**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**
**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

# FACT SHEET

**Docket Number:** H00015018

**Title:** Hereditary diffuse gastric cancer: Patient process of discovery.

**Name of Principal Investigator:** Cheryl Hersperger

We are inviting you to participate in a research study. Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research study at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

## What are the aims of the project?

The aim of this study is to understand the discovery and decision-making processes both for the discovery of finding the CDH1 marker and afterwards when deciding to have surgery to remove your stomach or to participate in watchful waiting with periodic biopsies of the stomach.

## Who is invited to participate?

The researcher would like to speak with adults with a positive CDH1 marker whether you have had surgery to remove your stomach or are in watchful waiting; adult family members who have a close relative(s) such as a parent, step-parent, brother, sister, step-child, cousin, aunt, uncle with a positive CDH1 marker; or professional health care providers who work with those with the CDH1 marker such as surgeons, endoscopic specialists, genetic counselors, nurses, nurse practitioners, physician assistants, dieticians.

## What will participants be asked to do?

Participants will be interviewed in person or by telephone. Some participants may be interviewed two times (or more) over a four to six-month period. Interviews will be held in a quiet, private location and will be audio recorded. The time commitment to complete the interview will range from less than 30 minutes to no more than 90 minutes. The first interview will most likely be longer than any subsequent interviews. Your interviews will be checked for accuracy with you.

Alternatively, or in addition, you may be invited to participate as part of a panel at the end of the study to review the results of the study, to add comments to the conclusions of the study and to see if the study results fit and make sense. The review panel may include No Stomach For Cancer NSFC Board members, persons with the CDH1 marker, family members, and key health care providers. Panel participation is strictly voluntary and follows the same procedures listed on this fact sheet for the interviews, including audio recording of the review panel meeting. This meeting is anticipated to be no longer than 90 minutes and will be held either by a private telephone conference call or at a quiet and private location at a NSFC Spotlight meeting.

## How will I be reminded that the next interview is coming up?

Any plans for a follow-up interview will be discussed at the end of the first interview.

The researcher will give you a reminder call before the second interview at the phone number you provide. She may leave a generic message on your voice mail if there is no answer at the

time of the call. If the researcher does not hear back from you after the reminder messages (up to three), it is assumed that you are no longer interested in participating.

**What are the risks of participating?**

There is a general risk of breach of confidentiality. This risk may be heightened because the NSFC community for those persons with the CDH1 marker is relatively small and a close community. All reasonable attempts will be made to keep the data confidential.

There is a risk of feeling uncomfortable or emotional during the interview(s) as you will be asked to recall your personal memories. The interview may be stopped at any time and you can withdraw from the study at any time. If you are upset during an interview I will follow-up with you in a day or so to see if you are okay and to ask if you wish to stay in the study or complete the interview already in progress later.

**What data or information will be collected and protected?**

All research data will be stored in a secure server at the University of Massachusetts. These computer networks have many levels of protection. To help protect your personal information, we will store your name and demographic data separately from your research data. We will keep all paper documents under lock and key.

All audio recordings will be erased after the data analysis is completed. The study will be open for one year. All de-identified data, including transcribed data, will be securely stored for at least three years after the study.

The results of the study may be published in a professional journal and presented at professional meetings such as the No Stomach For Cancer Spotlight meeting. However, you name will not be used in papers or presentations.

**Who has access to my personal information?**

We will try to limit access to your personal information to people who have a need to review this information. We cannot promise complete privacy. In addition to the researcher, others who may see your personal information include appropriate representatives of the University of Massachusetts Medical School, including the Graduate School of Nursing research dissertation committee, the UMMS Institutional Review Board (IRB), and the data transcriptionist. These individuals are required to keep information confidential.

**Additional commonly asked questions.**

**Why participate?** Your participation may add knowledge about the discovery process and decision-making for people who are positive for the CDH1 marker. However, there is no direct benefit to you.

**Is there an honorarium?** As a thank you for your participation, you will receive a $50.00 Visa card for each completed interview.

**How long will it be before results of the study are available?**

It may be at least one year before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

**Research-related injury.**

Neither the University of Massachusetts Medical School nor the Graduate School of Nursing provides funds for the treatment of research-related injury. If you are injured because of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by participating in this research.

**Who will answer my questions?**

If you have any questions about the research study, concerns, or complaints, or think that the research has hurt you, you can talk to the **Principal Investigator Cheryl Hersperger at (508) 864-5221.** You can stop an interview at any time. This research has been reviewed and approved by an Institutional Review Board. You can reach them at (508) 856-4261 or irb@umassmed.edu if you would prefer to speak with someone not associated with the study or have questions about your rights as a research subject.