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# ADULT RESEARCH SUBJECT INFORMATION AND CONSENT FORM and AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

## PATIENT PERCEPTIONS OF CARE: THE EFFECTS OF SOCIAL DETERMINANTS OF HEALTH

Principal Investigator: Heather Klepacz, M.D.

Other Staff (identified by role): F. Charles Brunicardi, M.D. Sub I
Stephen Markowiak, M.D. Sub I
Chris Sattler, RN Research Coordinator
Allison Gerren, Student Investigator

Contact Phone number(s): (419) 383-6852

**What you should know about this research study:**

- We give you this consent/authorization form so that you may read about the purpose, risks, and benefits of this research study. All information in this form will be communicated to you verbally by the research staff as well.
- Routine clinical care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.
- We cannot promise that this research will benefit you. Just like routine care, this research can have side effects that can be serious or minor.
- You have the right to refuse to take part in this research, or agree to take part now and change your mind later.
- If you decide to take part in this research or not, or if you decide to take part now but change your mind later, your decision will not affect your routine care.
- Please review this form carefully. Ask any questions before you make a decision about whether or not you want to take part in this research. If you decide to take part in this research, you may ask any additional questions at any time.
- Your participation in this research is voluntary.

## PURPOSE (WHY THIS RESEARCH IS BEING DONE)

You are being asked to take part in a research study of your perceptions of care and the effects of social factors on your health. The purpose of the study is to measure your satisfaction and communication with your health care team. We would also like to assess the social factors that affect your health and refer you to a community service, if needed. You may choose to decline the screening of health care social factors and still be elibigle to participate in the study.

You were selected as someone who may want to take part in this study because you were admitted to trauma services or general surgery services.

## DESCRIPTION OF THE RESEARCH PROCEDURES AND DURATION OF YOUR INVOLVEMENT

If you decide to take part in this study, you will be screened for a number of social factors that effect health. You will also complete a satisfaction survey and quality of life questionnaire. This will be done while you are in the hospital. Community service referals will be done based on social factors that effect health. You can refuse to be screened for social factors and/or refuse referrals and still participate in the satisfaction and quality of life questionnaires. Day 8-22 after discharge, you will receive a follow up phone call to verify use of community services, (if referral was suggested) and a second satisfaction survey. At day 23-37 after discharge, you will receive another phone call to determine community services used and a second qualityof life questionnaire.

| **Schedule of Events** | | | |
|---|---|---|---|
| | **Hospital stay** | **day 8-22** | **day 23-37** |
| social factors tool | x | x | |
| | | | |
| quality of life questionnaire | x | | x |
| | | | |
| satisfaction survey | x | x | |

## RISKS AND DISCOMFORTS YOU MAY EXPERIENCE IF YOU TAKE PART IN THIS RESEARCH

There is a minimal risk of loss of confidentiality. Your medical record will need to be accessed to obtain medical information and medical history, although your privacy and confidentiality will be maintained by keeping the collected data in a secure research room.

## POSSIBLE BENEFIT TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH

We cannot and do not guarantee or promise that you will receive any benefits from this research.

## COST TO YOU FOR TAKING PART IN THIS STUDY

There is no cost to participate in this study.

## PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARCH

There is no compensation for participating in this study.

## ALTERNATIVE(S) TO TAKING PART IN THIS RESEARCH

The alternative to taking part in this study, is to refuse participation. You can choose not to take part in the study. This will not affect your treatment, care or any procedure to be done.

## CONFIDENTIALITY - (USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION)

Participation in research involves using and sharing your health information to conduct the research. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. By agreeing to take part in this research study, you give to The University of Toledo (UT), the Principal Investigator and all personnel associated with this research study your permission to use or disclose health information that can be identified with you that we obtain in connection with this study.

We will use this information to assess satisfaction, improve communication and increase access to community sevices.

The information that we will use or disclose includes demographics, like zip code and healthand surgical history. We will also be sharing social determinants of health screening tool, HCAP abbreviated tool, and a quality of life questionnaire.

We may use this information ourselves, or we may disclose or provide access to the information. Under some circumstances, the information may be disclosed to the University of Toeldo Medical Center Institutional Review Board (IRB) and/or the department of Research and Sponsored Programs. The information may be used by either department for compliance of study activites.

The University of Toledo is required by law to protect the privacy of your health information, and to use or disclose the information we obtain about you in connection with this research study only as authorized by you in this form. However, the information we disclose with your permission may no longer be protected by privacy laws. This means your information could be used and re-disclosed by the persons we give it to without your permission.

Your permission for us to use or disclose your protected health information as described in this section is voluntary. However, you will not be allowed to participate in the research study unless you give us your permission to use or disclose your protected health information by signing this document.

You have the right to revoke (cancel) the permission you have given to us to use or disclose your protected health information at any time by giving notice to

**Dr. Heather Klepacz**
**419-383-6852 during office hours**
**419-383-4000 24 hours (through hospital operator)**
**Or**
**Chris Sattler**
**Research Coordiantor**
**419-383-6784 during office hours**

However, a cancellation will not apply if we have acted with your permission, for example, information that already has been used or disclosed prior to the cancellation. Also, a cancellation will not prevent us from continuing to use and disclose information that was obtained prior to the cancellation as necessary to maintain the integrity of the research study.

Except as noted in the above paragraph, your permission for us to use and disclose your protected health information will continue until study is closed and archived, up to 6 years.

A more complete statement of University of Toledo's Privacy Practices is set forth in its Joint Notice of Privacy Practices. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the University of Toledo's Privacy Officer at 419-383-6933.

**IN THE EVENT OF A RESEARCH-RELATED INJURY**

If you suffer a research-related injury, medical treatment is available but you can choose where to go for treatment.

The University of Toledo and The University of Toledo Medical Center do not offer reimbursement for medical expenses or other compensation for research-related injuries. In the event that any medical expenses are not reimbursed by the Sponsor, they will be billed to you or your insurance.

By signing this form you do not give up any of your legal rights if you are injured.

In the event of a research-related injury, contact:

**Dr. HeatherKlepacz**
**419-383-6852 during office hours**
**419-383-4000 24 hours (through hospital operator**

**VOLUNTARY PARTICIPATION**

Taking part in this study is voluntary. You may refuse to participate or discontinue participation at any time without penalty or a loss of benefits to which you are otherwise entitled. If you decide not to participate or to discontinue participation, your decision will not affect your future relations with the University of Toledo or The University of Toledo Medical Center

**NEW FINDINGS**

You will be notified of new information that might change your decision to be in this study if any becomes available.

**TEXT CONTINUED NEXT PAGE**

## OFFER TO ANSWER QUESTIONS

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over. If you have questions regarding the research at any time before, during or after the study, you may contact

**Dr. Heather Klepacz**
**419-383-6852 during office hours**
**419-383-4000 24 hours (through hospital operator)**

If you have questions beyond those answered by the research team or your rights as a research subject or research-related injuries, please feel free to contact the Chairperson of the University of Toledo Biomedical Institutional Review Board at 419-383-6796.

## SIGNATURE SECTION (Please read carefully)

**YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE INFORMATION PROVIDED ABOVE, YOU HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND YOU HAVE DECIDED TO TAKE PART IN THIS RESEARCH.**

**BY SIGNING THIS DOCUMENT YOU AUTHORIZE US TO USE OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION AS DESCRIBED IN THIS FORM.**

The date you sign this document to enroll in this study, that is, today's date, MUST fall between the dates indicated on the approval stamp affixed to the bottom of each page. These dates indicate that this form is valid when you enroll in the study but do not reflect how long you may participate in the study. Each page of this Consent/Authorization Form is stamped to indicate the form's validity as approved by the UT Biomedical Institutional Review Board (IRB).

| | | |
|---|---|---|
| Name of Subject (please print) | Signature of Subject or Person Authorized to Consent | Date |
| Relationship to the Subject (Healthcare Power of Attorney authority or Legal Guardian) | | Time a.m. p.m. |
| Name of Person Obtaining Consent (please print) | Signature of Person Obtaining Consent | Date |
| Name of Witness to Consent Process (when required by ICH Guidelines) (please print) | Signature of Witness to Consent Process (when required by ICH Guidelines) | Date |

**YOU WILL BE GIVEN A SIGNED COPY OF THIS FORM TO KEEP.**

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