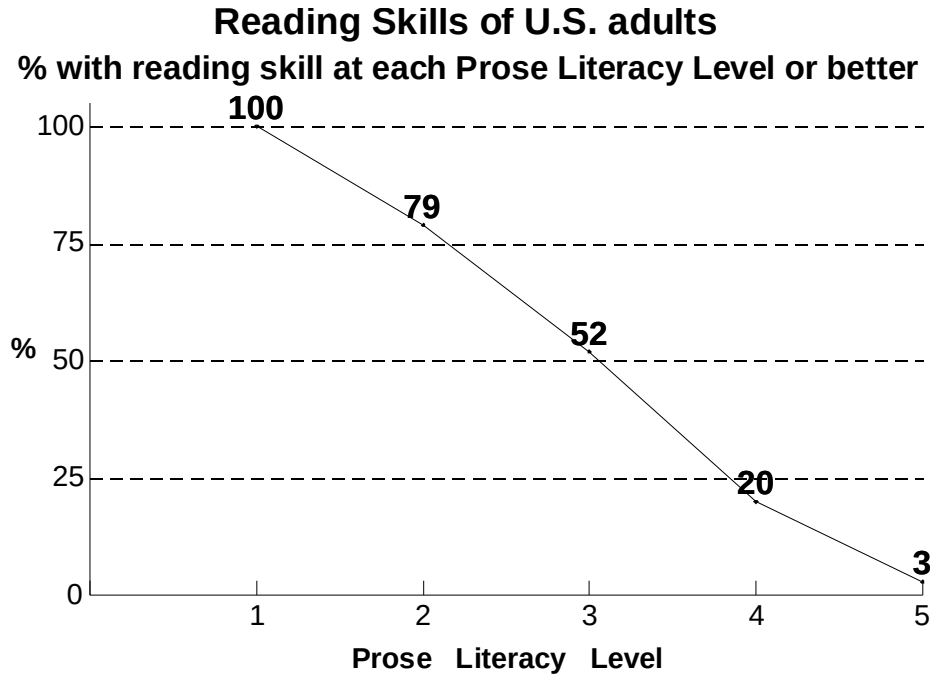
To reverse these factors above associated with fewer people understanding the NALS material, the Model Volunteer Consent Documents try to meet the following 6 criteria.

1. Be brief, but have complete basic information. *[Affects factors 1, 2, 3.]*

The first factor cannot be eliminated entirely, because 45 CFR 46 requires more than a dozen items of information. However, omitting unnecessary or irrelevant items of information will help minimize factor 1, and help reverse factors 2 and 3.

Many potential volunteers do not read long consent documents or information sheets. The longer the document, the fewer the people who read it in its entirety, and the smaller the fraction of the document that is read by the rest. Thus, trying to be more comprehensive by adding more information may result in less information actually transmitted.

The model documents include only the *basic information* needed by potential volunteers. We researchers have a bias: we tend to include too much scientific detail, and to minimize or omit some required elements of 45 CFR 46. The models are designed to counter that bias; they do not try to answer every conceivable scientific question. For example, the first model, for the experimental



(Percentages calulated from data in the National Adult Literacy Survey.)

vaccine, does not have information about how the vaccine was made. (That would be "basic information" only if it were controversial, *e.g.*, made by tissues from aborted fetuses.) But the models do include all items required by the regulations. We tried to make the model documents include only

information closely related to the core information needed to be understood, analyzed, thought over, and remembered by potential volunteers.

"Non-basic information" can be given in a separate handout, perhaps in a Question-and-Answer format. We suggest including a list of questions at the beginning of the handout, to permit people to go directly to those questions they are most interested in.

2. **Be less dense, *i.e.*, have easy readability, for most people.** *[Affects factors 3 and 4.]*

   All of us have encountered quite dense material that is difficult to read and to understand. Readability measures one aspect of density. Several computer programs have 1 or more readability formulas, usually expressed in school "grade" level. The readability formulas are usually a linear relationship of: the average number of words per sentence, and the average number of syllables or letters per word. Thus, a consent document with "ninth grade readability" means that the relationship between words-per-sentence and syllables-per-word of the consent document is similar to that in material read and understood by ninth graders.

   Unfortunately, words-per-sentence and syllables-per-word sometimes have little to do with understandability. Rare short words in short sentences may have a mathematical similarity to material read in the lower grades, but be understood only by rare people. Beyond short words and short sentences, ways to improve readability include the following.
   - Use active voice rather than passive voice verbs ("We did" rather than "It was done").
   - Use common words in general.
   - 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.")

   The readability of the Model Documents #1, #3, #5, and #8 is 8th grade, in spite of their complex topics. Readability for #6 and #9 is 6th grade; that for all others is 7th grade.

3. **Be clear and provide the background information needed.** (Use familiar terms, explain unfamiliar terms and concepts, and organize into logical sequences.) *[Affects factor #4.]*

   The models try to omit specialty terms and concepts not essential for being informed to make a decision, and to define and explain all new terms needed. The documents strive to be understandable, not scientifically precise. Also, people can comprehend organized new material better than unorganized new material. Thus, organizing new material into succinct blocks, and putting the blocks in a logical clear sequence, helps maximize comprehension. Writers of consent documents should ask "*What potential volunteer's questions are we trying to answer? What background information does s/he not have, but needs, to understand this?*"

4. **Use only 1 meaning for important terms; eliminate "distractors."** *[Affects factor #5.]*

   Distractors include the same word with different meanings; the multiple meanings confuses people. Many consent documents have two such distractors: [1] "risk"; and [2] "benefit."

   "Risk" means the *harms inherent in the research*, and also sometimes the risk *factors to come down with disease* that the research is dealing with. I suggest "risk" be used only in the former sense, *i.e.*, the *direct inherent possible risks of the research for volunteers and community*. "May get disease" or a similar phrase can be used for "risk factors."
   "Benefits" means *advantages inherent in the research*, but also *benefits not to be foregone* in the non-coercion disclaimer. "Benefit" may even mean *payment given for participation*. I suggest that "benefit" be used only in the first sense, *i.e.*, the *direct inherent possible benefits of the research for volunteers and community*. "Care or services" can be used in the non-coercion disclaimer; "reimbursement" or "payment" can be used for participating.

5. **Have a format that helps people comprehend and remember the information.** *[Affects factor 6.]*

Format can help people comprehend and remember complex material. Research has shown that certain elements of format help improve comprehension. Good format includes:

- **Headings**;
- indents;
- key words in **bold** or underlined;
- vertical lists (instead of run-on lists in long sentences);
- extra spacing between topics;
- short paragraphs, with only one major thought per paragraph;
- repetition (repeat important, difficult-to-understand, points);
- reasonable-size type (not small print to minimize pages);
- lower case, NOT UPPER CASE; 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.)

These elements of format help the reader to:

A] recognize the organization of the consent document;
B] recognize, know, and remember the key points; and
C] go back later to the document to retrieve important information, such as telephone number of the doctor to call if injury occurs.

6. Serve as a script for the face-to-face discussions with the potential volunteers. *[This criterion is not related to the above factors suggested by the NALS.]*

Face-to-face discussions between investigators and potential volunteers are the most important part of the process of informed consent. These model documents are intended to be both the **written consent documents** and the **script for the verbal explanation** by the investigators. If the verbal explanation is almost the same as the written document, each will reinforce the other and avoid inconsistency. Thus, each model is actually a combined *document-script*.

One benefit is this approach is that the document-script prompts investigators to use simple language for the verbal explanation. Another benefit is that the same document-script can be used for potential volunteers who have difficulty reading, have low literacy, or need a translation--which also increases consistency of explanation among all volunteers. Investigators need develop only one document-script, not two, to permit people of all literacy levels to be potential volunteers. The document-script could also be used to videotape the explanation.

The model document-scripts reinforce both the oral discussion and visual reading. For instance, the bolded headings are the key "take home" points of the information to be transmitted. The document-script approach should result in two editorial benefits.

1] Bolded headings attract attention and are remembered. By having key points as headings, the reader more likely will remember the key points. (Bolded headings that are just titles or questions attract attention, but unfortunately are not intended to be remembered.)
2] The length is shorter. There is little or no unnecessary verbiage.

Exemplary consent documents are not sufficient for informed consent.

Researchers and IRBs should go beyond the consent document in two ways.

First, the quality of the interpersonal communication in the process of consent--the two-way sharing of information by researcher and potential volunteer--is more important that the quality of written documents. The sharing should be two-way; the researcher needs to impart information, as well as find out the level of understanding by potential subjects and elicit questions they may have. IHS IRBs have not devised ways to assure high quality in the process of communication. One way may be that the researchers, the tribal government or personnel from the tribal health department, Health Boards, and IRBs work out consent processes as partners that are culturally sensitive and respectful of each person.

Second, because some research protocols are so distant from the background information possessed by most people, the amount of totally new information required to be in consent documents for those protocols may overwhelm even maximum clarity of writing. The model documents for the ribavirin trial (#5), and for the genetics study (#8), are examples. In such circumstances, 3 added steps may help.

1] Allow and encourage 24 hours or more for discussion and a decision. Simply having the person take the consent document home overnight can increase comprehension. [*] What people learn from written material varies by the background information they have about the subject. [@] Hence, a researcher could try to increase the background information of potential volunteers before they could understand enough to make an informed decision. *E.G.*, one could discuss the information in 2 stages, at least a day apart. The first stage would focus on the basic information about the purpose; the second stage would summarize and answer questions about the purpose, and then focus on procedures. This approach is feasible when time is not critical, unlike the ribavirin protocol.

2] Educate people before they are asked to participate, by publicizing and discussing the protocol repeatedly in the media. One should use as many media channels as possible, *e.g.*, radio, newspaper, TV, district or chapter house meetings, churches, etc. This approach is feasible when the community has high interest in the research.

[3] For one-on-one discussions with potential volunteers, use media in addition to the printed page, *e.g.*, videotapes, interactive computerized video discussions, etc.

In summary, we should follow the principles of effective written communication, *i.e.*, reverse the 6 factors leading to poor comprehension. We should write consent documents understandable by 70%-80% of the adult population. Even with more than 12 important items required by 45 CFR 46, Level 2 consent documents are achievable for most protocols.

[*] Morrow G, Gootnick J, Schmale A. A simple technique for increasing cancer patients' knowledge of informed consent to treatment. Cancer 1978; 42:793-799.

[@] Mosenthal PB, Kirsch IS. Learning from exposition: using knowledge modeling as a basis for assessing student's knowledge. *J Reading*. 1992; 35:668-678.

IHS Model Volunteer Consent Document, #1

Background: a randomized, placebo-controlled, Phase III clinical trial of an Investigational New Drug vaccine.

In all model documents, harms or risks are written as 'some people have gotten ....' [or similar wording. Many people understand the typical wording of 'the vaccine may cause ....' or 'you may get ....' as being a forecast of what will happen to the person, not a statistical statement.

Goodvacc Vaccine Research Study.

We ask you to take part in research for a new vaccine for Severe disease.

The NoName IHS Service Unit, Topdrug Pharmaceutical Company, and Academia University are doing this study. The study has 2 purposes:
1] to see if Goodvacc vaccine prevents Severe disease; and
2] to see if the vaccine is safe.

Goodvacc is an experimental vaccine. 2,500 adults have received it without problems.

Goodvacc is an "Investigational New Drug," because it is still being studied. That is, it has not been licensed by the FDA (Food and Drug Administration) for general use. The FDA may use this study to decide if it should be licensed.

Goodvacc has been given to more than 2,500 adults. Almost all of them made antibodies to Severe disease. (Antibodies are what the body makes to fight infections.) So far, no serious side-effects were seen in any of the people given the vaccine.

There is no other way to prevent Severe disease.

Severe disease is an infection that hits mostly elders. About one-third of elders with Severe disease die even though we give them the best medical treatment known. So we want to prevent the disease from hitting the elders, but there is no way known to prevent it now. If Goodvacc vaccine works, it would be the only way to prevent it.

We want to find out if this vaccine works, and to be sure it is safe.

This study will find out if Goodvacc, and the antibodies it produces, do prevent Severe disease. We also want to check for side-effects. We are testing Goodvacc vaccine here because many elders of NoName Reservation get Severe disease, and more than one-third of them die from Severe disease.

There are several steps to this study.

We ask all patients age 60 or older, who come to NoName Clinic, if they want to take part in this study. We will check to see if there is a medical reason that they should not take part.

If you take part, we will give you a shot of <u>either</u> Goodvacc vaccine, <u>or</u> sterile water (a "placebo") that does not produce antibodies.

If you volunteer to take part, we will put you in one of 2 groups. Groups are assigned by chance or randomly, as by a flip of a coin. People in one group will get a shot of Goodvacc vaccine. Ppeople in the other group will get a shot of sterile water ("placebo"). You will not know which shot you get, the vaccine or the water. All shots are given by trained nurses.

Then we will draw one tube of blood three different times.

A skilled lab tech will draw one tube of blood (about two teaspoonfuls). We will draw the blood before the shot, in 1 month, and in 1 year. We use the blood tests to see if you already have, or make, antibodies to Severe disease. To draw the blood from you, we will ask you to come back to the NoName Clinic in 1 month and 1 year.

When you come back, a nurse will ask you a few questions to find out if you had any side-effects after the shot, and if you had Severe disease. The questions take about 10 minutes. The nurse will also check your medical chart at the Clinic to see if you had Severe disease.

We will give you $10 for today's blood draw, and $20 each for the second and third draw, to pay for time, gas, and other expenses.

.....

<u>Schedule</u>:

Date	**Type of visit**	**What will be done**
Today	Clinic	health questions; blood draw; shot; $10
1 month	appointment with us	health questions; blood draw; $20
1 year	appointment with us	health questions; blood draw; $20

.....

The vaccine may have side-effects for some people.

So far, the side-effects of the 2,500 people given Goodvacc vaccine have been the following.

<u>Local reactions at the shot</u>:	<u>General reactions</u>:
redness or soreness or swelling.	fever for about 1 day.

Less than 4% (1 person in 25) of the people who received the vaccine had any of those reactions.

As with all blood draws, you may get a bruise where the blood was taken. It is very rare to get an infection at the site of the blood draw.

The vaccine may have risks that we do not know about.

Goodvacc may have a side-effect or reaction that we do not know about. A very few people who got other vaccines had rare severe reactions, or even death.

The vaccine may benefit some people who get it.

Some people who get the Goodvacc vaccine shot may be protected from Severe disease. We hope Goodvacc vaccine protects against the disease, because it protected animals in tests. However, we do not know for sure if it protects human beings from Severe disease. The purpose of this study is to find out if it does protect.

If you get the "placebo" shot, you will not get benefit now. But if this study shows that Goodvacc protects against Severe disease and is safe, we will offer to give you the vaccine immediately. NoName Reservation may also benefit from this study. If the vaccine protects elders from Severe disease, NoName elders will be the first to be protected. When we get the results of the study, we will report them to the Tribal Council first, before releasing the information to the general public.

We will guard your privacy.

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 anything about people in the study. Medical records are held in a secure room. The FDA may examine our records of those who take part in the study. It is possible but unlikely that a court order may force us to reveal medical records to other people, as is true for all medical records.

In case of injury or reaction, call Dr. Ida H. Service at ___-___-____.

If you have an injury or reaction that may be caused by your shot or study procedures, please call Dr. Service immediately. Her telephone number is ___-___-____. You may use the NoName Clinic phone, or call collect, to make the call.

The NoName Clinic will provide medical care for any injuries or reactions caused by the Goodvacc vaccine or study procedures. The Topdrug Pharmaceutical Company will pay for needed medical care that IHS does not provide.

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

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

You may use an NoName Clinic phone for the call.

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 care or services by IHS or others. You may quit at any time, with no penalty or loss of any care or service for which you are qualified.

We may contact you later about taking part in other studies related to Goodvacc vaccine or Severe disease. You may choose to take part or not at that time. Your decision to take part or not in the future will not affect any care or services by IHS or others.

You may stop taking part in this study at any time. You will be reimbursed for each blood draw taken. We may end your participation in this study at any point if we feel it is in your best interests for your health. We will tell you any information we find that may affect how willing you are to continue in the study.

If you have a **complaint, grievance, or other concerns**, call or write Ed Ethics:
NoName IRB, NoName Tribal Office
1000 Happy Ave
Happy City, XX 12398-7654
(telephone ___/___/____)
You may use an NoName Clinic phone for the call.

I agree to take part in <u>The Goodvacc Vaccine Research Study</u>. My questions have been answered. I received a copy of this form.

Signature:_____ Date: _____, 1993
[or thumb-print]

Witness:_____ Date: _____, 1993

.....

[Note: The readability of this Volunteer Consent Document is 8th grade. The text is 1,258 words.]

IHS Model Volunteer Consent Document, #2

Background: This is a hypothetical protocol for this community_based diabetes prevalence study. A team of service unit health care workers and local tribal members wants to determine the prevalence of diabetes in the community. The ultimate purpose is to determine which geographic or demographic (age and gender) groups have the highest rates of undiagnosed diabetes, which will lead to screening and intervention focussed on those groups. High random serum glucose will identify community members needing more definitive workup and final diagnosis. The team obtained technical assistance for project design and sample size calculations. ***General Methods:****. The team will determine prevalence of diabetes in a stratified random sample of community members. The sampling will use a list of tribal members maintained by the tribal census office. This list will be sorted by sex and age. After a random selection of the first person, every nth name on the list will be selected as well. A field worker will visit the homes of all selected people and ask them to participate in the study. Anyone positive on a random serum glucose will be asked to go to clinic for definitive testing and diagnosis.*

Is an "Informed Consent" document necessary? Is this truly "research"?

Screening for diabetes is part of clinical care; a detailed process of informed consent is not usually done when screening for diabetes in clinical care. One may therefore ask, is this project really clinical care with community outreach, and not "research"?

Although the project includes clinical care, it is also research, due to its use of sampling and to the purpose of the project. Sampling is done to ensure that the prevalence rates found are valid for the entire community. But sampling is a method of research, not of clinical care. The primary purpose of the project is to determine the prevalence rates of undiagnosed diabetes, and how the rates vary by geography and demography. That primary purpose is research, although the research results will be then used to plan better clinical care.

Informed Consent by potential volunteers*.*

Informed consent must be obtained before a person's participation. Although finding undiagnosed diabetes will likely benefit such people, making the diagnosis has risks. (For instance, driver license and insurability may be adversely affected by a diagnosis of diabetes.) The consent must describe all benefits and risks.

Community Diabetes Research Project: Informed Consent for Volunteers.

We ask you to take part in research for the Community Diabetes Project.

The Project is sponsored by the Tribal Health Program and IHS. We want to find out how many people have diabetes but do not know it.

Diabetes means that a person has too much sugar in the blood. Many people in this Tribe have diabetes. Although many people with diabetes are diagnosed in the Clinic, some people may not know they have it. If we know where most of those people live, we can set up stations to screen for diabetes in those Districts.

We want to check 200 adults from all parts of the Reservation. We picked the people randomly from the Tribal Census, like picking bingo numbers out of a drum.

We want to check your height and weight, and do a blood test for sugar.

If you agree to take part, we will ask some questions about your health and how you are feeling. We then will check your height and weight, and get a drop of blood from you by a finger-stick. We will **test your blood for sugar right away, and tell you the results**. All this takes about 15 minutes of your time.

When we get back to the Clinic, we will put all the results in your chart, for the doctors to see.

If your test shows high blood sugar, we will ask you to go to the Clinic.

The test today does not diagnose diabetes. High blood sugar on the test today means just that you may have diabetes or tend to have it.

If the test today is high, we will make a Clinic appointment for you. **You can get the final tests to check for diabetes there.**

People and the community may benefit if you agree to take part.

People may benefit because they may learn if they have diabetes or not. If you have diabetes but do not know it, the Clinic can help you stay healthy. Our community may benefit because we will be able to plan for better health services.

We want you to know the risks for taking part, as well.

The finger-stick will sting for a couple of seconds.
Some people may worry a lot if the test today is high. But a high test today does not mean a person has diabetes for sure. The Clinic will do those tests. And for people who have diabetes, **the Clinic can help them return to good health**.

If you have diabetes, you may need to have the Clinic OK your Driver's License each year. Having diabetes also means it is more difficult to get insurance. (But most insurance companies test for diabetes when people apply, anyway.)

We will keep all your information private.

All results go right to your Clinic chart for your doctor's use. After that, the Community Diabetes Project will remove all names. Because there are no names, no-one can know what your results are from the Project.

If you have questions about this Project, please call Mary Doeswell at ___-____.

You may use a District or Clinic phone for the call. You can visit also her at Tribal Headquarters.

If you have a **complaint, grievance, or other concerns**, please call **Ed Ethics at ___-___-____**, or visit him in the Tribal Office. You may use a District or Clinic phone for the call.

Taking part in this study is voluntary.

If you do not take part, you will have no penalty and will lose no care or services by IHS, Tribe, or others. You may quit at any time, with no penalty or loss of any care or services for which you are qualified.

We will give you a copy of this form.

I agree to take part in the <u>Community Diabetes Research Project</u>. It will check my blood for sugar, and put the results in my Clinic chart.

.....

[Note: The readability of this Document is 7th grade. The text is only 646 words.]

IHS Model Volunteer Consent Document, #3

*Background: This consent document is for a survey of adults 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 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, **real** services of prevention and treatment.*

Research involving emotionally-vulnerable subjects should avoid institutional pressure by caregivers. Many 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 documents. 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 document 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 Document. 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 research about violence in families on the NoName Res.

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 study. 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.

Some people have felt discomfort by taking part.

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.

The Family Crisis Center has tried to prevent any risk to you.

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 tries 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. You 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, like your medical record.

No reports about the survey will contain your name or the name anyone 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 NoName 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 concerns**, please contact **Jane Goodlawyer**. She is a staff attorney for the Noname Legal Defense Office (NLDO). She is also a member of the NoName Institutional Review Board (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 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 Volunteer Consent Document is 8th grade. The text is only 1,031 words, yet it meets all requirements for consent documents for complex research that is greater than minimal social risk.]

IHS Model Volunteer Consent Document, #4

Background: This anonymous survey of adults asks for no sensitive information. The research is no more than minimal risk and does not involve vulnerable subjects; thus, it may be exempt from IRB review. Nonetheless, the consent process should minimize institutional pressure to participate possibly found in IHS settings; this document assures potential volunteers that their IHS services are totally unrelated to their choice of participation.]

NoName Health Service Research Study.

The NoName Indian Health Board asks you to take part in research about what services IHS Clinic patients need.

We will use the results of the study to plan for better services for all of us. The Health Board wants to know what things are done well, what things need to be improved, and what new services are needed.

We ask all adult patients seen by the IHS Clinic, and parents of children, to fill out the form. We know of no risks to you to taking part, because the survey is anonymous. That is, no-one can know who filled out a form, because no names are on it. It takes about 10 minutes to finish.

The NoName Tribe will benefit if most patients answer the survey and give their ideas!

Taking part is voluntary.

If you do not answer the survey, you will have no penalty and will lose no care or services by IHS or others. 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**, phone **___-____** or at the NoName Tribal Office. If you have a **complaint, grievance, or other concerns**, please contact **Ed Ethics**, Chair, NoName IRB. Call him at **___-____** or visit him at the Tribal Office. You may use a Clinic phone to make the calls.

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.

Thank you for helping build a healthier world.

We will report the results of this survey at the Nation's Annual Meeting, May 2. Please attend!

.....

[Note: The readability of this Volunteer Consent Document is 7th grade. The text is only 292 words and 1/2 a page, yet it meets all requirements for consent documents.]

IHS Model Volunteer Consent Document, #5

Other collaborators for this generic consent document were: Drs. Louisa Chapman [CDC], Greg Mertz [UNM], and Ray Reid [a Navajo physician-researcher with Johns Hopkins U].

Ribavirin Treatment of Hantavirus Illness Acquired in the United States.

We offer ribavirin as a treatment for the "Mystery Illness."

"Mystery Illness" is an infection caused by a type of **hantavirus**. The illness is now called "Hantavirus Illness." This **hantavirus** is a tiny germ, a virus. It comes from a mouse. Some people infected with **hantavirus** get sick but get well. Since May, more than half of people sick with **hantavirus illness** have died.

There are different types of **hantaviruses**. We are not sure of a way to treat the type here. But **ribavirin** may be a treatment. A study suggested that **ribavirin** may help cure illness caused by a related **hantavirus**.

The use of ribavirin to treat hantavirus illness is experimental.

There is no medicine now to treat this type of **hantavirus illness**. **Ribavirin** is a medicine used in the U.S. When given by breathing it in, it helps cure a severe viral lung infection in children. But we do not know if **ribavirin** can treat the **hantavirus illness**. We feel **ribavirin** may be able to treat your illness. Because **ribavirin** is experimental for **hantavirus**, it can be used only in research.

The purpose of the research is to see if ribavirin can treat the hantavirus illness.

We also will check the side-effects and safety of **ribavirin**.

Dr. Infection Doctor, School of Medicine, is in charge of the study.

Doctors in the hospital can use **ribavirin** under the research plan by Dr. Doctor.

For the treatment, we will give ribavirin injections by vein for 10 days.

We will give it every 6 hours for 4 days, then every 8 hours for 6 more days. The first dose will start right away. We will give bigger doses in the 4 days, and smaller doses the last 6 days. Those are the same doses used for many years to treat other viruses.

We will get lab tests every day.

Before we give the first dose, we will get some urine to test for **hantavirus** and check your kidneys. We will get 3 tubes of blood to check your blood, liver, and kidneys. If you are a woman, we will ask you if you are pregnant. We will do a urine or blood test for pregnancy, as a check.

While you get **ribavirin**, we will get 3 tubes of blood each day to check your blood count, liver, and kidneys. We will get 1 tube of blood a month from now, as a final check.

We want to learn how to better diagnose and treat the **hantavirus illness**. We will save some blood and urine samples to do that research.

There are possible risks with ribavirin. Only people with hantavirus illness should get it.

We think you are infected with **hantavirus**. But if we find out by our tests that you are do not have **hantavirus illness**, we will stop the medicine. If the **ribavirin** causes damage to you, we will stop the medicine.

We cannot give ribavirin to women who are pregnant.

When tested in pregnant animals, **ribavirin** caused severe birth defects or death of the unborn animals. Thus, if given to a pregnant woman, **ribavirin** may cause severe birth defects, or the unborn baby may die. So, **we will not give ribavirin to pregnant women.** That is why we test women for pregnancy, and ask about the history of last menstrual period.

Women who receive ribavirin must not become pregnant for 3 months.

The medicine can stay in the body for 3 months. Because it can harm an unborn baby, women should not get pregnant for 3 months after finishing it. **If you are a woman, you must not get pregnant for 3 months.**

Ribavirin may cause minor changes in the blood.

Most people treated with **ribavirin** elsewhere got a mild anemia, or low blood count. The low blood count did not cause permanent damage. After the 10 day treatment, the blood count returned to normal.

Also, about 1 of every 50 patients who received **ribavirin** had slightly higher bilirubin in the blood. Bilirubin can cause some people's skin to look yellow. The bilirubin returned to normal after finishing the medicine.

Less than 1 of every 250 patients had a small increase in uric acid for a while. It returned to normal.

Ribavirin may have other risks we do not know about.

It may have a rare side-effect or reaction not known now. Any medicine can, very rarely, cause death from an allergic reaction.

Ribavirin may have benefits, too. We hope it will help you.

There is now no other medicine for **hantavirus illness**. We hope **ribavirin** will treat this **hantavirus**, because a study suggested that it may help cure illness by a related virus.

If you decide not to take ribavirin, we will give you the best standard treatment we can.

We will give all patients the best care we can, whether they take **ribavirin** or not.

We will guard your privacy.

We will keep information about you, and your taking part in this study, private to the best of our ability. We will not use your name outside this study. If you take part, the U.S. Centers for Disease Control and Prevention, and the U.S. Food and Drug Administration, may check your medical records. A court could order us to show medical records to other people, but that is not likely.

All reports to the Tribe, community, other doctors, and medical journals will not have any patient name.

If you later have questions about the study, call Dr. Doctor at (___) ___-____.

Call Dr. Doctor in at ___-____ between [times]. All other hours, call **( ) ___-____** and ask for **Dr. Oncall**.

If you have an **injury or reaction** that may be caused by **ribavirin** or procedures, please call Dr. Doctor at ___-____ right away. The Hospital will give you all the care you need.

The ribavirin is given to you free.

There is no charge for the medicine.

We will provide care to you for any adverse affects of ribavirin.

There is no program to pay patients for adverse affects.

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 care or services. You may quit at any time, with no penalty or loss of care or services for which you are qualified.

You may stop taking ribavirin at any time. We may stop it if we feel stopping is best for your health. We will tell you any information we find that may affect your willingness to keep getting the medicine.

We may contact you later about taking part in a follow-up study related to **ribavirin** or the **hantavirus illness**. You may choose to take part or not at that time.

For answers to your questions about a complaint, grievance, or other concerns, call the University Institutional Review Board (IRB) at (___) ___-____.

I agree to take part in the research Ribavirin Treatment of Hantavirus Illness. My questions have been answered. I received a copy of this form.

Signature:_____ ***Date: _____, 1993***
[or thumb-print]

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

.....

[Note: The readability of this Document is 8th grade, in spite of the research's complexity. The text is 1,161 words.]

IHS Model Parental Permission Document (Youth Risk Behavior Survey) #6

Background: Many states, Tribes, and school districts want to measure or monitor the levels of various risky behaviors of the adolescents in middle and high schools by a Youth Risk Behavior Survey (YRBS). There is a version of YRBS by the Centers for Disease Control and Prevention (CDC); the University of Minnesota have another version. Most YRBSs ask about risky behaviors such as sex (both protected and unprotected), drug and alcohol use, violence (both receiving and giving), and emotional health (such as desires to commit suicide). The purpose of the YRBS is that the school district, Tribe, or state use the information to do appropriate interventions for problems identified, if any. (The data from the YRBS usually must activate the citizens of the district, Tribe, or state to demand interventions for major changes to occur.)

Many states in the past have conducted their YRBS without IRB review or sometimes even Tribal review. Most school districts have reviewed the YRBS and usually had the option of not participating (i.e., disapproving the YRBS in their district). Most YRBSs are done by "passive consent," in which if the parents do not send back to the school a signed document refusing to let their adolescent child take part, the YRBS "assumes" that the parent has given permission.

IHS considers every YRBS to be research, because the YRBS is a "systematic investigation ... designed to develop or contribute to generalizable knowledge" [45 CFR § 46.102(d)] about, in this case, the behaviors of students in the district, Tribe, or state. Usually the protocol of YRBS should ensure anonymity of the individual adolescent. According to Subpart D (research with children) of the DHHS regulations 45 CFR 46 about ethical research, the exemption from IRB review, of survey research that is conducted anonymously, does not apply to research involving children. (The Department of Education has proposed almost identical regulations for itself.) ***Therefore, the YRBS must be reviewed and approved by the local IRB[s].***

"Passive consent" does not meet the definition or standards of informed consent (in this case, informed parental permission). An IRB can waive some or all elements of informed permission-consent by 45 CFR § 46.116(d), if four conditions are met: [1] the YRBS involves no more than minimal risk to the children; [2] the waiver will not adversely affect the rights and welfare of the parents or children; [3] the YRBS could not practicably be done without it; and [4] the subjects will be given pertinent information after the YRBS is done. Thus, for the YRBS to be done using "passive permission," local IRB[s] must determine that the survey meets those four conditions. (Condition [1] can be met by procedures to ensure rigorous anonymity, and to prevent stigmatization of students who choose not to participate or whose parents prevent participation. Condition [4] usually means reporting the results to the school district in public. Conditions [2] and [3] are judgment calls by the local IRB[s].)

In a separate document, I have outlined a possible set of procedures for doing the YRBS under which a local IRB might want to waive full informed parental permission. The document was a presentation to the ARENA meeting in 1992, and is available from the IHS Research Program.

This model document #6 assumes full permission. The document can easily be adapted to serve as "passive permission" if the local IRB[s] approve the waiver of permission. The assent document for students can be adapted from the permission document. To fully ensure anonymity, the assent document should be an information sheet, neither signed nor collected. As with the permission document, it should have the name and telephone number of counselors for students.

To ensure a good response rate with "active permission," the school will probably have to send it out three times, perhaps by both mail and as a take-home by the students, and with multiple announcements in multiple media and settings. To ensure that "passive permission" in fact reaches every parent, the school should also do three distributions with multiple announcements. Those activities will also help establish a receptive framework in the community for the results.

The NoName School's Youth Risk Behavior Survey.

The NoName Tribe and School District ask that you give permission for your child to take the Youth Risk Behavior Survey.

This research survey asks students in grades six to twelve about risky behaviors they may do. The survey ask about the following.

Drug and alcohol use, if any -- what drugs, how often.
Auto passenger and driving habits -- seat belt use, driving while intoxicated.
Sex, if any -- how often, protection used.
Violence, if any.
Feeling down, thoughts of suicide.

The purpose is to try to prevent unhealthy behaviors among our kids.

We will use the results of the survey to see if many students have problems with these. The Tribe and School will let you know the results. We may need to improve programs of prevention, or develop new ones.

You can look at the survey, if you want, to see what the questions are.

Copies of the survey are in the school, in the front office.

The survey will have no name of any student. It will take steps to make sure the survey is anonymous.

The survey will be handed out in each class on Friday morning, May 1. Each student will be free to take or not take the survey. Each student can not answer any or all questions. A booklet about Tribal history will also be given out in the same envelope.

The survey takes less than one hour to finish. At the end of the hour, each student will seal the survey in a blank envelopes, and put them in a large box. The school will send all sealed surveys to the Area Indian Health Board for analysis.

If you do not let your child do the survey, he or she will receive a survey with no questions and the history booklet. He or she will hand in the blank sealed survey, like the other students.

The survey has little risk for your child.

The steps will prevent anyone from knowing which survey was handed in by any student. The survey may make some students want to talk to a student adviser about their behaviors or concerns. Students can talk with **Mary Leader** or **Al Mentor** at the school, phone **___-____**.

Each student will not directly benefit by doing the survey.

However, the NoName Tribe and School may benefit from finding out what problems our kids are having. That may lead to helping our kids be more healthy.

Taking part is voluntary.

If you do not give permission, you and your child will have no penalty. If you give permission, your child may leave blank any or all questions. You and your child will lose no care or services by the school or anyone else.

If you have **questions about the survey**, please contact **Mary Leader**, phone **___-____**, at the School.

If you have a **complaint, grievance, or other concerns**, please contact **Ed Ethics**, Chair, NoName IRB. Call him at **___-____** or visit him at the NoName Tribal Office. You may use a school phone to make the calls.

Please sign this permission form, if you agree. Then send it with your child to the school.

You may also mail the form in the attached envelope. Please keep the copy of this sheet.

Thank you for helping our kids keep healthy.

We will report the results of this survey at the first PTA meeting next fall, and in the NoName Newspaper.

I agree to let my child, _____, take the Youth Risk Behavior Survey, if he or she wants to. I can read the survey at the school, if I want.

.....

[Note: The readability of this Parental Permission Document is 6th grade. The text is only 592 words.]

IHS Model Volunteer Consent Document ("CBPR," Qualitative) #7

Background: Some researchers think that qualitative research cannot harm anyone. That is not correct. As shown by this example, of feelings experienced by women who had a miscarriage, significant harms are possible. In psychologically-sensitive research, minimizing harms depends in part on the interpersonal skills of the researcher. The consent document also has a role; for instance, the lay word "miscarriage" is used, instead of the medical terms "spontaneous abortion" or "early fetal death" that would be harsh and severe to the women being asked.

Some medically-oriented IRBs feel unsure about how they can judge the possible scientific benefit of qualitative research. One article in particular,

- *"Assessing quality in qualitative research" in 1999 BMJ (2000; 320:50-52), http://www.bmj.com/cgi/content/full/320/7226/50,*

can help IRBs understand and recognize good qualitative research with the potential for scientific benefit. The article also has a set of good references.

This example is also community-based participatory research (CBPR). Some IRBs have little experience with CBPR. Two articles can help IRBs understand and review CBPR protocols:

- *"Participatory research maximises community and lay involvement" (BMJ 1999; 319:774-778), http://www.bmj.com/cgi/content/full/319/7212/774 -- the references are a good set of additional sources to understand CBPR, and it describes a Community Advisory Board; and*
- *"Using qualitative methods in health related action research" (BMJ 2000; 320:178-181), http://www.bmj.com/cgi/content/full/320/7228/178 -- also is about qualitative research.*

An expanded set of references about "Qualitative Research for IRBs" is available; if you want it, please send me an e-mail to request it.

Feelings about Miscarriage in the NoName Tribe.

This is a modification of the consent document for an actual research project, by: Kristen M. Swanson, RN, PhD, FAAN; Professor and Chair, Dept. of Family and Child Nursing; University of Washington, Box 357262; Seattle, WA 98195; 206_543_8228, fax 206_543_6656.

I am First Lastname, a researcher and a nurse.

I have worked for many years with people who have had miscarriages.

I am asking you to take part in a research project.

I would like you to talk with me and share your story about miscarriage and healing. I want to learn what miscarriage and healing has been like for the NoName people.

I have two purposes with this project.

1] I want to help the NoName people. In my work as a nurse, I have found that people who miscarried often feel better after talking about it.

2] I also want to teach nurses and others how one community dealt with many pregnancy losses. They may then be better able to care for women and families with miscarriage.

This is both a research and a healing project.

It is different from most research, because one purpose is to help the NoName people deal gently and respectfully with the miscarriage of their children.

It is different, also, because tribal members help plan the project. This project will try to help tribal members themselves address the pregnancy losses with respect. The Tribe and I hope to learn together how best to deal with these experiences.

I would like to ask you a few questions and listen to you.

If you agree to take part, we will set up a time to talk. I can meet with you alone, or in a small group.

I will keep a personal journal about this project. I will write down what I learn each day. I will also summarize talks that are shared with me. I will not show my journal to anyone from the community.

I will come to the NoName Tribe once or twice a month for several months. I will stay two days each time. If you want to talk with me when I come, please call me at ___-___-____. You can use the Clinic phone to do so. Or, you can ask Clinic Person to call me. Or, you can e-mail me at ___.

If you agree to take part, I may ask you later for reactions to what I think I have learned. That is, I will want to check with you, to make sure I have it 'right.'

You, the Tribe, and others <u>may</u> benefit by this project.

Some people <u>may</u> feel better after talking with me about their experience. I have helped people for many years to care for themselves, their feelings, their memories, and those they love after a miscarriage.

The Tribe and Health Program <u>may</u> learn good ways to deal with pregnancy loss. The Tribe has named a Community Advisory Board to help plan the project. The Board will help increase the benefits of the project to the Tribe.

The Tribe's experience <u>may</u> teach nurses and others how pregnancy loss affects people, families, and communities, and how to care for them.

I want you to know about possible harms, as well.

Taking part <u>may</u> bring up hard feelings in some people who talk about their miscarriages. To help deal with that, I will give you a list of local counselors who can help. If I think you need help, I will refer you for counseling.

Some people <u>may</u> want to talk more about the miscarriages after I leave. They may feel lonely. To help prevent that, I will let you know about other women in the Tribe who would like to listen and share experiences.

If you take part, other people in this small a community <u>may</u> wonder what you are up to. To help prevent that, I and others will inform the Tribe about the project.

Some research has harmed communities. To prevent that, the Community Advisory Board has helped plan this project. That Board will review all articles and presentations before I make them. The Tribal government has approved this project.

You can get help, if you want it, without taking part in this project.

If you do not take part in this project, you still can get counseling from the Health Program if you want. I will not be the person you will talk to, however.

I will try to keep all information confidential.

I will keep all material in a locked file cabinet in the School of Nursing.

I will not give or tell your name to anyone. No names or identifiers will be in any article or presentation. Even so, some people who know you may think they recognize you, when I describe some things that happened to people. To help prevent that, I will try to disguise those reports. Review by the Community Advisory Board may help prevent that, as well.

If you have any questions about this project, please call me at ___-___-____.

You can use a Clinic phone to call me. You can also ask questions to Clinic Person.

Please ask me now any questions you have about this project. After all your questions are answered, you can decide if you want to talk with me or not.

If you have a concern or grievance about this project, please call IRB Person at ___-___-____.

She is at the School of Nursing. She answers complaints by people in research. She is not part of this project. You can use a Clinic phone to call her.

You can also talk to a member of the Community Advisory Board. Clinic Person can give you their names.

If you think you have been injured or hurt by this project, please call IRB Person at ___-___-____.

Being in this project is up to you.

If you do not wish to be in this project, it is perfectly ok. If you do not take part, you will not lose any rights to health care or any other benefits that you already have.

If you start to take part in this project, you can change your mind later on. You can stop being in the project at any time. If you want, you can also ask me to delete all your stories and facts from the project. If you do so, you will not lose any rights to health care or other benefits.

When you and I sign this form, we agree to treat each other with respect.

I promise to honor what you have shared with me. I promise to treat your personal story with the dignity that you and your memories deserve. I promise to write about your experience so that your identity is hidden.

I will give you a copy of this form.

I agree to take part in the research into feelings about miscarriage.

My questions were answered. I received a copy of this form.

.....

[Note: The readability of this Volunteer Consent Document is 7th grade. The text is 1,109 words.]

IHS Model Volunteer Consent Document (Genetic Research) #8

[Background: Genetic research is sensitive for many Native American people and tribes. Parts of the document are one of many valid choices. An example is the page-long 'I understand' summary at the end--vs. an also valid 3-sentence summary; however, a long summary should include possible harms, the most frequent being psychosocial. Many projects let the person decide future uses; this limits future use without personal consent, and IRB and tribal approval. As always, harms or risks are written as events that 'some people have gotten-felt-(etc.).']

Genetic research about cancer in families: Hereditary Nonpolyposis Colorectal Cancer.

This is a modification of the consent document for an actual research project, by:
Henry T. Lynch, MD; Creighton University School of Medicine.

We ask you to take part in research about genes that lead to the Hereditary Nonpolyposis Colorectal Cancer (HNPCC) disease.

We are asking many people in the NoName Nation to take part. All people asked have a type of cancer, or have HNPCC cancers in their family. To take part in the study is wholly voluntary.

Dr. Longtime Researcher, of the Cancer Research Center, heads the study.

Many people with HNPCC have come down with cancer of the colon (large bowel), rectum, womb, ovaries, or other cancers.

"Colorectal cancer" is of the colon and rectum. It is a common cancer in humans.

HNPCC colorectal cancer runs in families. That means colorectal cancer in at least two generations in a family, in several family members, and at younger ages than usual.

Some HNPCC family members have come down with other cancers, such as of the womb, ovary, or stomach.

Some people with a HNPCC gene get one of those cancers.

A change from the usual in one of four genes seems to cause HNPCC. We call that an "HNPCC gene."

In HNPCC families, the HNPCC gene is passed down from parent to child.

An HNPCC gene can be found by a genetic test of blood or other tissues. "Genetic test" is also called a "DNA test."

One purpose of this study is to see who has an HNPCC gene. Another purpose is to see what kind of HNPCC genes are present in NoName families with HNPCC.

The study will draw blood from people who take part. We then will do a genetic test to see if an HNPCC gene is present.

If we have already found a specific HNPCC gene in other members of the person's family, we will test the blood for only that gene.

This study has several steps.

First, we will discuss with you the pros and cons of getting tested. That step is part of asking for your consent for this study.

Then we let you take time to decide. Some people want to go home and talk with their family before deciding. Some people decide to take part, while other people decide not to.

Then, if you want to take part, we will take a medical history here in the NoName Clinic. We will also do a "family tree," of your relations. This may take up to one hour.

Then we will draw about 14 teaspoons (seven tubes) of blood, by a standard blood draw. If you are having surgery, the surgeon may use a small piece of the tissue removed for the test, instead of blood.

Then a certified genetics lab will make a sample called a "living cell line" from the blood draw or tissue. In a living cell line, the cells grow for ever in the lab. We get the DNA we need to test from these living cell lines. That way, we do not have to ask people over and over to do another blood draw. The Center will store the sample.

Then the certified lab will test the DNA for HNPCC genes. Due to the time needed to run the tests, we can not say when we can give you your test results.

When your results are ready, we will contact you for a meeting to give them to you. You can bring other family members or friends with you if you want.

In that meeting, we will first describe again what the HNPCC is. We will discuss what are the options to prevent HNPCC and other cancers.

Then we will discuss the pros and cons of receiving the test results. Some people decide to get the results, while other people decide not to get the results.

Then, if you want to get your results, we will ask your consent to do so. We will also ask you to sign a second consent form.

Then we will give you a copy of your genetic test results. We will also explain the meaning of those results.

We may want to contact people in the study later, for new requests. We may ask to do other tests on the stored sample or to update the medical history. We will do so only after the person agrees. We ask people who take part to tell us if they move.

We also discuss the study and HNPCC with families.

Family members may also discuss the study with us. We will explain the pros and cons to the family of the test. We will also explain what the test means. We will not give the results of your test to any family member without your permission.

Twice a year we invite HNPCC patients and family members to meet with us. We explain HNPCC. We talk about the findings of the study, and what we and other researchers have learned about HNPCC. And we discuss how to prevent cancer. We do not mention any person or family by name.

We discuss the study and HNPCC with the NoName Tribe, too.

We discussed this study with the Tribal Council. The Council approved this study. We update the Council about the study once a year.

We also discussed this program with the NoName Health Department. We update it every year, as well.

We want to answer all your questions.

Many people think of new questions later. So you or your family may call to talk with us in the future. We will also give you a list of local genetic counselors, if you or your family want to talk with someone else.

It is important to know before getting tested what the results will mean.

It is very unlikely that the results of this genetic test will be in error.

A positive genetic test, that the person has an HNPCC gene, means these points.

Out of 20 people with an HNPCC gene, about 16 to 18 may get colorectal cancer. About three to four of them may get other cancers, too, of the womb, stomach, ovary, and others.

Some people may get emotional distress if they learn they are more likely to get cancer, due to having an HNPCC gene. Some people get spiritually troubled.

If you take part, we will discuss with you the meaning of your results. We will also recommend cancer screening, and give choices for cancer prevention and management. We will give you a written summary.

A negative test means these points.

People with no HNPCC gene do not have an increased risk to get colorectal cancer. They have the same risk to get colorectal cancer as everyone else. About one out of 20 people with no HNPCC gene may get colorectal cancer. We advise that all people follow the advice of the American Cancer Society to prevent cancer. We will give you a written summary.

People with no HNPCC gene can not give their children any HNPCC gene.

Some people may get emotional distress or spiritually troubled if they learn they are different from family members with an HNPCC gene, who are more likely to get cancer.

The meaning of results is limited, however.

Some people with an HNPCC gene have never developed cancer. Having an HNPCC gene does not mean that the person will surely get cancer.

Some people with no HNPCC gene have developed colorectal or other cancer. They still have the risk of the general population for all cancers. We recommend that people with no HNPCC gene follow the advice of the American Cancer Society advice about cancer screening.

A few people have test results that we can not interpret. We will discuss such results with each person. We then may ask for another blood test.

We may not know some future consequences of genetic testing.

We plan store your "living cell line" sample permanently, at the Cancer Research Center.

The Center, however, may dispose of your sample after 15 years. The Center will handle your sample carefully, but there is a small chance of accidental loss or destruction. All samples will be disposed with respect.

We may do more research, but only about HNPCC.

If we do not find a specific HNPCC gene in your family, in the future we may test for other genes that may become known.

We may send DNA from your sample to other researchers. The sample will have only a code number, no name. They will only test for changes in the HNPCC genes under study. When they are finished testing, the sample will be disposed or returned to the Center. All disposed samples will be treated with respect.

Only researchers at Center who are doing the present study can access the stored samples. The Center will do no tests on the stored samples other than the tests noted in this consent, unless it first obtains another specific consent.

No sample from this study will be used for any other research or purposes, unless the NoName Tribe agrees and the person consents to it. The NoName, Center, and IHS Institutional Review Boards (IRBs) oversee this study. They must also approve that use.

We try to keep private every person's medical history, testing, and results.

We also try to keep private who took part in this study.

We store all data only with code numbers, no names. The labs keep the samples only with code numbers. We keep the list of each person's code number and name only in a separate, locked, file.

We store all data and samples at the Center. Only researchers in this study can access the data and samples.

All publications or talks about this study will not identify any person, family, or Tribe. They all will be reviewed and approved by the Tribe, to make sure that the Tribe can not be known.

We try very hard to keep private all data about each person. Our records, however, could be subpoenaed by a court of law. To prevent a release of our records, the Center has a Certificate of Confidentiality. We got it from the federal government, Department of Health and Human Services. (The Certificate is not an endorsement of this study by the Department.) It protects us from giving anyone's name to any Federal, State, or local court. It also protects us in all civil, criminal, administrative, legislative, or other actions. It lets us keep private all data in this study. It gives permanent protection. The protection continues even after death of a person. If you want a copy of the Certificate, please ask us for one.

The Certificate does not protect data from this study that is in a medical record by a health care provider. It does not protect information voluntarily given out by you or the researchers.

Certain audits, reviews, or program evaluations may look at the data. The Food and Drug Administration, and the National Institutes of Health, can review records of people in this study. The NoName, Center, and IHS IRBs can review records of people, if needed for their oversight. All people doing such reviews are required to not reveal any person's name.

If you want, we will give the results of your genetic test to your personal doctor. You must first ask us to do so.

Please be aware that once your doctor has your results, we can not protect your privacy as fully. Our Certificate does not cover your doctor. If the doctor records your results in your chart, other health care people, and health or life insurance carriers, may learn your genetic status. They may also learn your status if your doctor screens or does preventive treatments for HNPCC.

Some people want their personal doctor to know their test results, but to keep those results from others. If so, please ask your doctor not to record in your medical record your test results or that you had a genetic test done.

There may be some potential direct benefits for some people, if they take part.

We will give each person advice about how to prevent cancer, based on their gene status.

Some people get relief from the uncertainty about their gene status, no matter what their result.

People with a negative test will not need to see the doctor to prevent cancer more often than recommended for the general population.

But some people who take part may get no personal benefit from the study.

There may be some potential benefits for families.

People in your family may learn important information about their risk for HNPCC, based on your results. They then may seek genetic counseling, tests, or advice for cancer prevention. It is your choice whether to tell them about your results. You can ask us to tell your family members about your results, if they want to hear about them. (To do so, you must give written consent to give them your results.)

Members in some families come closer to each other.

There may be some potential benefits for other people.

We hope to learn more about HNPCC, to better help all people and families with this condition.

There may be some potential physical harms for some people if they take part.

The physical risks of having blood drawn are small. Some people have had local discomfort or bruising at the blood draw site. Rarely has anyone had a clot, an infection, or pain.

There are some potential personal, familial, social, and tribal harms, too.

Some people have suffered personal harms.

Some people with a positive test have felt distressed due to anxiety, worry, or depression. Some people have gotten spiritually troubled.

Some people with a negative test have developed feelings of guilt because they are more fortunate than others in their family.

Please consider carefully your own possible reactions to positive and negative results before agreeing to this genetic test.

If any of that happens to you, please let us know. We have counselors who can help people handle those problems.

Some people have suffered harms in their family.

A few people with a positive test have been shunned by some family members who hear about the results. It is your choice whether to tell your family about your results. You also can ask us to tell family members about your results, if they want to hear about them.

The genetic test may reveal that family relationships are different than had been assumed. For instance, a genetic test may show that a parent could not be a biologic parent of a son or daughter. This information may disrupt the person or family. Our policy is not to tell anyone of those results, however.

Some people who learn about their genetic status change their ties with family members. Before deciding to get tested, many people find it helpful to discuss possible testing with their family. That discussion could be with parents, sisters, brothers, spouse, and children. The discussion could include the meaning for the family of positive and negative test results.

If any of that happens to you, please let us know. We have counselors who can help families handle those problems.

Some people have suffered harms from their friends or society.

A few people with a positive test have been shunned by friends. It is your choice whether to tell other people about your results. If you tell your results to even just one person, the results often get passed on to other people.

Loss of secrecy about a positive test has cause bad things to some people. Some people have been hurt or stigmatized by others. Some have been discriminated against in hiring, job retention, or promotion. Some have been refused health or life insurance.

If any of that happens to you, please let us know. We have counselors who can help people handle those problems, and fight discrimination.

A few tribes have suffered disruption, as well.

Many tribes are worried that other studies may use the stored samples without the tribe's permission.

We have promised the Tribe, and promise you, that NO study will ever be done on the samples we collect without the Tribe's permission.

A few tribes have been stigmatized by society because they have a "genetic problem." A few tribal members have felt badly about their tribes because some families have a genetic disease.

If any of that happens, please let us know. We will help the Tribe handle those problems, and fight discrimination.

A few tribal people have felt that genetics is simply not a good thing to do or learn about, or that it is against tradition.

We will discuss those concerns with anyone.

Some people may experience benefits or harms in the future we do not know about now.

We will let you know if we learn about new potential benefits or harms.

You have an alternative to being in this study.

You can choose not to be tested, or not to receive your test results. If you do, we will still discuss how to screen for and prevent cancer, based on what we know from your family tree.

You are also invited to the meeting of HNPCC patients and families we hold twice a year.

People will not have any money costs from the study.

No-one is billed for the sample, testing, or counseling. We can not pay for genetic counselors outside the study. The IHS will do all recommended steps to screen for and prevent cancer for IHS-eligible people.

The study will not give a money payment to people to take part.

You can see all your personal data from the genetic tests done in this study.

You may not see the results of tests of <u>other</u> family members, however, unless we receive their permission.

You can refuse to take part, without penalty to you.

All people who do not take part will <u>not</u> lose IHS care, or other care for which they qualify.

You can also change your mind after you start in the study, without penalty to you.

You can refuse any more genetic testing.

You can quit the study.
You can have us destroy your stored sample. You can have us remove unused medical data about you from our records. We will keep the data we have used before to your decision to quit or have sample destroyed.

After people who take part are deceased, their guardian or next of kin control the samples.

They can let us keep the stored samples, to continue the tests. Or they can ask us to destroy the samples. Or they can request that we send the samples to the IHS hospital, to be disposed there.

IHS will give medical care for any injuries due to the study.

The care will be at no expense to the person injured.

The study does not compensate for injuries from taking part in this study. The study does not give payment for lost wages or other losses due to those injuries.

If you have any question about the research, please call us.

You can call Dr. Longtime Researcher, at ___-___-____. You can use the Clinic phone, or call collect.

You can also call Dr. Local Doctor at the Clinic, ___-___-____.

If you think you have been injured by the study, please call Dr. Local Doctor.

Please call right away. Her telephone number is ___-___-____. It is answered 24 hours a day.

If you are not satisfied with this study, please call an IRB.

If you have a grievance or complaint, please call an IRB. The NoName, Center, and IHS IRBs oversee with this study. Their telephone numbers are as follows.

You can use the Clinic phone, or call collect.

We will give you a copy of this consent.

I was offered a translation of this consent into the NoName language. I have () have not () used such translation.

I understand that I am being asked to take part in genetic research. It will find out if I have an HNPCC gene.

I understand that some people benefited from the testing. The tests told the doctors the best way to prevent cancer. Some families benefited, too.

I understand that some people with positive test results were distressed or troubled. Some people with negative results felt guilty that they do not have the HNPCC gene. Some families were disrupted by the results. The study has staff to help people and families deal with those problems.

I understand that I can refuse to take part with no penalty, or loss of IHS care or other care for which I qualify. I can also change my mind later, and quit the study.

I understand that the study may store my "living cell line" sample permanently, even after my own death.

I understand that the Cancer Research Center may contact me in the future to ask for my consent to use my stored sample or medical data.

All my questions have been answered to my satisfaction. I understand that I can ask any question in the future.

I volunteer for this research.

.....

[Note: This Consent Document is about a quite complex topic, and must cover much information. Nevertheless, its readability is 8th grade. The text is 3,480 words, almost 3 times longer than the next longest model document.]

IHS Model Permission Documents, #9 and #10

Background: These 2 model information sheets are for public health investigations, the first of a simple outbreak, the second of a new, complex, serious epidemic. These investigations are "public health care," not "research." Both investigations involve a survey and a blood draw.

Because initial public health ("EPI-AID") investigations are not research:
- *compliance with 45 CFR 46, including review by an IRB, is not required;*
- *the word "research" should not be used in the information sheet; and*
- *a signature need not be required.*

[That latter point is important because simply requiring a signature reduces the participation rate by about 15% among people already fully informed who agree to participate before being asked to sign a consent document (Singer E. Am Soc Review 1978; 43:144-162).]

Information sheets for public health studies should have 7 elements:

[1] purposes of the study;
[2] procedures;
[3] benefits to the community and individual;
[4] risks, if any;
[5] confidentiality;
[6] reporting results; *and*
[7] whom to call with questions*.*

Sheets with these 7 elements both inform potential volunteers and increase the participation rate.

The first hypothetical investigation is of a simple outbreak such as gastroenteritis; it does not involve unusual or strong concerns by potential volunteers. The sheet gives "basic" information.

The other hypothetical investigation is of a new severe disease. It involves all possible strong concerns of volunteers, i.e., asking about sensitive information [e.g., sexual behavior, drug use or other illicit behavior, sexual orientation, etc.], testing blood for stigmatizing diseases, and doing the study in the workplace with the secondary concern of possible affect on employment. Because the sheet addresses almost all possible major concerns, it gives "maximal" information.

Some EPI-AID investigations involve concerns more than "basic" but less than "maximal." [For instance, a study might involve only non-sensitive questions, but be done in the workplace.] The relevant sentence(s) in the "maximal" sheet [in the example cited, about employment] can simply be added to the "basic" model sheet.

Many Indian communities have a high prevalence of mistrust of studies; people perceive and remember studies as "taking away information" about the community without anything of value being returned to the community. Thus, reporting the results to the Tribal Government and the affected districts of the reservation -- and telling potential volunteers about that reporting -- also will increase participation. Because reporting is important to people in non-Indian communities as well, it should be included in most or all sheets, referring to the local government.

The "basic" sheet has a 6th grade readability level, the "maximal" has 7th grade. Making information understandable helps engender a feeling of reciprocity between the investigator and the potential volunteer. In addition, the inclusion of the name and telephone number of people to call with questions also increases the feeling of reciprocity. The increased feeling of reciprocity, of being respected and sharing the endeavor, helps increase the participation rate.

These model information sheets suggest that giving complete information is not a barrier, but rather is an aid, to fuller participation in public health studies. People who refuse to participate only because they have not been told sufficient information in an understandable way, or because their concerns have not been answered, are lost to the study. They also have not been permitted to make a truly informed decision, or to contribute to the public health.

"Basic" IHS Model Information Sheet, # 9

The study of a Mystery outbreak.

The Centers for Disease Control ask you to help find the cause of a Mystery outbreak.

An outbreak of Mystery struck 50 people of the NoName Reservation last week. We are doing this study to find the cause. We ask all people affected to answer some questions, and let us draw blood. The questions will take about 20 minutes. They ask what you did just before you got sick. We will also draw a tube of blood, to test for possible Known disease.

The study may tell us the cause of the Mystery outbreak and how to prevent it.

Only CDC will see the answers and blood test results. The blood draw may sting for a second. We know of no other risks to you by taking part. We will tell the NoName community what we find out.

Taking part is voluntary.

If you have questions about the study, please ask them now. You may ask questions later by calling **Dr. Clara D. Clark** in Atlanta, at ___-___-____, or locally **Dr. Ida H. Service**, at ___-____. You may use a Clinic phone to make the calls.

Thank you for helping.

.....

[Note: The readability of this "basic" Information Sheet is 6th grade. The text is only 188 words and 1/3 a page, yet it has all 7 key elements to be informed.]

"Maximal" IHS Model Information Sheet, # 10

The Search for the Cause of the Mystery Disease.

The NoName Tribal Government, Council of Elders, NoName Service Unit, and Centers for Disease Control ask for your help. They are fighting the Mystery Disease. We need you to take part in a study to find the cause of the Mystery Disease.

The Mystery Disease struck 25 people of the NoName Reservation in the past month. We do not know the cause. This study will try to find out the cause. From that, we hope to prevent it from striking more people.

We ask all adults living in NoName Town to answer some questions and let us draw blood. The questions will take about 20 minutes. They ask what you did in the past month. We hope you will answer all questions. A trained person will draw 2 tubes of blood in your home, just like in the Clinic. We will test the blood for infections you had in the past. We may use your blood later to do other tests about the Mystery Disease. We also may want to ask you a few other questions later.

This study may help the NoName community, your family, and you.

Everyone's answers, and their blood tests, may tell us what causes the Mystery Disease. We will tell the community what we find out, and how to prevent the disease. We will let you know if we find out anything about your health from your tests.

Only CDC will see the answers and blood test results. Your employer will not see your answers or test results. Taking part or not will not affect your employment.

Your answers and tests are protected like a medical record. They are private, under the federal government's Privacy Act. CDC has studied more than 100,000 people in several thousand outbreaks in the past 40 years. It has maintained the privacy of all those people.

The blood draw may sting for a second. We know of no risks to you by taking part.

Taking part is voluntary.

If you have questions about the study, please ask them now. You may ask questions later by calling **Dr. Clara D. Clark** in Atlanta, at **___-___-____**, or **Dr. Ida H. Service** locally, at **___-____**. You may use a Clinic phone to make the calls.

Thank you for helping the NoName Reservation get well again.

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[Note: Although the subject of the study touches many serious concerns of potential volunteers, this Information Sheet's readability is 7th grade, and its text only 380 words. Yet it has all 7 information elements for a public health response to an epidemic, and directly answers those serious concerns.]

@ Items required by regulation [45 CFR 46.116(a)]			Yes	n/a	No
@ [(a)(1)]	A.	A clear statement that the study is "research"	___	___	__
@ [(a)(1)]	B.	All the research purposes [*i.e.*, research objectives] clearly stated	___	___	__

[(b)(6)] C. How and why prospective volunteers are selected ___ ___ __

@ [(a)(1)] D. Expected duration of the volunteer's involvement ___ ___ __

@ [(a)(1)] E. Procedure(s) or treatment(s) to be done ___ ___ __

@ [(a)(3)] F. Reasonably expected benefits to volunteer and others ___ ___ __

@ [(a)(2)] G. Reasonably foreseeable discomfort & risks--including all in protocol ___ ___ __

[(b)(1)] H. Especially for experiments, a statement that the treatment(s) or procedure(s) "may involve risks that are currently unforeseeable" ___ ___ __

@ [(a)(1)] I. Which procedures or treatments are experimental--say *experimental* ___ ___ __

@ [(a)(4)] J. The alternatives to the research's diagnostic method or treatment ___ ___ __

[(b)(4)] K. Procedure for the orderly termination of a volunteer's participation ___ ___ __

[(b)(4)] 1) Consequences of a volunteer's withdrawal from the research ___ ___ __

(b)(2)] 2) When may the researcher terminate a volunteer's participation without the volunteer's consent ___ ___ __

[(b)(5)] L. Plans to inform volunteers of significant research findings during or after the study relevant to their continued participation or treatment ___ ___ __

@ [(a)(6)] M. If > minimal risk: "In case of injury or severe adverse affect..." ___ ___ __

@ 1) will medical care for adverse affects be given? who? where? ___ ___ __

@ 2) is compensation for adverse affects available? how? ___ ___ __

@ [(a)(6)&(7)] 3) whom should a volunteer contact with injury or adverse affect? ___ ___ __

@ [(a)(7)] N. Who will answer questions about the research itself? ___ ___ __

@ [(a)(5)] O. How confidentiality (__) or anonymity (__) are maintained ___ ___ __

@ [(a)(7)] P. Who on IRB will answer other concerns, complaints, or grievances? ___ ___ __

[(b)(3)] Q. Financial factors (extra costs of, or compensation for, participation) ___ ___ __

[.109(b)] R. Other elements a reasonable person would want to know ___ ___ __

S. If a Certificate of Confidentiality, an appropriate description ___ ___ __

@ [(a)(8)] T. Non-coercion disclaimer. *"Taking part is voluntary. You may refuse to take part without any penalty or loss of care or services by IHS or others. You may quit at any time, without penalty or loss of care or services for which you are qualified."*