

APPENDIX E1. Sample of survey template.

Hello, my name is _____ calling on behalf of University of _____ from Hebert Research, an independent research firm in Bellevue, Washington.

May I speak to someone who is at least 18 years of age? Thank you.

[IF NECESSARY, REINTRODUCE YOURSELF]

We would like to get your opinions about a medical study involving people who have been severely injured. The survey will take approximately 10 minutes. I will describe the research studies and ask for your opinions about them. You can skip any questions or stop the survey at any time. Your opinions will help guide how best to inform your community about this study. Your answers will be kept anonymous.

Is now a good time to do the survey? Thank you!

Introduction: [READ]

First, I am going to describe the research study to you.

[READ THE FOLLOWING PRIOR TO ASKING SURVEY QUESTIONS]

An experimental intravenous fluid is being tested in a study involving patients with severe injuries, such as those in severe auto accidents, who have a 25-50 percent chance of dying from their injuries. Usually, patients in a study must provide written consent for participation after being told about the study, its risks and its potential benefits. In the case of severe injury, it is not always possible for patients to give written consent, because they may be unconscious, and their families may not always be available to speak for them.

The U.S. Food and Drug Administration allows for certain studies to be performed without written consent in emergency settings but only if patients have a high risk of dying without treatment, cannot communicate because of their illness, and don't have family available to speak for them. When there is no known treatment available to improve their chance of survival, patients may be given an experimental agent, but only if it has been approved in advance by an independent University group set up to review these situations. We would like your opinion on one such study that is proposed involving severely injured patients.

Injury is the leading cause of death in children and younger adults. The usual cause of death in these patients is blood loss or severe head injury. Sometimes a patient will survive the injury but die several days later due to organ failure of their heart, lungs, liver or kidneys. Researchers at the _____ are trying an experimental intravenous fluid that may prevent organ failure and improve survival after severe injury. This fluid may also improve outcome after brain injury.

This intravenous fluid has been used in previous clinical studies with no adverse events and is currently approved for use in Eu-

rope. As with any medication there is the risk of allergic reaction or other unexpected side effects.

Previous studies suggest that this fluid is most effective if given as the first intravenous fluid after injury. As a result, this study fluid will be given by the paramedics at the scene of the accident and consent to continue enrollment in the study will be obtained in the hospital. Patients in this study will be randomized to receive either the standard fluid (normal saline), or one of two experimental fluids, concentrated salt water or concentrated salt water and sugar. Patients will be randomized (similar to flipping a coin only with a 1/3, 1/3, or 1/3 chance to receive a 250cc dose (about half a pint) of one of three study resuscitation fluids. After receiving the initial fluid, standard treatment will be given for the remainder of medical treatment. We are considering whether to allow the study fluid to be given by the paramedics without written consent.

We would now like to ask you some questions about your opinion on this.

1. If you were severely injured and had a one in three chance of dying with standard treatment, would you want to be entered into the study and possibly receive this experimental treatment, even though you couldn't give consent?

1. Yes [GO TO Q3]
2. No
3. Don't know
4. Question refused

Alternate question 1 (when this question was used, question 5 regarding allergic reaction was not used)

1. At any moment, we are all at risk of serious injury, especially in an automobile. If you were severely injured, such that you had a 25-50 percent chance of dying with standard treatment, would you want this experimental fluid given to you without written consent, knowing that it might improve your chance for survival or recovery from head injury, but that there is a risk of allergic reaction or other unexpected side effects?

1. Yes [GO TO Q3]
 2. No
 3. Don't know
 4. Refused
2. What is the reason for your concern?
1. Fear about possible side effects
 2. Patients should not lose the right to provide consent for themselves
 3. Other _____ [SPECIFY]
 4. Don't know
 5. Refused
3. If one of your family members was severely injured and had a one in three chance of dying with standard treatment, would you want them to be entered into the study and possibly receive this experimental treatment, even if they or you couldn't give consent?

1. Yes [GOTO Q5]
2. No

3. Not applicable (respondent doesn't have family members)
4. Don't know
5. Question refused
4. What would be the reason for your concern?
 1. Fear about possible side effects
 2. Patients should not lose the right to provide consent for themselves
 3. Other _____ [SPECIFY]
 4. Don't know
 5. Refused
5. If there was less than 1 in 100,000 risk of an allergic reaction, would you still want the experimental treatment given to you?
 1. Yes
 2. No
 3. Don't know
 4. Question refused
6. Do you believe or not believe that this exception to written consent is justified and in the best interests of the patients and community?
 1. Believe it is [SKIP TO Q8]
 2. Do not believe it is
 3. Don't know
 4. Refused
7. What is your reason for concern? [SKIP TO Q9 AFTER ANSWERING]
 1. Fear of the possibility of side effects
 2. Patients should not lose the right to provide consent for themselves
 3. Other _____ [SPECIFY]
 4. Don't know
 5. Refused
8. Why do you feel this exception to consent is justified?
 1. It is in the best interest of the patient
 2. It is in the best interest of the community
 3. It is in the best interest of both the patient and community
 4. Other [SPECIFY]
 5. Don't know
 6. Refused
9. Injury is the leading cause of death in people ages 15 - 44 years. Injured adolescents have the same benefits and risks from the experimental fluid as adults. Do you think it is appropriate to include 15-17 year olds in this study?

1. Yes
2. No
3. Don't know
4. Question refused
10. What are your reasons for your answer? [VERBATIM]

The following questions are only to make sure that we have a representative sampling of the community's opinions. Your answers will be kept anonymous.
11. What is your age? _____
12. What is your race? [RECORD ONE RESPONSE]
 1. Caucasian/White
 2. African American/Black
 3. Asian
 4. Hispanic
 5. American Indian/Native American
 6. Mixed Race
 7. Other _____ [SPECIFY]
 8. Don't know
 9. Refused
13. What is the highest level of education you have completed?
 1. Less than high school
 2. High school
 3. Associate, Technical or Vocational degree
 4. Bachelor's degree
 5. Post-graduate degree
 6. Refused
14. What is your occupation? _____
15. What is the zip code where you live? _____
16. Into which of the following categories does your approximate annual household income fall?
 1. Less than \$20,000
 2. \$20,000 to \$35,000
 3. \$35,000 to \$50,000
 4. \$50,000 to \$65,000
 5. \$65,000 to \$80,000
 6. \$80,000 to \$100,000
 7. Over \$100,000
 8. Don't know
 1. Refused

THAT CONCLUDES OUR SURVEY. THANK YOU VERY MUCH FOR YOUR TIME AND COOPERATION

POSTCODE GENDER:

1. MALE
2. FEMALE

DATE: _____

INTERVIEWER: _____