
Background

of a simple outbreak, the second of a ne are "public health care," not "research." Both investigations involve a survey and a blood dra

Because initial public health ("EPI-AID") investigations are not research:

- compliance*
- the*
- a signature need not be required.*

[That latter point is important because simply requiring a rate by about 15

asked to sign a consent form (Singer E. Am Soc Revie

Information sheets for public health studies should have 7 elements:

purposes of the study;

[2] procedures;

[3] benefits to the community and individual;

[4] risks, if any;

[5] confidentiality;

[6] reporting results;

hom to call

Sheets

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 ne

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 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 orkplace.] 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 a 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 non-Indian communities as 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 bet and the potential volunteer. In addition, the inclusion of the name and telephone number of people to call 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 participate only because they have not been told sufficient information in an understandable ay, or because their concerns have not been ans have not been permitted to make a truly informed decision, or to contribute to the public health.

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 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]. We know of no risks to you by taking part in the study. We will tell the community and tribal government 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 [Dr. Ida H. Service] locally, 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 175 yet it has all 7 key elements to be informed.]

The Search for the Cause of the [Mystery] Disease

The NoName Tribal Government, Council of NoName Elders, NoName Service Unit, and Centers for Disease Control ask you to help fight 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 and tribal government 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 medical records; they are confidential 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.

We know of no risks to you by taking part in the study.

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.

[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 368 public health response to an epidemic, and directly ans