Functional Outcomes in Ulcerative Colitis Patients with Ileal Pouch Anal Anastomosis Treated with High Intensity Focused Electromagnetic Stimulation

NCT has not yet been assigned

6/16/2025

CONSENT FORM FOR RESEARCH
For Cedars-Sinai and Participating Affiliates[1]

Study title:
Functional Outcomes in Ulcerative Colitis Patients with Ileal Pouch Anal Anastomosis Treated with High Intensity Focused Electromagnetic Stimulation: A Prospective Pilot Study

Study support provided by: Internal Department Funding

Cedars-Sinai Principal Investigator: Karen Zaghiyan , MD

Cedars-Sinai study contact phone number: (310) 423-1682

Cedars-Sinai after-hours emergency contact (24 hours): (310) 423-1682

To help guide your review of this form, the main sections include:

---

[1] The **Cedars-Sinai Affiliated Covered Entity ("ACE")** is comprised of covered entities under the common ownership or control of Cedars-Sinai Health System, including Cedars-Sinai Medical Center (CSMC); Cedars-Sinai Medical Care Foundation; Cedars-Sinai Marina Del Rey Hospital (MDRH); Torrance Memorial Medical Center (TMMC); Torrance Health Association, Inc., d/b/a Torrance Memorial Physician Network; Huntington Hospital (HH), and Huntington Medical Foundation.

Signature Page

1. Key Information

Thank you for considering research participation. Research helps make medical and scientific advancements possible. In this form, we are asking for your consent to take part in this research study. Taking part in this research study is voluntary.

This section provides key information about the study. Please take your time to read this entire form. Also, please ask questions before deciding whether to take part in this research study. You are welcome to talk with family, friends and other healthcare providers before you decide.

- **Purpose:** The purpose of this research is to see if treatment with the Emsella Chair improves fecal incontinence (inability to control bowel movements) and quality of life in patients with Ulcerative Colitis and Inflammatory Bowel Disease Unclassified (IBDU) who have received an ileal pouch anal anastomosis (IPAA), commonly referred to as a J pouch.

- **Duration:** Taking part in this study will last about 3 months.

- **Procedures:** The main things that will happen in this study are: Completing surveys on fecal incontinence symptoms, quality of life, anxiety, depression and gastrointestinal habits. Additionally, participants will receive treatment with Emsella chair twice a week for three weeks. Section 3 includes more details.

- **Benefits:** The possible benefits of taking part in this study are improved fecal incontinence symptoms and improved quality of life. Additionally, the information from this study may help others in the future. Section 4 includes more details.

- **Risks:** All research studies involve some risks. Risks or discomforts from this study may be embarrassing or personal questions about sexual and bowel health as well as possible gluteal pain, changes in bowel habits or discomfort with urination: Section 5 includes more details.
    - If you have problems during the study, contact the study team using the contact information on the first page of this consent form.

- **New Information:** During the study, we may find out new information about this study. We will tell you about any important changes or new findings that may impact your decision to continue taking part in the study.

2. Purpose of the Study

We are doing this study to evaluate whether patients with ulcerative colitis or IBD-U who have received an ileal pouch anal anastomosis (IPAA), commonly referred to as J pouch, have improvement in fecal incontinence and quality of life after 3 weeks of treatment with Emsella chair.

J Pouches are a surgical option for patients with ulcerative colitis whose disease is not well managed with medications. They provide disease management while avoiding a permanent ostomy. However, a known side effect of a J pouch surgery is fecal incontinence, which can occur in up to 5-15% of patients. Fecal incontinence is the inability to control bowel movements, which can have a significant impact on quality of life. The Emsella chair uses a type of high intensity focused electromagnetic (HIFEM) stimulation to contract and strengthen the pelvic floor muscles. Patients sit on the chair and electromagnetic energy is directed at the pelvic floor muscles for 28-minute sessions 2 times per week over 3 weeks, to help improve muscle tone. It was first developed in the early 2000s as a noninvasive treatment option for urinary incontinence. A growing number of studies have shown improvement in urinary incontinence in half of the patients one month after treatment. The nerves and pelvic floor muscles are the same for urinary and fecal incontinence, so we think that treatment with the Emsella chair will improve patient fecal incontinence and quality of life. Treatment of fecal incontinence with HIFEM has not yet been studied. If this study can show improvement in fecal incontinence, the Emsella chair could provide an accessible, noninvasive, treatment plan for patients struggling with fecal incontinence.

You are being asked to take part in this research study because you are an adult with a history of ulcerative colitis treated with a J pouch and have experienced some difficulty with fecal incontinence since getting the J pouch.

The study will include up to 20 people total.

The U.S. Food and Drug Administration (FDA) approved the Emsella chair for urinary incontinence. However, in this study, we are using it differently from what was approved by the FDA. We will be evaluating the use of the Emsella chair for fecal incontinence, using the same protocols used for urinary incontinence.

3. Main Study Procedures

This section talks about what will happen in this study. When you read this section, also read the table of procedures. The table is given with this consent form.

The table of procedures shows:

- When study procedures will occur,
- Whether they will be covered by the study or billed to you and/or your insurance, and
- Which study procedures are research-related and which are standard of care (routine).

Research-related procedures are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** are routine care generally given to people with your condition. They would be performed even if you did not take part in this study. The researchers will schedule the visits and procedures at the listed timepoints.

Description of main research procedures:

This study has one study group. Every participant will receive treatment with Emsella chair.

You will be treated 2 times per week for 3 weeks, for a total of 6 treatments. For each treatment, you will sit on the Emsella chair for 28 minutes. You will be fully clothed for the treatment, but you cannot wear anything metal. Treatment should not feel painful, but you may feel a tingling sensation.

We will administer surveys before your first treatment and at 1 and 3 months after your final treatment.

How long will you be in the study?
We think you will be in this study for/until about 3 months. This includes twice weekly sessions with the Emsella therapy for three weeks and questionnaire follow up at initial appointment, 1 month and 3 months. Each treatment session is 28 minutes long. Your medical records will be evaluated from your preoperative screening to the current post operative period.

4. Possible Benefits From Taking Part in the Study

Being in this research study may or may not have direct medical benefit to you. The possible benefits of taking part in the research study are improved fecal incontinence and overall quality of life. However, no benefit is guaranteed. It is possible that your condition may stay the same or even get worse.

We hope the information learned from this research study will allow the use of Emsella as a noninvasive treatment option for those struggling with fecal incontinence.

5. Possible Risks and Discomforts of the Main Research Procedures

This section talks about the possible risks and discomforts of the main study procedures. Emsella is not part of the current stand of care for patients with fecal incontinence. Risks of the Emsella include possible gluteal discomfort or pain, changes in bowel habits including possible worsening of fecal incontinence and discomfort with urination.

Risks of common medical procedures being done for research purposes are described below in Section 6. Side effects and risks of standard of care procedures are not described in this consent form.

Unknown Risks
There may be other risks that we cannot predict. Many complications are minor and do not last long. However, in rare cases, they can be long-lasting.

Pregnancy and Reproductive Information
Pregnant people are excluded from the study. However, it is possible that someone participating could become pregnant during participation in this study. The next sections review the potential risks if this were to happen.

Unknown Risks to the Developing Embryo or Fetus (an unborn baby)
If you are pregnant, or become pregnant during participation in this research, the Emsella Chair might involve risks to an embryo or fetus, which are currently unknown. It is important that you contact the researcher immediately if you believe you might be pregnant.

6. Common Medical Procedures Performed for Research Purposes and Risks

The procedures listed below are often part of routine care for a person with your condition. They are not experimental procedures. That said, for this study these procedures and their risks are research-related. This means they are being *repeated* or performed *more frequently* for this study. These common procedures and their risks should be the same as when performed outside this study.

Study Procedure	Related Risks
Medications: We will ask you about your past and current medications. Talk with the study team about any non-study medications. Non-study medications include any prescription drugs, over-the-counter drugs, supplements and vitamins.	This does not have any physical risks.
Demographic Information: We will ask you about demographics, which may include your age, gender identity, sexual orientation, race and ethnicity.	This does not have any physical risks.
Medical History Review: We will ask you about your medical and surgical history. We will also ask about your history with irritable bowel disease, prior surgeries, fecal incontinence and prior treatments utilized for your fecal incontinence.	This does not have any physical risks.
Questionnaire: You will be asked to complete a questionnaire. We will ask you questions to find out your quality of life, mental health, fecal incontinence and sexual health. We think it should take 5-10 minutes to complete the questionnaire. Questionnaires will ask you to respond to	Some questions may make you feel uncomfortable or embarrassed. The questionnaire will be labeled with a unique study number. This will link your identity so that only the research team can recognize you.

sensitive questions about your sexual health.	

7. Reasons Participation May Be Stopped by the Researcher or Sponsor

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. If your participation is stopped early, the study doctor will discuss next steps with you. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

8. Voluntary Participation and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

You can decide not to take part in this study. You have other choices. For example, you may choose:

- To be treated following the usual clinical approach: antidiarrheal medications such as loperamide, stool bulking agents (fiber), dietary modification (limiting high lactose or fructose containing foods), pelvic floor physical therapy, sphincter repair, sacral nerve stimulation, or an injectable bulking agent
- To take part in a different study at Cedars-Sinai
- To not be treated.

The study team will discuss these options and their risks and benefits with you. You may also choose to discuss these with your treating physician.

9. Confidentiality Protections

General Confidentiality

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitors the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

Sharing Information or Samples

We might share your information and/or research samples collected in this study. The information shared may include genomic data and health data or samples that could be used in future genomic research. It might be shared with other researchers at Cedars-Sinai, other researchers outside of Cedars-Sinai, or third-party commercial entities for future research without additional informed consent from you. In some cases, your information and/or specimens may be submitted to a database or repository for future research. These databases and repositories have safeguards to prevent inappropriate access to and use of the information and specimens. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai. However, there is a remote possibility that someone could identify you.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

10. Research-Related Illness or Injury

Contact in Case of Illness or Injury

We do not expect you will have any illness or injury from this research study. If you believe that you are ill or have been injured from this study, please contact the study team at the phone number listed on page 1 of this consent form.

Who pays for my research-related illness or injury?

Cedars-Sinai has no plans to pay for costs associated with the treatment of research-related injury or illness. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and copayments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Financial Assistance Program. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783. You do not waive any of your legal rights by signing this form.

11. Financial Considerations

Costs of Participation
You and your insurance company will not be charged for your participation in this research study. The Study Sponsor will cover the cost of all items, drugs and services required by this study. This includes any procedures required by the study that may be standard of care.

Payment
You will not be paid for taking part in this research study.

Financial Interest in the Research
The principal investigator and institution have no potential financial conflict of interest with this study.

12. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH
FOR CEDARS-SINAI AFFILIATED COVERED ENTITIES[2]

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Functional Outcomes in Ulcerative Colitis patients with Ileal Pouch Anal Anastomosis Treated with High Intensity Focused Electromagnetic Stimulation: A Prospective Pilot Study" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☒ Pathology reports
☒ Imaging reports (e.g., x-rays or scans)
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Billing records
☐ Photographs or videos of your image
☒ Demographics, which may include, but is not limited to, age, gender identity, race, ethnicity, and/or sexual orientation
☐ Mental health records
☐ Substance abuse records
☐ HIV test results
☒ Other tests or other types of medical information: Surveys

[2] The **Cedars-Sinai Affiliated Covered Entity ("ACE")** is comprised of covered entities under the common ownership or control of Cedars-Sinai Health System, including Cedars-Sinai Medical Center (CSMC); Cedars-Sinai Medical Care Foundation; Cedars-Sinai Marina Del Rey Hospital (MDRH); Torrance Memorial Medical Center (TMMC); Torrance Health Association, Inc., d/b/a Torrance Memorial Physician Network; Huntington Hospital (HH), and Huntington Medical Foundation.

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Table of Visits, Tests and Procedures

Legend
R = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.

Procedures	Screening Visit	Visit #1 Week 1	Visit #2 Week1	Visit #3 Week2	Visit #4 Week2	Visit #5 Week 3	Visit #6 Week 3	1 month	3 months
Informed Consent	R								
Medical History	R								
Emsella Treatment		R	R	R	R	R	R		
Surveys	R							R	R

Signature Page

Consent Form for Research and Authorization
for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Signature by the Interpreter/Witness

(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved "short form" consent processes. The witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter, study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subjects who has been determined to have capacity to consent is unable to read or physically sign the consent form, but choses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

Interpreter/Witness name (please print)	Signature	Date