INFORMED CONSENT DOCUMENT

Project Title: Comparative Effectiveness of Fecal Immunochemical Tests with Optical Colonoscopy
Principal Investigator: Barcey Levy, PhD, MD
Research Team Contact: Jeanette Daly, PhD, RN 1-866-890-5963

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are scheduled for a colonoscopy at either the University of Iowa Hospitals and Clinics or Iowa River Landing. The purpose of this research study is to test the accuracy of the five most commonly used fecal immunochemical tests (FITs) in the U.S. against the gold standard, optical colonoscopy. A FIT is a screening test for colon cancer. It tests for hidden blood in the stool, which can be an early sign of cancer.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 2,300 people will take part in this study conducted by investigators at the University of Iowa. Nationwide, approximately 3,600 persons will take part in this study.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for the time it takes to complete a Health Questionnaire (10 minutes), a stool sample collection (10 minutes; done in the privacy of your home), and an optional FIT Product Questionnaire (5 minutes). All study items are completed at your home.

WHAT WILL HAPPEN DURING THIS STUDY?

With this mailing, you have received a cover letter, an Informed Consent, and a Health Questionnaire. We ask that you read the cover letter and this Informed Consent document to see whether you are interested in participating.

If you decide to participate, you will need to fill out the forms (Informed Consent and Health Questionnaire) and mail them back to us to proceed to the next step of the study.

- Filling out 2 forms (about 10 minutes): Sign and date the Informed Consent forms (keep one copy for yourself) and complete the Health Questionnaire. The Health Questionnaire will ask about prior colorectal cancer screening, your family history of colorectal cancer, and specific medications you may be taking. You may skip any questions you do not wish to answer on the Health Questionnaire. These forms should be returned in the provided postage-paid return envelope. If there are answers that are not clear, we may contact you or check your medical record for the information.

After we receive these documents, you will be mailed or given a package with instructions and materials for completing the FITs and a FIT Product Questionnaire (optional).

- Collecting stool samples (about 10 minutes): FITs are tests designed to look for hidden blood in your stool. This will involve using the provided plastic stool collection container (hat) to collect a single bowel movement. You will sample one of your stools using each of the five FIT collection devices provided. You will write the date the stool samples were collected on the enclosed yellow card and return the FIT samples and date card in the provided postage-paid box.
- FIT Product Questionnaire (about 5 minutes; optional): After you have done the stool sample collection, you may complete the optional FIT Product Questionnaire. This questionnaire should be returned using the postage paid return envelope.

All procedures will take place in the privacy of your home. No visits to the hospital are necessary for this research study. However, you should keep all medical appointments, including the one for your colonoscopy.

Once we have your FIT samples, we will evaluate the samples for blood. We will check to see that you have completed your colonoscopy and retrieve your colonoscopy report and associated pathology report from the electronic medical record. We will use this information to compare with the results of your FIT samples. The medical professional doing your colonoscopy will be responsible for getting the results of your colonoscopy to you.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. You may be uncomfortable or become nauseated collecting stool samples. We will provide you with gloves, a plastic stool collection container (hat), and a garbage bag to dispose of all soiled items.

There is a risk of loss of confidentiality of data. Measures in place to protect confidentiality are indicated in the 'What About Confidentiality' section later in the document.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we will determine if the FITs work well or not.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

If you participate, you will be paid $25 for being in this research study once you have returned the signed Informed Consent, the Health Questionnaire, the five FITs, and have completed your colonoscopy. The FIT Product Questionnaire is optional and does not need to be completed for payment.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health is funding this research study. This means that the University of Iowa is receiving payments from the National Institutes of Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Institutes of Health for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will keep all hard copy materials in locked file cabinets in a locked research room in the Department of Family Medicine. All computer files will be in password protected files on University of Iowa computers. Only the study personnel will have access to this information. A study identification number will be linked with your name and address and placed on your questionnaire. The file linking your name to the study identification number will be available only to the study team and in a separate file from the questionnaire information. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Barcey T. Levy, PhD, MD, 200 Hawkins Drive, Iowa City, Iowa 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will keep a copy of this Informed Consent document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WILL I RECEIVE NEW INFORMATION ABOUT THE STUDY WHILE PARTICIPATING?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Jeanette Daly, RN, PhD at 319 384-8995 or toll-free at 1-866-890-5963. You may contact the Principal Investigator, Barcey T. Levy, PhD, MD at (319) 384-7622.** If you experience a research-related injury, please contact: **Jeanette Daly, RN, PhD at (319) 384-8995 or toll-free at 1-866-890-5963 or Barcey T. Levy, PhD, MD at (319) 384-7622.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will keep a copy of this form.

If you agree to participate in the study, please PRINT YOUR NAME below and SIGN and DATE the form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 05/07/22.

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(Signature of Subject) (Date)