UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

Study title: Randomized Trial of Text vs. Video Patient Educational Materials in Cirrhosis
IRB: HUM00204958

Principle Investigator: Patricia Bloom, MD
Co-Investigator: Elliot Tapper, MD

We are doing a study to learn more about how effective we are at providing cirrhosis education to our patients, and what we can do to improve moving forward. To get this information, we'd like approximately 300 people to respond to our questionnaire. The questionnaire will involve answering questions about a topic related to cirrhosis before and after you review some educational materials. You will also have an opportunity to provide us with feedback on these materials. We expect this to take about 15 minutes to complete.

Participation in this study is voluntary. You do not have to answer the questionnaire if you don't want to, and you can skip any questions you'd rather not answer, whatever the reason. Choosing not to answer our questionnaire will not affect the medical care you might receive at the University of Michigan Health System.

To confirm that you are eligible to participate we will obtain information regarding your medical history and contact information from your medical record. To help us understand other factors that may impact responses to the questionnaire, we will also ask you to complete a brief demographics survey. This information, and any other personally identifying information collected during the course of this study, will be kept strictly confidential, and will be de-identified as early as possible in the data analysis process. Your participation will be considered complete following the end of the questionnaire.

By participating in this research study, you may have to opportunity to learn something new about cirrhosis. There are no other direct benefits to you participating in this study, but we hope that what we learn will help others in the future.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:
-Hospital or doctor's office records, including text results.
-All records relating to your condition, the treatment you have received, and our response to treatment.
-Demographic information
-Personal identifiers

It is possible that researchers or others will need access to information about you during or after this study, such as:
-Researchers may need the information to make sure you are eligible to take part in this study
-The University of Michigan or a government agency may need the information to make sure that the study is done safely and properly.

The results of this study could be published in an article. Any publication related to this study would not include any information that could identify you as a participant.

As a rule, the researchers will continue to use information about you until the study is completed and will keep that information secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities, but use of this information will not reveal your identity. With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information see http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information have been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

To find out more about this study, to ask a question, to express a concern related to the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principle Investigator: Patricia Bloom, MD
Mailing Address: 1500 E Medical Dr, Ann Arbor MI
Phone: 734-936-4000
Email: ppbloom@med.umich.edu

Study Coordinator: Caitlyn Fisher
Email: fishercj@med.umich.edu

You may also express a concern about the study by contacting the Institutional Review Board:
Mailing Address: University of Michigan Medical School Institutional Review Board (IRBMED), 2800 Plymouth Rd, Building 520, Room 3214, Ann Arbor, MI 48109-2800
Phone: 734-763-4768
Email: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

Checking the box below gives researchers permission to obtain, use, and share information about you for this study. This is required in order to participate in this research study. Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting a member of the study staff listed above.