



**Clinical Investigation Cytosponge Consent Form**  
**The Rockefeller University Clinical Research Center**

IRB Rev 2026

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**Title of the research study:** *Detection of pre-malignant changes in Fanconi anemia mucosa*

Informed consent is the first step in deciding whether you want to join this research study. Informed consent is a process of sharing information and having your questions answered. This information will include: the purpose of the research study, what will happen in the study, and possible risks and benefits. All this information will be explained to you in detail. You should keep asking questions until you understand what the study is about and what is being asked of you. You may then want to enroll, or you may decide not to join the study. The decision to participate is entirely up to you. You can always ask additional questions at any time during the study. You have the right to withdraw from the study and you can change your mind about participating in the study at any time.

**Summary of Key Information**

You are being asked to join a research study. The study will take place at The Rockefeller University Clinical Research Center (CRC). Joining a research study is voluntary. You can decide not to participate in this study. This consent form tells you about the research. The persons explaining this form to you will answer your questions. You are free to ask as many questions as you want to. You may take an unsigned copy of this form home to read again before deciding if you want to enroll. After you feel that you understand the research, you will be asked to sign this consent form if you decide to enroll. Participating in a research study is not part of your routine medical care. Alternatives to joining this study include not participating.

The purpose of this study is: to assess the safety and feasibility of the Cytosponge device on healthy adult volunteers and use it in the future as a sampling technique to assess for genetic changes in cells from the esophagus.

The study procedures will include: We will collect your demographic and medical history information and ask you to participate in the Cytosponge procedure. This involves swallowing a small capsule attached to a string. We will assess any adverse events during the study visit and ask that you report any events experienced in the next 30 days following the study visit. An **adverse event** is an unwanted or harmful medical problem that happens during or after a treatment, medicine, or medical study. It can include things like side effects, injuries, new symptoms, or worsening health problems. An adverse event may or may not be caused by the treatment itself, but doctors and researchers record it carefully to help keep patients safe.



How long will you be in the study: If you join the research study, you will take part for 1 day. The research study will last about 2 hours and it will involve 1 study visit.

Number of participants involved: We are recruiting up to 10 healthy adult volunteers.

Before you decide whether to participate in the study, it is important for you to know the main risks of the study: The main risk of being in this study is that you might experience gagging, sore throat or minor bleeding during the investigational procedure used as a part of the study. The most severe known risk is sponge detachment, which occurs in less than 1 out of 2,000 procedures. The sponge would need to be removed by a doctor using a standard endoscopy, and we will facilitate transfer to the hospital for evaluation and intervention, if necessary. You will not receive standard treatments for any disease while you participate.

The possible benefits of participating in this study are: There is no direct benefit to you for participating in this study, but the information that researchers get may help to support the use of Cytosponge for surveillance in the Fanconi anemia population.

Researcher's contact number: Francis J. May, MD. Phone: 212-327-7850

## **I. What this research study is about, and the reason for doing this research.**

Fanconi anemia (FA) patients have an increased risk of esophageal cancer that ranges from 1266–6200x higher than the general population, based on adjusted data from within the Surveillance, Epidemiology and End Results (SEER) database. A study of 40 asymptomatic FA patients found 11 FA patients with abnormal esophageal lesions, compared to none in the non-FA control group.

The device being used in this study, the Cytosponge, has been 'cleared' by the U.S. Food and Drug Administration (FDA) for the collection of cells from the esophagus, and is used for patients with conditions including Barrett's esophagus and eosinophilic esophagitis. This means the FDA has determined it is safe and effective for this use, and it is currently available for doctors to use in standard medical care. However, its use in this specific research study as a sampling technique is not yet approved and is considered investigational.

Given the increased risk of esophageal cancer in the FA population, and the demonstrated presence of abnormal lesions in asymptomatic patients, we believe that piloting the Cytosponge device in this study could lead to evidence supporting the use of Cytosponge for surveillance in the FA population.

This consent form has been prepared to give you information regarding this additional and optional study activity (Cytosponge). If you choose not to participate in the Cytosponge procedure, you can still participate fully in the other aspects of the study if you are eligible, interested, and provide consent for the rest of the activities by signing the main Consent form.

## **II. What is going to happen in this research study?**

For your first study visit, you can choose to either come into the Rockefeller University Clinical Research Center (CRC) or to schedule a virtual visit. At this first visit, you will be given a consent form to read that will describe the entire study. You will be given time to read the consent form and ask questions. If you are in person, you will have a private area to do this. When your questions have been answered to your satisfaction, you will sign the consent form in the presence of a study team member and be given a copy.

You will be asked about demographic information (date of birth, race, ethnicity, social history) and about your medical health history. If you completed your consent conversation remotely, your in-person visit will be scheduled for you to arrive at the Rockefeller University's CRC at an agreed-upon time. During the in-person study visit, we will confirm your continued consent to participate and to have the Cytosponge procedure:

You will be asked to come in having fasted for at least 4 hours (**do not consume or drink any foods or liquids for at least 4 hours before your visit**). To start the procedure, you will be asked to swallow a small capsule (about the size of a large vitamin pill) attached to a thin medical string. You will hold the end of the string while the capsule, which is made of vegetable-based material dissolves in your stomach (for about 5–7 minutes). Once the capsule dissolves, a small sponge is released. A trained healthcare provider will then gently pull the string to remove the sponge through your mouth. This process collects a sample of cells from your esophagus (the tube connecting your mouth to your stomach).

If you are unable to swallow the capsule after one attempt, we will stop the activity. Any adverse events (AEs) will be assessed at the end of the procedure, and we will ask you to report any other AEs that occur during the next 30 days following the procedure.

### **Test and Procedures Involved with this Study**

#### Study Visit #1 (virtually; about 2 hours):

1. Informed Consent
2. Screening and enrollment

#### Study Visit #2 – 4-hours fasted (in-person; about 2 hours):

##### Confirm continued consent to participate

1. Collecting demographic and medical history information
2. Completing Cytosponge procedure
  - If you experience throat soreness following the Cytosponge procedure, you will be offered a lozenge with an anesthetic to help reduce discomfort:  
Cepacol (benzocaine-menthol 15mg-2,6mg mucous membrane lozenge)
3. Adverse Events

In this study, you will not receive routine care for any medical conditions related to this protocol, and you will not receive routine care for any other medical conditions you may have.

The study team will provide a plain language summary of the overall results of the study after the study is complete. A Return of Results report usually includes a summary of the purpose of the study, who participated (e.g., age, sex, race, ethnicity, if appropriate), what the study involved, and the main results. Aggregate results, meaning the combined results from all the participants, will be shared. As the research tests are not validated tests nor certified by New York State for sharing, individual research results are not shared in the summary reports. The Return of Results report will be provided through one or more platforms such as a landing page with specific details provided when the results are ready to be shared. You should update the research team if your contact information changes to be sure to receive notification when the Return of Results report becomes available.

### **III. What are the risks of taking part in this research study?**

There may be some risks and discomforts in taking part in this study. These are the ones we know about now:

**Privacy Risks:** There is the risk that there could be computer security breaches that could reveal your identity. There may be the risk that data about you may become public and could be used by employers or law enforcement agencies. These privacy risks are described in greater detail below.

#### **Common Risks and Discomforts of the Cytosponge device:**

- **Gagging:** Most people (about 60%) experience a brief gagging sensation while the sponge is being removed. This usually lasts only a few seconds or less.
- **Sore Throat:** You may have a mild sore throat after the procedure. This typically goes away on its own within 24 to 48 hours.
- **Minor Bleeding:** There is a small chance of very minor bleeding (spotting) in the throat or esophagus. This is more common if you are taking blood-thinning medications.

#### **Rare but Serious Risks of the Cytosponge device:**

- **Sponge Detachment:** In very rare cases (less than 1 in 2,000 procedures), the string may detach from the sponge while it is in your stomach or esophagus. If this happens, the sponge may need to be removed by a doctor using a standard endoscopy (a procedure where a flexible tube with a camera is passed down the throat while you are sedated). If this were to occur, the Rockefeller University is prepared to transfer you to a nearby facility where an extraction using an endoscopy can be done.

The Cytosponge Cell Collection Device may be at risk of the sponge detaching from the string during removal of the device from the patient, which could lead to device fragments in patient, obstruction, airway obstruction, secondary intervention, secondary intervention

(with the primary procedure), supraglottic airway obstruction, and aspiration. On 6/2/23, Medtronic sent recall notices to customers and have now reinforced the device. In prior studies, risk of detachment was less than 1 in 2,000 procedures. Since reinforcement, there have been no reported string detachments.

Rare but serious risks also include: mucosal laceration or perforation requiring secondary intervention (for example during endoscopy to remove the detached sponge), major and minor bleeding, airway obstruction, infection, aspiration, intestinal obstruction, tissue damage, allergic reaction, dysphagia, pain. Secondary intervention including endoscopy and/or surgery may be required to treat any of the potential complications listed. The Cytosponge is too large to pass through the GI tract and in the rare event of string detachment, procedure(s) such as esophagogastroduodenoscopy may be necessary to remove the detached sponge. If you experience throat soreness following the Cytosponge procedure, you will be offered a lozenge with an anesthetic to help reduce discomfort: Cepacol (benzocaine-menthol 15mg-2,6mg mucous membrane lozenge).

There have been no reported allergic reactions to the Cytosponge device. Theoretically, there is a risk of allergy, which may present as:

**Nasal/Respiratory:** Runny nose, sneezing, coughing, wheezing, and asthma exacerbation,

**Skin/Eyes:** Itchy, watery eyes; hives (urticaria); rashes; and swelling,

**Severe Reaction (Anaphylaxis):** A life-threatening emergency causing severe airway swelling, low blood pressure, and trouble breathing.

There may be other risks and discomforts that we do not know about now, but we will tell you if any new information is discovered that might affect your decision to participate or remain in the study.

#### **IV. What are the alternatives to participating in this research study?**

The alternative to participating in this study is not to participate.

#### **V. What are the benefits of taking part in this research study?**

There will be no benefit to you. Instead, others may benefit in the future from what we learn from this study.

#### **VI. Who will be able to see the information learned about you in this research study?**

We will keep your personal information private and will do our best to keep this information confidential. We will listen to what you say about what we may do with this information, and we will follow the law. For example, by New York State law, hospitals

must inform the New York State Department of Health if we find that you have a reportable communicable disease, such as a viral disease like COVID-19, or a sexually transmittable disease, like chlamydia, hepatitis, gonorrhea, syphilis, and HIV-1. Also, the researchers must report to the authorities if they believe that child abuse or neglect has happened, or to prevent serious harm to you or others.

During this study, only the researchers will know that your samples came from you, because your stored samples will be identified only by a special code instead of your name. As a result, others who study your samples will not know that they came from you and will not be able to figure out that they came from you. For example, the data received by sponsors would be identified only by a code. However, auditors and regulators from government agencies that oversee research, and people at the Rockefeller University CRC and at Rockefeller University may see your information in the course of their duties. Staff that view data with personal identifiers have received privacy training and are required to adhere to privacy and confidentiality laws and policies.

Your privacy is very important to us, and we will use many safety measures to protect your privacy. However, despite all the safety measures that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Therefore, it is possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. We may deposit your genetic data to databases/repositories available to others for research. While neither the public nor the controlled-access databases/repositories developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in a database/repository back to you. For example, someone could compare information in one database/repository with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or that person's blood relatives. Moreover, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease or that your biological parentage differs from what it had previously been understood to be. All confidential information, inclusive of genetic diseases and biological parentage, will be guarded and would be disclosed only as legally required under the applicable law.

When the researchers publish the results of this study, they will not mention your name or other information that could identify you. However, FA is a rare disease so when you read a published study, you may identify your family from the description. By participating in this study, you give us a permission to publish our research findings.

The Rockefeller University protects information and privacy as required by law, and at the same time, it complies with all legal requirements of disclosure as noted above in the section about your genomic information.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

### **Genetic Information Nondiscrimination Act**

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal in the United States of America for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information is available in the RUCRC Participant Handbook.

There may also be privacy risks that we have not foreseen.

### **Sharing of the results**

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that collect the results of whole genome studies. The NIH or other data banks will store your genetic information and give it to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your whole genome analysis with these databanks; however, we cannot predict how genetic information will be used in the future. The information will be sent with only your code number attached, and your name or other identifiable information will never be given to them. There are many safeguards in place to protect your information while it is stored in repositories and used for research. Research using your whole genome information is important for the study of virtually all diseases and conditions. Therefore, the databank will provide study data for researchers working on any disease, which could include conditions such as HIV/AIDS, cancer, mental illness, and others.



There may also be privacy risks that we have not foreseen.

## **VII. What are the payment arrangements?**

There is no cost to you for being in this research study.

You will be compensated \$100 for completing your participation in this activity.

Payment will be made to participants who are eligible for and want to receive payment and who fill out a brief form with tax identification information from The Rockefeller University Finance Office. Your information will remain confidential unless required to be disclosed by federal, state, or local laws. If you do not want to complete the form, you can still participate in the study but will not be eligible for compensation.

## **VIII. What happens if you don't want to stay in this study or your participation is ended?**

You can choose if you want or do not want to be part of this study. If you do not join, there is no penalty, and no one will hold this against you. You may change your mind and stop taking part in this study at any time, and this will not be held against you. Information about you up to the time you stop participating in the study may remain a part of the study.

During this study, the researchers may learn new information that might make you change your mind about whether you want to stay in the study. You will be given that information promptly.

If you decide to join the study now but later want to stop, you should let the researcher know. The way to let us know is by calling Dr. Francis May at (212) 327-7850.

The researchers may stop you from continuing to take part in this study, even if you do not choose to stop being in it.

## **IX. Whom do you call if a medical problem results from this research study?**

If you believe that this study has led to a medical problem, you should call the researcher listed below right away. The researcher will help you get appropriate, available medical care.

Name: Frank May, MD

Phone No.: 212-327-7850

Email: fmay@rockefeller.edu

The Rockefeller University does not plan to pay for medical care that you may have as a result of taking part in this study at The Rockefeller University CRC. However, you do not give up any rights you may have to seek compensation by signing and dating this consent form.



## **X. Whom do you contact if you have questions about the research study**

Please ask as many questions as you want about this research study and this consent form. If you agree to take part in this study and have questions later, contact the following researcher:

|                                  |              |                                                                |
|----------------------------------|--------------|----------------------------------------------------------------|
| Study Coordinator – Yu-Chien Lin | 212-327-8613 | <a href="mailto:ylin@rockefeller.edu">ylin@rockefeller.edu</a> |
| Frank May, MD                    | 212-327-7850 | <a href="mailto:fmay@rockefeller.edu">fmay@rockefeller.edu</a> |

If you have any concerns about your experience while taking part in this research study, you may contact The Rockefeller University Institutional Review Board (IRB) Office at (212) 327-8410, or the Office of Clinical Research at (212) 327-7396.

## **XI. Consent to the use, storage and sharing of your samples and other data for separate research studies**

The scientific value of your samples and the information obtained from them is greatly increased if we can share them with other scientists at universities and pharmaceutical or technological companies worldwide. Your samples and information will be used for biomedical research including genetic analyses. You will not be provided details of any specific research studies or their purpose. In general identifiers will be removed from the identifiable private information or identifiable biospecimens. Thereafter the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative. The genetic information obtained from your DNA is called genotype. The information about your disease condition and the physiology of your cells is called phenotype. We may:

- store, use, and share for many years your biospecimens and information including genotype and phenotype data, with other investigators at Rockefeller and elsewhere, possibly worldwide, and including pharmaceutical and technology companies, sample and/or data banks/repositories for separate studies for many years. Your biospecimens will either be stripped of information identifying them as yours or coded (we will hold the key to the code) so that they cannot be identified as having come from you. Other data related to your biospecimens, but that does not identify you, may accompany the specimens; and
- put anonymous data information from the analyses in a completely public database, available to anyone on the Internet; and
- put your coded genotype and phenotype medical data information and data information from more detailed analyses of your coded samples in a NIH controlled-access database/repository. The information in this database/repository will be available only to qualified researchers from academic institutions and commercial organizations, both domestic and foreign who have received approval from an NIH Data Access Committee.

Any time in the future, you may withdraw your consent to use any samples that have not already been used in research or shared. If you withdraw your consent, the remaining unused



samples will be destroyed, unless the samples cannot be identified as having come from you. Data generated using your samples will continue to be used.

We realize that some people may not want to have their samples and/or data stored and shared with others and if that is your feeling, then you should not participate in this study.

**I. May we have permission to contact you about future studies?**

May we contact you by phone or email to find out if you are interested in hearing about new research studies? (We will not share your contact information for any other purpose). Contact would be made by the staff of the Rockefeller Clinical Research Support Office for recruitment. If you decide at any time that you no longer want to be contacted, please tell us, and we will no longer attempt to contact you.

Would you like us to contact you about future research studies?

Yes \_\_\_\_\_

No \_\_\_\_\_

If you say “no” to this question, this will not affect your participation in this study.



**AGREEMENT TO PARTICIPATE -- SIGNATURES REQUIRED**

**I have read this consent form, and my questions have been answered.**

A copy of this consent form will be given to you. Please keep a copy of the form as it contains important information that you may wish to refer to during the research study and afterwards.

**I hereby voluntarily consent to take part in this research study.**

**Name of the Study Participant (Print)** \_\_\_\_\_

\_\_\_\_\_  
**Signature of Study Participant                      Date (To Be Filled in by Study Participant)**

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## ALTERNATE SIGNATURE BLOCK

### Adult not legally capable of giving consent

Name of the Study Participant (Print) \_\_\_\_\_

Name of Legal Representative (Print) \_\_\_\_\_

\_\_\_\_\_  
Signature of Legal Representative

\_\_\_\_\_  
Date (To Be Filled in by Representative)

- Documentation, such as a health care proxy, showing authorization to act as a legal representative, is attached.

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## ALTERNATE SIGNATURE BLOCK

### Participant requires assistance by a translator

Translation Services Provided by (check only one box below):

☐ **Pacific Interpreters**

|                          |                                                  |
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| _____<br><b>Language</b> | _____<br><b>Translator Identification Number</b> |
|--------------------------|--------------------------------------------------|

Name of the Study Participant: \_\_\_\_\_  
(Print Name)

Witness to telephone translation: \_\_\_\_\_  
(Print Name)

|                                      |                      |
|--------------------------------------|----------------------|
| _____<br><b>Signature of Witness</b> | _____<br><b>Date</b> |
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☐ **Other Translator:**

|                                    |                      |
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| _____<br><b>Name of Translator</b> | _____<br><b>Date</b> |
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Witness to oral presentation: \_\_\_\_\_  
(Print Name)

|                                      |                      |
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| _____<br><b>Signature of Witness</b> | _____<br><b>Date</b> |
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## ALTERNATE SIGNATURE BLOCK

### **Protocols Involving Pregnant Parent and Fetuses**

Because this study holds the prospect of direct benefit to the pregnant parent, or direct benefit to both the pregnant parent and the fetus, or no direct benefit to either the pregnant parent or the fetus but is of minimal risk to the fetus, the consent of only the pregnant parent is required.

If the signatory descriptions below do not apply to your research participants (for example in the case of surrogate pregnancies), please consult the IRB for guidance.

**I hereby consent to participate in this research study.**

**Name of Pregnant Parent (Print)**

\_\_\_\_\_

\_\_\_\_\_  
**Signature of Pregnant Parent**

\_\_\_\_\_  
**Date (To Be Filled in by Pregnant Parent)**

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**Signature of the Person Conducting the Informed Consent Discussion**

I have explained the research protocol and this consent form to the participant and have answered the participant's questions about this research study and/or the consent process.

**Name of Person Discussing Consent** \_\_\_\_\_

**(Print)**

\_\_\_\_\_  
Signature of Person Discussing  
Consent

\_\_\_\_\_  
Date (To Be Filled in by Person Discussing  
Consent)