UH Research Recruitment
TOOLKIT

RECRUITMENT RESOURCES

The UH Research Recruitment Toolkit is a compilation of resources to aid in your clinical trial recruitment efforts.

Inside you will find guidance, tips, and UH branded templates that can be personalized and used as part of your study recruitment plan.

APPROVALS

All recruitment plans, materials, scripts, and any patient-facing materials must be submitted to the IRB for review and approval prior to use.

University Hospitals
Clinical Research Center

WWW.UHHOSPITALS.ORG/CLINICAL-RESEARCH

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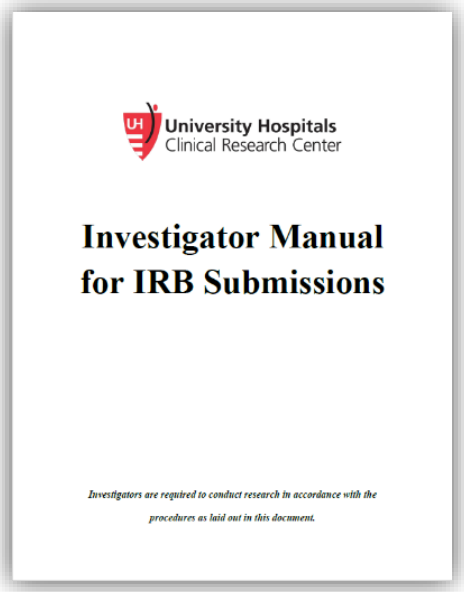
APPENDICES

STUDY RECRUITMENT GUIDANCE & IRB POLICY

Please refer to the UH Investigator Manual for IRB Submissions, **Chapter 16: Recruitment,** for information on appropriate recruitment methods for various types of studies. Additional details can be found in SpartaIRB. The UH IRB provides a variety of resources and guidance for the ethical recruitment of study subjects into research studies.



**** All recruitment materials, patient-facing materials (anything that patients see), and plans must be reviewed and approved by the IRB prior to use. ****

Contact the IRB at UHIRB@UHhospitals.org or 216-844-1529

DETAILED RECRUITMENT PLAN

- Your detailed recruitment plan should include all immediate, future, and backup recruitment methods you may employ (even if you may not utilize them all) so that in the event enrollment does not go as quickly as anticipated, there are not delays when you decide to employ alternate methods of contacting potential study subjects
    - E.g., mail, email, telephone, social media, physician referrals, community engagement events, etc

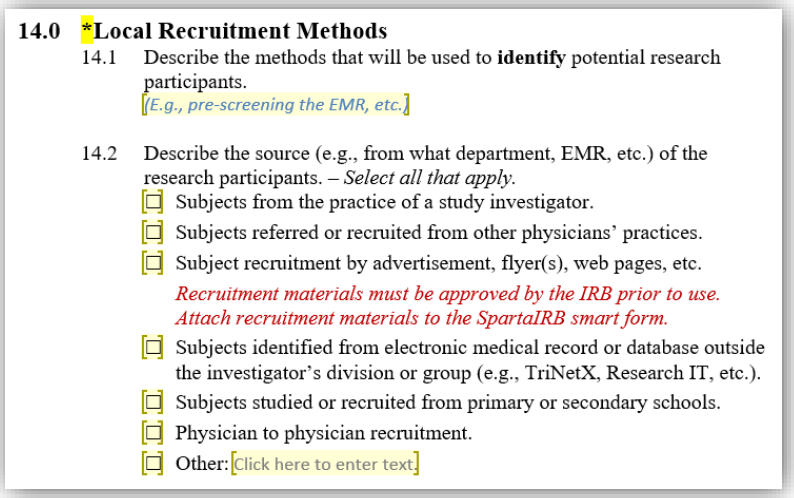
- Your study Sponsor should approve the materials before they are submitted for review by the IRB.

- Submit your recruitment materials for approval with your initial IRB submission so that recruitment efforts are not delayed
    - E.g., flyers, brochures, advertisements, scripts, storyboards, sponsor-produced videos, study-specific promotional items, etc.

- Include all details regarding how you plan to screen and pre-screen potential study participants with your initial submission to the IRB. In order to pre-screen potential study participants for eligibility, a waiver of HIPAA must be submitted to the IRB.

- If new recruitment methods are added later on in the study, a modification is required to be approved by the IRB before using the new methods (*this may include adding new forms of the same mediums, e.g. listing the Plain Dealer newspaper in the initial plan then deciding to advertise in the Case Daily later on*).

- Below is an example from the Supplemental Form in Sparta IRB detailing the information you will need to include:



14.0 *Local Recruitment Methods

14.1 Describe the methods that will be used to **identify** potential research participants.
(E.g., pre-screening the EMR, etc.)

14.2 Describe the source (e.g., from what department, EMR, etc.) of the research participants. – *Select all that apply.*

- ☐ Subjects from the practice of a study investigator.
- ☐ Subjects referred or recruited from other physicians' practices.
- ☐ Subject recruitment by advertisement, flyer(s), web pages, etc.
  Recruitment materials must be approved by the IRB prior to use. Attach recruitment materials to the SpartaIRB smart form.
- ☐ Subjects identified from electronic medical record or database outside the investigator's division or group (e.g., TriNetX, Research IT, etc.).
- ☐ Subjects studied or recruited from primary or secondary schools.
- ☐ Physician to physician recruitment.
- ☐ Other: Click here to enter text.

RESEARCH REPORTING AND TRINETX

Research Reporting (formally known as Research IT) and TriNetX can help search for UH patients in both the inpatient and outpatient ambulatory EMR that may meet eligibility criteria for your research study (*Non-UH employees must be UH credentialed in order to request information*).

RESEARCH REPORTING

Research Reporting can be used as a tool to help screen patients once a protocol is IRB approved and there is an IRB approval number.

- Make sure to list Research Reporting/IT in the initial application to the IRB via SpartaIRB.

- Before contacting the patients provided by the Research Reporting, make sure to get permission from their treating physicians. Once permission is granted, mail out a letter from the investigator and follow up with a phone call 1-2 weeks later. *Be sure to keep track of all the physicians who granted permission.*

- Submit your inclusion criteria and if applicable exclusionary ICD-10 codes.

- Complete the Research Reporting form via Workfront, see the Clinical Research Toolbox under Clinical Research Data Requests.

- Additional questions or issues should be directed to ITReporting@UHhospitals.org.

TRINETX

TriNetX is a global health research network that connects healthcare organizations, biopharmaceutical companies, and contract research organizations to optimize clinical research and enable discoveries. TriNetX provides more effective querying of our electronic medical record allowing us to optimize the data for research activities such as study feasibility and patient recruitment. Services are available at *no cost* to UH Principal Investigators and study teams.

- **Study Feasibility**
  Mandatory process to help determine if a particular protocol can be implemented at University Hospitals.
  - Please read Research SOP SP 201: Protocol Feasibility Assessment
  - For questions and additional assistance regarding contact CRCFeasibility@UHhospitals.org
  - Submit for Feasibility Assessment HERE

- **Patient Recruitment**
  The TriNetX Export ID process allows us to identify patients who meet a study's eligibility criteria
  - Please read Research SOP SS 307: Obtain an Identified Patient List through UH CRC's TriNetX Export ID Feature
  - For questions or additional assistance regarding Export ID contact CRCExportID@UHhospitals.org
  - Submit for Export ID patient recruitment list HERE

UH MARKETING

BRAND CENTER

The UH Brand Center contains everything you need to familiarize yourself with the brand and identity of University Hospitals. This encompasses all UH locations, services, practices, partnerships and technology. Included are downloadable templates and logos; instructions for creating flyers and newsletters and ordering materials; and resources that outline our brand, design and writing standards.

It is highly recommended to include the University Hospitals logo when recruiting UH patients. The logo can be found here.

* Materials may have both UH and CWRU logos as long as they are spaced apart.

Additional questions can be directed to BrandCenter@UHhospitals.org

UH MARKETING, DIGITAL MEDIA & INTERNAL COMMUNICATIONS

For assistance with official UH and RBC social media, radio & advertising, display/banner advertising, or other digital media advertising involving official UH media platforms, contact the UH Marketing Department or Lisa Hackle directly at Lisa.Hackle@UHhospitals.org.

For submissions to the Digital Work Place (DWP) or other internal communications avenues, please complete one of the forms below or contact Kelly.Kershner@UHhospitals.org. This may include your research study or PI featured in News You Need to Know, Organizational News and more.

- Social Media Submission Form

- DWP Article Submission Form
- UH Events Submission Form
- UH Window Monitor Submission Form

If you are interested in having your research study featured in the Clinical Update newsletter, submit a Workfront request. If you need access to Workfront, contact Kathy.Adams@UHhospitals.org

RECRUITMENT FLYERS, PERIODICAL ADVERTISEMENTS, & BROCHURES

It is recommended that researchers create UH branded materials rather than, or in addition to, materials provided by the sponsor. Visit the UH Brand Center for UH branded templates. Patients will more likely identify with UH rather than the sponsor. Many times sponsor-provided materials will have a space provided for site-specific branding and contact information. Also it is best to keep information less detailed and easier for the general public to comprehend.

FLYERS

Flyers are an effective way to advertise and communicate key details about your study, quickly make an impression and pique interest with clinicians and community members.

- Flyers should be appropriately eye-catching and easy to read from a distance.
- Offer the major points of the study consistent with your protocol with your target audience in mind, and keep content brief. Too much information can be difficult to read. The goal is to pique interest enough that the potential participant contacts the study team to learn more. The coordinator can answer more detailed questions.
- Write a call-to-action. Include a name, phone number and/or website to refer potential participants, such as www.UHhospitals.org/Research. E.g.:
    - "Interested in learning more? Call 1-833-78TRIAL to speak with a coordinator"
    - "Visit www.UHhospitals.org/Research to learn more"
- Flyers can be displayed in lobby areas, waiting rooms or other designated approved areas around the campus. **Elevators and restrooms are disallowed**.
    - Highly recommended by the UH IRB. Refer to UH Policy GM-64 for approved location for flyer placement.

See **Appendix A** for research flyer templates consistent with UH Brand Standards for use. If none of these templates suit your needs, you can create your own for review by UH Marketing.

PERIODICAL ADVERTISEMENTS

Periodical advertisements can include ads placed in newspapers, magazines, and other publications. Periodical advertisements may include the same language as on your recruitment flyers, or language specific to these advertisements can be submitted separately.

Ad and Flyer Dos and Don'ts

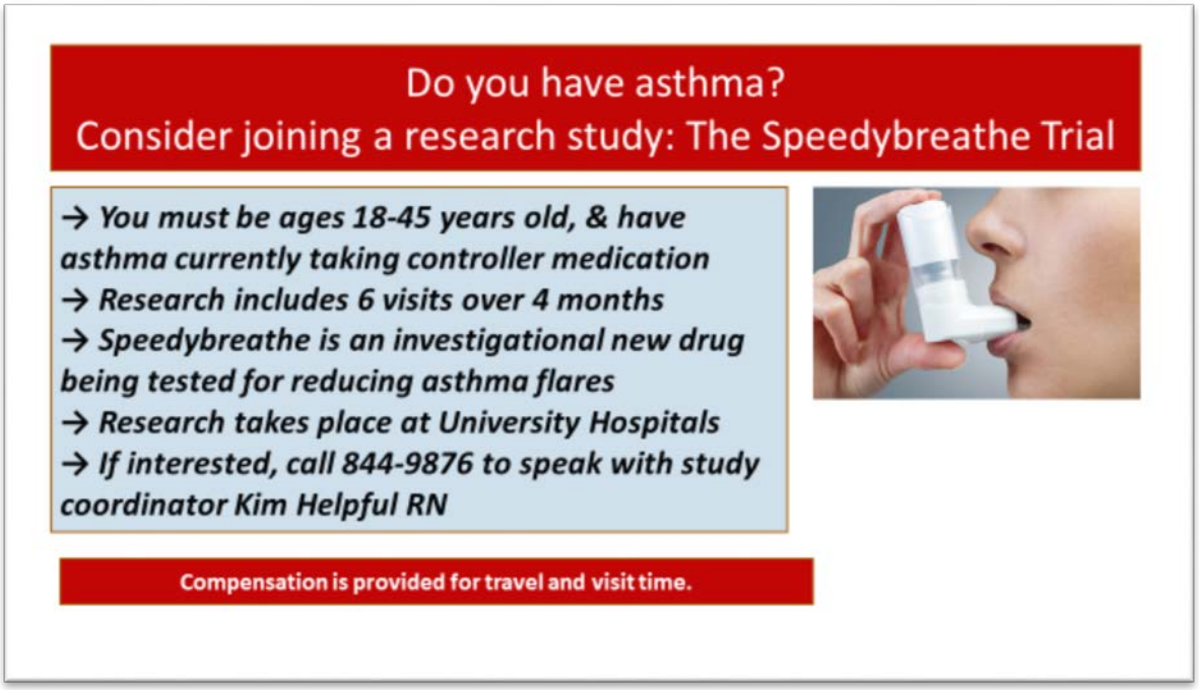
Do Include:

- Statement that the study is research.
- The condition under study and/or the purpose of the research in summary form.
- The criteria that will be used to determine eligibility for the study in summary form.
- The location of the research.
- Information about the person or office to contact for further information (*e.g., a work-related phone number, email address, etc*.).
- When appropriately worded, the following items may also be included in advertisements:
  - A brief list of participation benefits, if any (*e.g., a no-cost health examination*).
  - The time or other commitment required of the participants.
  - Compensation may be mentioned, but not as a specified amount or as a benefit.

Do Not Include:

- Claims, either explicitly or implicitly, that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation.
- Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention.
- Terms such as "new treatment," "new medication," or "new drug" without explaining that the test article is investigational.
- Promises of "free medical treatment" when the intent is only to say that participants will not be charged for taking part in the investigation.
- Mention of a specific amount of financial remuneration or overemphasize in the materials that remuneration is available.
- Any exculpatory language.
- Photographs or graphics that could be considered attention-grabbing but not study related.

Example of a **GOOD** ad or flyer



Example of a **BAD** ad or flyer

BROCHURES

Whereas flyers and periodical advertisements offer key high-level study information, brochures provide more detailed information about your study for clinicians and community members.

- Design the brochure and develop the content with your target audience in mind. Make it eye catching.
- Include clear, concise, and easy to follow information that you feel is important to educate the reader about research, the disease being studied, and the study itself that is consistent with your protocol.
- Write a call to action. Include a name and phone number and possibly a website to refer to such as UHhospitals.org/Research
    - Eg,
        - "Interested in learning more? Call 1-833-78TRIAL to speak with a coordinator"
        - "Visit UHhospitals.org/Research to learn more"
- Having a brochure available can be beneficial when patients request information about the study.
- With permission, brochures can be included in certain office lobby areas, waiting rooms & medical office countertops.

Departments may also create general educational brochures containing information related to their research program and common clinical research educational information. General educational materials should not contain specific study information and do not have to be approved by the IRB.

See SOP SP-204: Research-Related Patient Education and Recruitment Materials for more information.

See **Appendix B** for brochure templates and examples that are consistent with UH Brand Standards and are approved for use.

You may also create your own for review by UH Marketing (See the UH Brand Center for additional templates). For a cost, if you need help with design, layout and brand standards, you can contact:

TAYLOR COMMUNICATIONS
www.taylorcommunications.com
111 W First St, Dayton, OH 45402
Office: 937-221-2686

RECRUITMENT LETTERS & EMAILS

Recruitment letters and email may be helpful when targeting current UH patients. Letters and emails can be sent:

- To physicians (*IRB approval is not required for letters sent directly to treating physicians*)
- To patients from a treating physician
- To patients from the PI with permission from the patient's treating physician

Permission from the patient's treating physician to contact the patient is required prior to sending emails or mailing letters

Specific IRB and compliance requirements apply when using letters and email as a recruitment tool. Please refer to the UH Interventional Recruitment Template and UH Survey Recruitment Template. The most current versions can be found in SpartaIRB Library (Templates).

UH INTERVENTIONAL / SURVEY RECRUITMENT TEMPLATE


UH INTERVENTIONAL RECRUITMENT TEMPLATES

Use this form if the study is interventional and aims to recruit research participants (e.g., blood draws, drug/device trials, etc.)

STUDY TITLE:

1. This study will be utilizing:
   - ☐ Email recruitment
   - ☐ Letter recruitment
2. How many research subjects do you plan to enroll?

The most current version can be found in the SpartaIRB Library (Templates).

One of these forms must be used when contacting potential participants via letter mailing and/or email. The Interventional Recruitment Template should be used when recruiting participants for interventional study (blood draw, drug or device study, etc.). The Survey Recruitment Template should be used when recruiting participants for a survey study.

The correspondences must have an option for opting out of future communications.

Permission from the patient's treating physician to contact the patient is required prior to sending any letters or emails.

PHYSICIAN REFERRAL RECRUITMENT LETTER

- Send out emails or letters to referring physicians early in the recruitment process to determine interest and gain permission for contacting or approaching patients
  - Example:

    Dear Dr. [NAME]

    We plan to approach the following patients in your clinic next week for the [STUDY NAME] Study. If you would prefer that we skip any of these patients, let us know and we'll remove them from our schedules. We greatly appreciate all of your help!

    Best Regards,
    Your name

- Patients may feel more comfortable with participating in a study with permission from their physician.
- When emailing providers, include a list of patients that have already been identified or prescreened as a potential participant for the research study prior to contacting the patient or prior to approaching patients in the clinic (May come from a report requested from Research Reporting or TriNetX)
- Include a brochure, relevant study materials, or inclusion/exclusion criteria
- Reminder emails to the physicians throughout the study may be helpful.

GRAND ROUNDS

The purpose of the Grand Rounds is to spread awareness about research, pre-screen the presented patients, and to encourage extended participation throughout the department. During Grand Rounds, have the protocol available for the presenting/treating physician to review. The treating physician will need to formally refer the patient to the clinical trial before a study team reaches out to the patient.

Physician referrals are key for successful enrollment. Patients will more likely participate in a research study if their current provider recommends research as an option. The more places/opportunities that studies can be promoted and that providers can learn about research, the more likely that physicians will feel more comfortable referring their patients.

TELEPHONE & VOICEMAIL

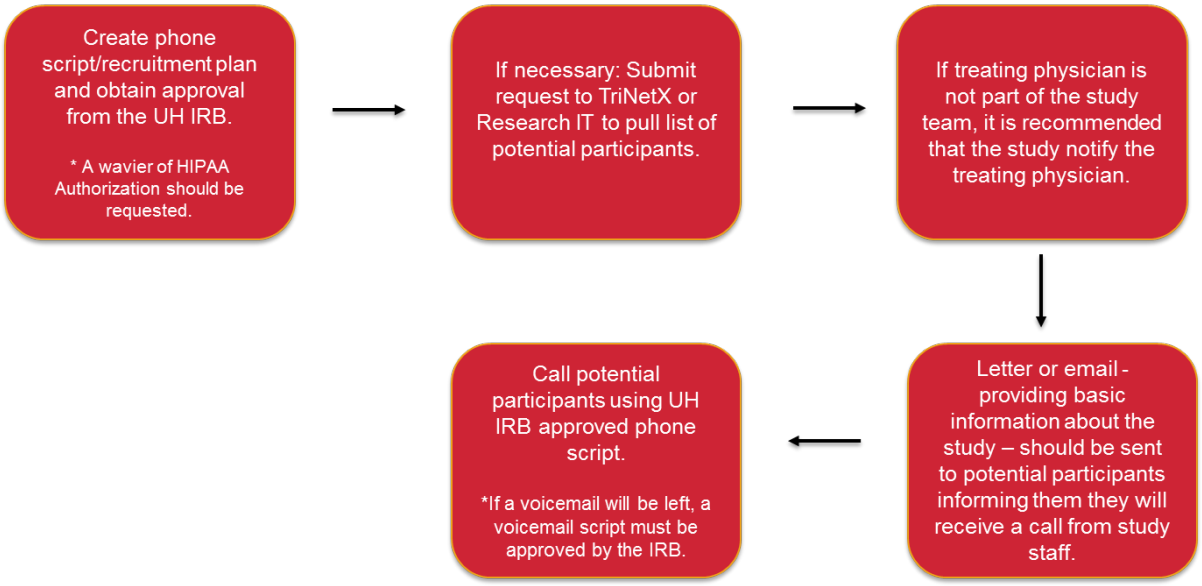
Generally, when recruiting via phone a waiver of HIPAA Authorization must be granted by the IRB.

The IRB strongly discourages cold calling of potential research participants. As such, generally, a letter or email providing basic information should be sent that informs the potential participant that he or she will be receiving a call from the study staff. This communication must include how to opt out of being contacted if he or she chooses to do so. Opt out can involve calling a phone number or sending back a postcard, for example, and must be simple and easy.

Similar to recruitment letters and emails, phone scripts must be submitted to the IRB before use.

**A Phone Script Template can be found in the SpartaIRB Library (Templates)*

TELEPHONE RECRUITMENT PROCESS



UH TELEPHONE ON-HOLD MESSAGING

Your research study information can be included with the repeating recorded message that patients listen to when placed on hold by UH operators. In this manner, patients become captive audience.

If utilizing this medium, your message must be IRB approved. Submit your message with your other recruitment materials to the IRB for review.

For more information, contact Kim Fatica, Sr. Media Strategist, for more information at Kim.Fatica@UHhospitals.org

VOICEMAIL

Leaving a voicemail message for a potential participant is permitted however the information must be limited. A template can be found in the UH Phone Script Template, which can be found in the SpartaIRB Library (Templates).

INTERNET & VIDEO RECRUITMENT

If posting study information on the internet, IRB approval is NOT required if the information is limited to* **:

- Study Title
- Purpose of Study
- Protocol Summary
- Basic Eligibility criteria
- Study site location(s)
- Contact information

Anything additional will require IRB review and approval.

* Postings in the Case Daily, the CWRU newspaper, typically do require IRB approval.

** Two specific Internet clinical trial listing services (National Cancer Institute's cancer clinical trial listing and the government-sponsored AIDS Clinical Trials Information Service) have been given an exemption to this requirement and do not require prospective IRB approval.

To inquire or begin the process please submit a Workfront Request or contact Lisa.Hackle@UHhospitals.org.

UH employees without Workfront Access may request access by contacting Kathy.Adams@UHhospitals.org.

BASIC ELEMENTS OF INTERNET ADVERTISING

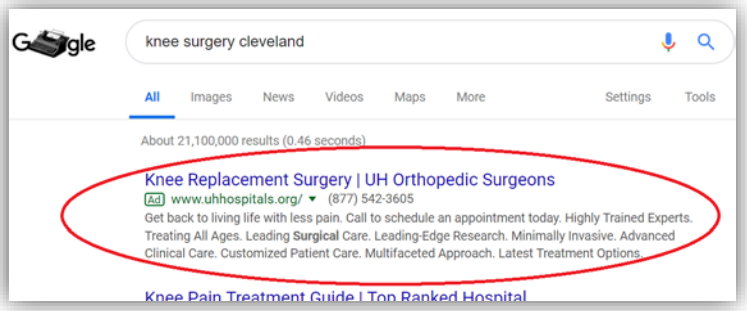
- Attention Grabbing Headline
- Short Description
- Call-to-action (CTA) - A statement suggesting users to act in a certain way after seeing or reading an advertisement or post, eg:
  - "*Click here to learn more about this and other research studies at UH*"
  - *"Call 1-833-78TRIAL to find out if you are eligible for this study"*
- Landing page – A web page that contains more study details and contact information about a study; CTAs from advertisements or posts may typically direct users to a landing page.

**** For more information on the process and pricing, visit the DWP website: HERE.** *You must be on the UH server to access this link. ***

SEARCH ENGINE MARKETING (SEM)

Search Engine Marketing (SEM) such is a form of paid advertising which relies on keywords typed into search engines. By paying for search engine marketing, your webpage will populate at the top or near the top of search results when users search for the keywords that you specify. This can be a very cost efficient way to target your study's demographic audience. You can request this advertisement via Workfront.

Google is the most popular platform for SEM:



SOCIAL MEDIA

Social media is an effective medium to help build awareness about your research study by either free/organic posts or paid posts

Twitter

Twitter allows for up to 280 characters of text and is useful for studies that do not require lengthy details to pique interest. The UH Twitter account has ~ 20,000 followers

Facebook

Facebook is a way to advertise your study and get the attention of users organically via word-of-mouth or user-to-user sharing; or through sponsored/paid posts and paid display advertising.

Sponsored/paid Facebook posts and advertising allow you to choose the demographics of whom your post or advertisement will reach. Costs will vary depending on demography and geography.

Free Post

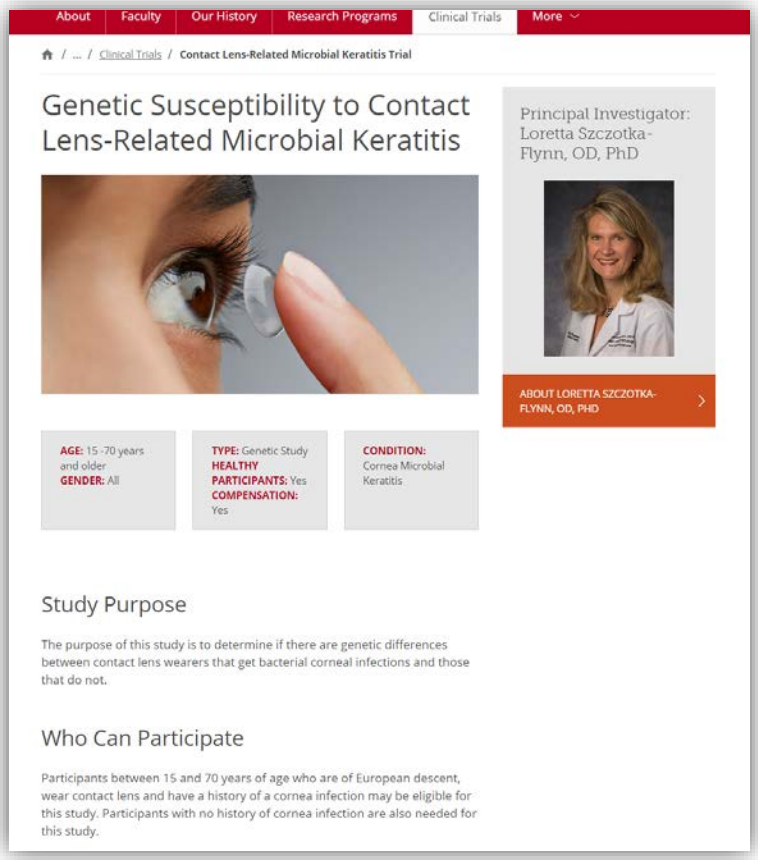
Paid/Sponsored Post

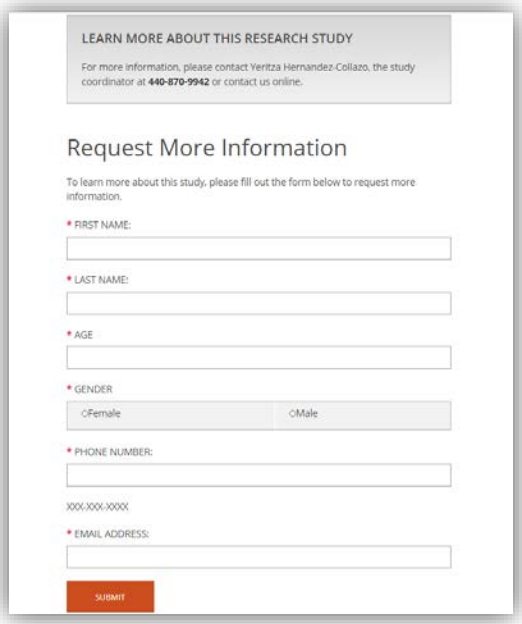
Related Social Media Accounts:

	CRC	UH Research & Education Institute	UH Main	RBC Main
	University Hospitals Clinical Research Center	UH Research & Education Institute	University Hospitals	---
	@UHClinicalResearch	@UHResearchandEducation	@UniversityHospitals	@UHRainbowBabies
	@uhclinicalresearch	---	@uhhospitals_cle	@uhrainbow
	@UH_CRC	@UH_RE_Institute	@UHhospitals	@UHRainbowBabies

LANDING PAGES

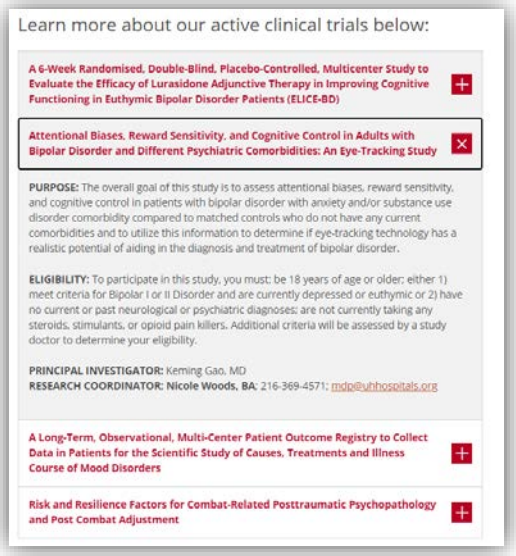
Landing pages can contain more details about your specific study. CTAs from advertisements or posts may typically direct users to a landing page. Some items to add to the page can be basic eligibility criteria, study purpose, and contact information. These pages can also be trackable, and can include trackable forms and phone numbers (be sure to check the box when completing the Workfront request).





Even though these are tracked digitally, keep of track referrals manually on a screening log as backup.

A Department Research Landing Page can also be created. The department can list numerous trials and contact information. Listing the currently enrolling trials and supplying a REDCap eligibility form link on the page are simple ways to increase recruitment.



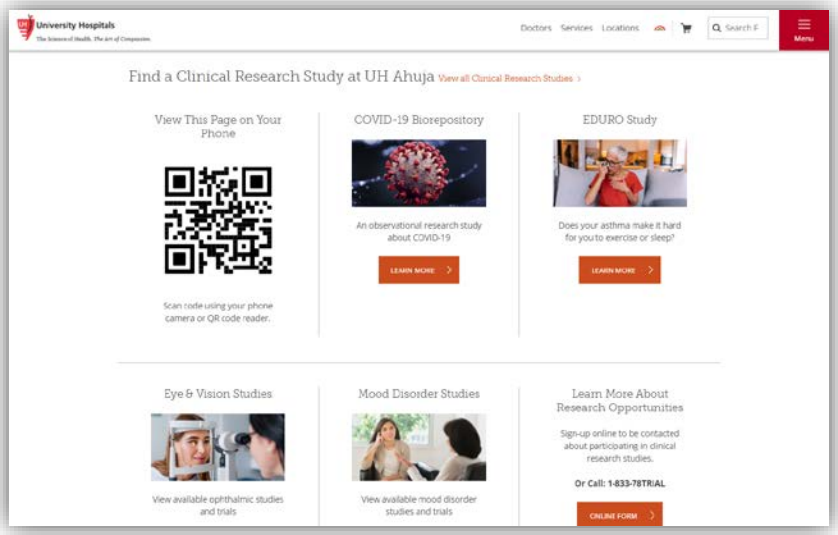
Landing Page Possibilities:

- UH Clinical Research For Patients Page: UHhospitals.org/Research
- UH Clinical Trial Finder: https://clinicaltrials.uhhospitals.org/
  - Main page
  - Specific study information page if your study is listed
- Specifically created study landing pages
- Department research web pages

CLINICAL RESEARCH KIOSKS

The clinical research kiosks are a passive way to recruit potential participants and education patients about clinical research. There are nine kiosks located at six different UH campuses. All are placed in high traffic areas to allow visibility to patients. Be sure “Subject recruitment by advertisement, flyer(s), web pages, etc.” is selected on the Supplemental form in your IRB application. Attach the recruitment materials to the SpartaIRB smart form. As you know, Recruitment materials must be approved by the IRB prior to use.

A link to your study’s information or landing page can be placed on the kiosk. QR codes on each Kiosk allow users to access the kiosk information on their mobile devices.



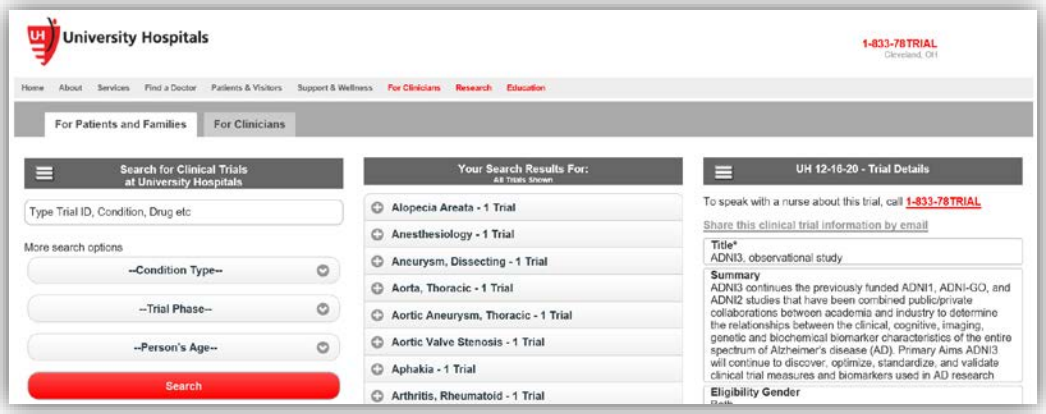
UH Marketing Support for SEM, Social Media, Custom Landing Pages, and Clinical Research Kiosks Advertising are available for UH clinical research studies.

The CRC and UH Marketing have developed a process for researchers with any sized budget interested in these methods. To inquire or begin the process please submit a Workfront Request or contact Lisa.Hackle@UHhospitals.org. For more information on the process and pricing, visit the DWP website. *You must be on the UH server to access this link.*

UH employees without Workfront Access may request access by contacting Kathy.Adams@UHhospitals.org

UH CLINICAL TRIAL FINDER

The UH Clinical Trial Finder is a web based application that allows patients and providers to search and sort all IRB approved studies that are currently recruiting at University Hospitals by condition, trial phase, and/or age.



Direct links to the Cancer and Non-Cancer Trial Finders are located on the UH Research For Patients webpage where patients can visit to educate themselves about research and clinical trials.

The only way for your study to populate in the Non-Cancer Trial Finder search results, and therefore use as a recruitment tool, is by submitting your study into the UH CRC Research Study Database. If you have not yet begun to use this database, a link to the study database as well as a step-by-step user guide can be found in the Research Toolbox.

All researchers who submit studies to the UH IRB are strongly encouraged to add studies.

For more information or to make sure all of your enrolling studies are registered, please contact Heather Tribout at Heather.Tribout@UHhospitals.org.

THIRD PARTY RESEARCH RECRUITMENT WEBSITES

These third party websites can be used to recruit both healthy volunteers and those with specific medical conditions by giving volunteers the ability to search for studies and helping connect them to the researchers.

1. ClinicalTrials.gov

   Registration for some clinical studies is required. Find out more by referring to UH Research SOP 401: Registration of Clinical Trials in ClinicalTrials.gov

2. ResearchMatch OR contact Info@researchmatch.org

   Listing on ResearchMatch requires IRB approval. More information and templates are available at ResearchMatch.

   researchmatch.org
   Difficult diseases have met their match.

   Instructions for ResearchMatch can be found here.

Sample ResearchMatch Posting:

This study is looking to see how the hand is involved in holding a pencil. The purpose of this study is to gain better understanding of how people evaluate shapes.

We are inviting volunteers who use pencils and do not have any diagnosed conditions to participate in this study.

The data we collect will be used for comparison with data collected from people who write with pens.

This study is open to men and women between the ages of 18 and 65. The study takes up to two hours and requires a visit to our facility in Honolulu, HI.

You will have to participate in surveys and a neurological test to determine any underlying conditions that might affect hand dexterity. You may be asked to provide a blood sample.

Volunteers will be compensated for participating.

3. Center Watch http://www.centerwatch.com/clinical-trials/post/

4. Case Daily: (CWRU Newspaper) http://thedaily.case.edu/research/ or contact Katie: kmh@case.edu

TELEVISION & RADIO COMMERCIAL ADVERTISING

Television and radio advertisements typically feature professional actors or voice actors and could be relatively expensive depending on production cost and the time of day in which your advertisement is broadcast (More expensive to broadcast during primetime television hours and radio “drive time” during rush hour).

RADIO ADVERTISING

Since this form of advertising is audio only, the message must both develop rapport and deliver key information simultaneously.

Listeners may feel an emotional connection with their favorite radio stations and each station may attract different demographics of the community.

Here are some tips to keep in mind:

- Make sure you radio has a call to action.
- Radio can have a large reach and therefore target a large patient demographic.
- Listeners tend to be very loyal and listen to only a few stations. Having your research study advertise with frequency may be effective.
- Be sure to mention the following in your ad:
  - Condition being studied or nature of study
  - The word investigational if a drug study
  - Age range for eligibility
  - Do not make any promises of getting better
  - Do not use the word “free”
  - Contact information for study team

Sample Radio Templates:

****Examples only. These templates are not IRB approved. All scripts must be submitted to the IRB for approval ****

30-second script:

"Are you or someone you know suffering from [CONDITION]? University Hospitals is currently looking for volunteers to participate in a research study for an investigational medication for the treatment of [CONDITION].

If you are [AGE RANGE] and diagnosed with [CONDITION] or daily life is affected by these symptoms, you may be eligible to participate in this study. Study procedures may include medical tests and study medication.

To learn more, call [PHONE NUMBER] that's [PHONE NUMBER]. "

60-second script:

"Are you or someone you know suffering from [CONDITION] or feeling symptoms such as [SYMPTOM 1] or [SYMPTOM 2]?

Right now, doctors at University Hospitals are accepting new participants for the [STUDY NAME]. The study is for an investigational medication that may help improve [CONDITION OR SYMPTOMS].

If eligible, there's no cost to participate, and you may receive study-related care from a team of specialists. Also, if you join the study, you may be compensated for your time and travel.

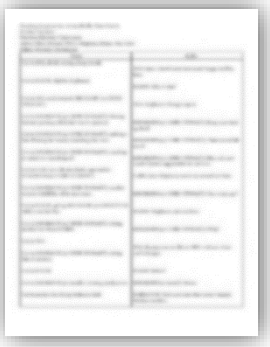
To learn more, and to see if you might qualify, please call [PHONE NUMBER] or visit [WEBSITE]. Again, That's [PHONE NUMBER] or visit [WEBSITE]."

The UH Marketing department can help you create a radio ad and an advertising schedule that works within your budget and targets your patient population. Contact UH Marketing Department or Lisa Hackle directly at Lisa.Hackle@UHhospitals.org.

TELEVISION/VIDEO ADVERTISING

If your study sponsor has already produced a television commercial for use, you must submit the final product to the IRB via an online link or file.

If not yet produced, all scripts and commercial story boards must also be submitted to the IRB for approval prior to production and use



COMMUNITY ENGAGEMENT

Community Engagement activates are an opportunity to be face-to-face with patients and other local community members, and build a personal rapport. If considering community engagement as part of your recruitment efforts, your recruitment plan should include locations from which you plan to recruit as well as promotional items you plan to distribute (health fairs, etc.)

Find ways to increase the diversity in research populations. This can be done through education and engaging communities. Broader representation in clinical research will lead to better science.

Know the barriers to recruitment and strategize ways to overcome. Below are examples of common barriers and objections you may experience and strategies to overcome them:

- **Side Effects**
  - Research is mandated to list every single side effect during other phases of the trial, sometimes these side effects are not related to the medication; ie, dizziness may be related to a different condition someone had who participated in the trial.
  - Do the potential benefits outweigh the risks? Talk to your PCP
  - Also every medication even those FDA approved has potential side effects.

- **Don't want to stop existing treatment**
  - If the current medication is helping, a study team would not recommend patients to go off, however, if it isn't working there may be a benefit and it may actually help the condition being studied.
  - Participants can always come out of the study at any time.

- **Risk to overall health**
  - Do the potential benefits outweigh the risk? Can the study treatment potentially increase your quality of living?

- **Clinical Trials are dangerous because they use new medicines**
  - Most of the time, the study medicine has been tested in previous phases.
  - Often, by the time, the study is tested on a large group of people, safety testing has already happened and this is the last phase of the trial before approved by the FDA.
  - Patients can take the medicine usually at no cost and before it is available to everyone.
  - Patients are monitored very closely by a whole study team and have access to care 24/7.
  - Patient safety is the number one priority - IRB # 1 job is patient safety! Participants are closely watched and rigorously screened.

- **"I don't want to be a guinea pig"**
  - Research is always completely voluntary and every trial has an informed consent. This is a document that includes all the information about the study to help people make their own decision as to whether they want to participate. It includes the purpose of the study, the study details, as well as risks and benefits. The decision to participate is the patients!

- **"I don't want to get a sugar pill or placebo"**
  - Explain that is how medication is tested to see if it is effective, sometimes there is only a 1/3 or a 1/4 chance of receiving placebo depending on protocol. It varies.
  - There is a "placebo effect"; sometimes people are taking a medication, being seen regularly and getting good care, so often people may "feel" better. Patients sometimes improve because of psychological reasons. This is how scientists determine whether a new medical treatment is safer and more effective than no treatment. Regardless of what treatment arm people receive they are monitored very closely.

- **"Why would I want to participate in a clinical trial?"**
  - Aiding in scientific advancement, altruistic (Helping others with similar conditions).
  - Receive special care from health care professionals, improving disease outcomes, have access to cutting edge treatments before the general public

- **"I don't have the time to participate in a trial"**
  - Most studies do compensate for your time and travel.

- **"I had a bad experience with research in the past"**
  - The process at UH is very rigorous, also each study team is different and there is always the option to report any issues to the IRB or the compliance officer.

Only IRB approved recruitment materials should made available to provide. Study specific promotional items (pens, bags, etc.) should also be reviewed/approved by the IRB.

Connect and develop relationships with potential volunteers from clinics, community, etc.
- Engage, build trust, and be transparent
- Educate the public and increase their knowledge of research.

COMMUNITY ENGAGEMENT FAQS

What is community engagement?

Examples of community engagement includes when study team members are involved in participating in community events such as walks and health fairs as a mechanism for getting information about a study out to the community. This can also be done by sponsoring an event or setting up a vendor table.

Another example of community engagement is providing educational forums or discussions in the local community. This may include educating other health professionals or community members about a disease, health concern or research study that pertains to the discussion. Consider offering CEUs if appropriate.

Is my research team required to use community engagement as a recruitment option?

No, this is optional. You may want to discuss with your study team whether this option is viable or not. Often, these community events occur during evenings or weekends.

At what point in the research process should I plan for community engagement?

If you think you may utilize community engagement as a recruitment tool, make sure it is included in your initial IRB submission.

Is community engagement study-specific?

Community engagement activities can be study specific or general, it's up to you. Discussion with the study team and with the IRB will be necessary and IRB approval of these activities is required. Make sure to include community engagement with your initial IRB submission or submit a modification if needed.

Why would our research team want to participate in community engagement?

Participating in community engagement allows you to target a specific disease population, show support and develop relationships with community organizations. This could lead to referral sources.

Community events tend to draw large crowds that may target your study population and help boost enrollment.

How do I find community events in which to participate?

There are many ways to find community events. Conducting a Google search for terms such as "upcoming health fairs [REGION or CITY or LOCATION]", or "[DISEASE or CONDITION] awareness events", etc. could populate many results. Word-of-mouth may be useful as well.

What does it cost to sponsor a walk or participate in a community event?

There are usually separate costs for vendor tables and for sponsorships. Vendor tables may range in cost from $100 - $500. Sponsorships may range in cost from $500-$10,000. Often times, sponsorships include a vendor table.

Are there any other costs involved?

You may want to set aside budget for promotional giveaway items, an activity, or a small food items to give away. Having promotional giveaway items to hand out with your phone number or website in addition to research fliers, brochures, etc. may be advantageous.

Sponsorship	Estimated Cost Range	$500-$10,000
Vendor Table	Estimated Cost Range	$100-$500
Copies of Research Materials	Estimated Cost Range	$50-$250
Food items	Estimated Cost Range	$25-$100
Promotional items	Estimated Cost Range	$100-$500
Total	**Estimated Cost Range**	**$775-$11,350**

Helpful tips:

- *Don't rely on your own site for recruitment contacts.*
- *Reach out to community organizations and community leaders.*
- *Develop collaborative relationships around educational programming pertaining to the diseases being studied.*
- *Find ways to present clinical trial information that complement the values people in the community hold.*
- *Reach out to a variety of organizations that can help raise awareness about your clinical trials. (i.e. Minority based organizations, non-profit organizations like the Crohns and Colitis foundations or Alzheimer's Awareness foundation, disease support groups, civic organizations, churches/religious institutions, community health centers, professional organizations, senior citizens organizations, etc.)*

To reserve your own table at University Hospitals Cleveland Medical Center, contact Barbara Nalette, Director of Volunteer Services at Barbara.Nalette@Uhhospitals.org or 216-844-1504.

To reserve a table through CaterTrax, follow the instructions here. For other approved UHCMC locations, please contact 216-286-7069.

PROMOTIONAL ITEMS AND GIVEAWAYS

Items that patients can use on a daily basis that feature study contact information and branding can generate top-of-mind awareness of your study with the patient and community. These can include pens, microfiber glasses wipes, stress/squeeze items, etc.

The UH Brand Center has provided a list of approved promotional item vendors available to contact.

CRC PROVIDED RECRUITMENT OPPORTUNITIES

UH RESEARCH RECRUITMENT TABLES

The UH Clinical Research Center supports the research community by highlighting the many research opportunities available at University Hospitals at our periodic research recruitment tables.

Recruitment tables are an opportunity for UH researchers to display their IRB approved recruitment materials for UH employees and patients. The tables are displayed regularly at bi-monthly or quarterly intervals and are typically located in high traffic areas throughout the UH system (CMC Atrium, Ahuja, Parma, Southwest General, St. John, etc).

When a Recruitment Table is scheduled, an email communication is sent from the CRC informing the UH research community of the location, time and date of the event. Researchers who are interested in participating can drop off their IRB recruitment materials by the stated deadline to the UH CRC Main office or Recruitment Specialist managing the Recruitment Table.

CRC RECRUITMENT SPECIALIST

The UH Clinical Research Center Study Recruitment Specialist, Kimberly Bass, is available to consultation or assistance for your study recruitment efforts.

Please contact Kimberly directly at Kimberly.Bass@UHhospitals.org or 216-286-7250 for additional information.

Now Enrolling

Research Study Name/Condition being studied

Study details here including the word "research". Include purpose of the study, criteria of the study, length of study or number of study visits. Location of study should be included. A brief list of benefits can be mentioned. Compensation may be mentioned but not a specified amount or as a benefit.

Contact information with a name, phone number and/or email address

University Hospitals

1-833-78-TRIAL (1-833-788-7425)
UHhospitals.org/Research

Now Enrolling

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Contact information with a name, phone number and/or email address

University Hospitals
Rainbow Babies & Children's

1-833-78-TRIAL (1-833-788-7425)
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Now Enrolling

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Case Western Reserve University EST. 1826

University Hospitals

1-833-78-TRIAL (1-833-788-7425)
UHhospitals.org/Research

Now Enrolling

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University Hospitals

1-866-UH4-CARE (1-866-844-2273)
UHhospitals.org
11100 Euclid Avenue, Cleveland, Ohio 44106

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University Hospitals

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Questions to ask your doctor or study coordinator:

Taking part in a research study is voluntary and completely up to each patient as long as the patient is eligible and meets the criteria for a particular study.

When considering participating in a research study, it is important to understand and learn about what may be involved before making a decision. Here are some questions to ask your doctor or study coordinator:

- Why is this study being done?
- What kinds of tests or treatments are involved in this study?
- What are the risks and benefits?
- What are my other options?
- What are my responsibilities?
- How often will I have to come to the hospital or clinic?
- Are there costs involved with participating?
- Can I withdraw at any time?
- Who can I contact in case I have any questions?

UH Clinical Research Center

Our mission is to responsibly grow research and scientific innovation to improve patient care.

Among the nation's leading academic medical centers, UH Cleveland Medical Center and Rainbow Babies & Children's Hospital are recognized for quality clinical care, as well as biomedical and translational research.

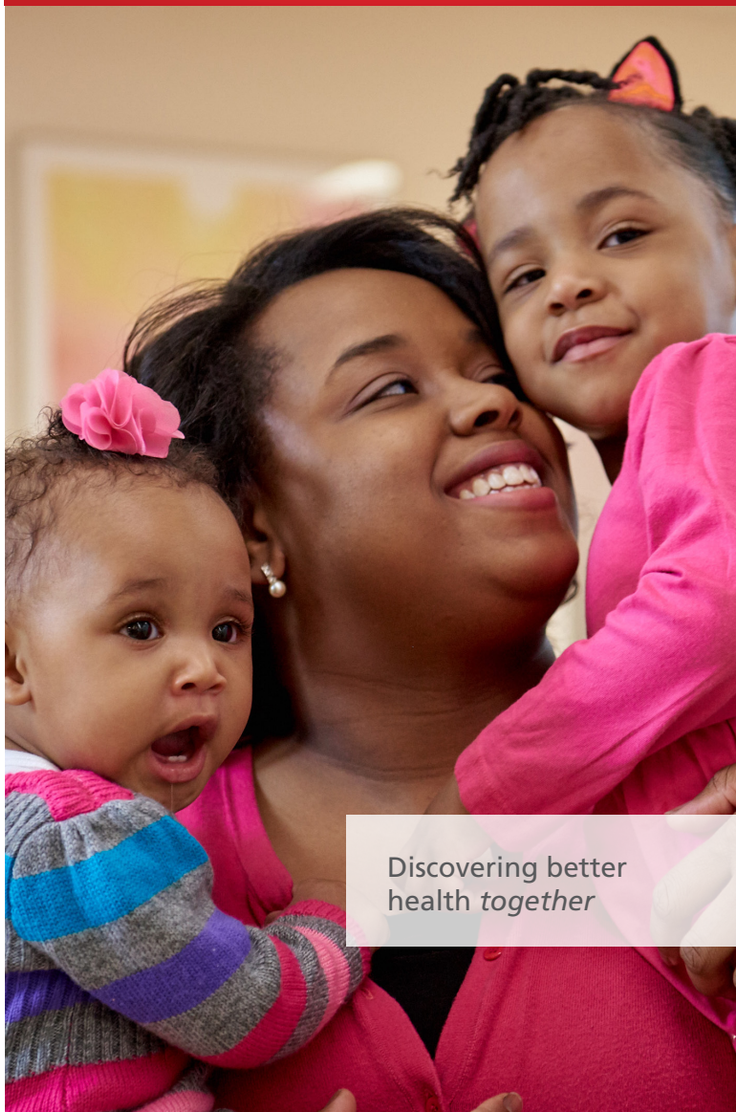
University Hospitals

1-833-78-TRIAL (1-833-788-7425)
UHhospitals.org/Research

11100 Euclid Avenue, Cleveland, Ohio 44106

University Hospitals
Rainbow Babies & Children's

Research & Clinical Trials



WHAT IS CLINICAL RESEARCH?

Clinical research studies and clinical trials are projects that involve human volunteers to answer specific health questions. Carefully conducted research studies are the mechanism to find new treatments that work in people and new ways of using established treatments. The results of these studies also help contribute to the greater knowledge of medicine.

WHO CAN JOIN A RESEARCH STUDY?

All research studies and clinical trials have guidelines about who can participate, so anyone can join a study as long as they meet those guidelines.

These guidelines are based on factors such as age, gender, the type and stage of a disease, previous treatment history and other medical conditions. They are used to identify appropriate participants and keep them safe. Some research studies seek participants with illnesses or conditions to be studied while others need healthy participants.

These guidelines also help ensure that researchers will be able to answer the questions they plan to study.

WHAT ARE THE BENEFITS AND RISKS OF PARTICIPATING IN A RESEARCH STUDY?

Research studies that are well-designed and well-executed are the best approach for participants to:

- Play an active role in their own health care.
- Gain access to investigational treatments before they are widely available.
- Help others by contributing to medical research.

There are also risks to research studies:

- There may be unpleasant, serious or even life-threatening side effects to treatment.
- The treatment may not be effective for the participant.
- The study may require more time and attention than would a non-study treatment, including more trips, treatments, hospital stays or complex dosage requirements.

> Many successful treatments used today are the result of ***research studies.***

WHAT STUDIES ARE AVAILABLE RIGHT NOW?

Thousands of active clinical research studies are in progress across University Hospitals for participants of all age ranges.

To find out about research studies that may be available to you:

Call 1-833-78-TRIAL (1-833-788-7425), visit **ClinicalTrials.UHhospitals.org** to search for studies, or ask your doctor about studies that may be available.

To gain a better understanding of research and informed decisions before participating in research studies, visit: **hhs.gov/About-Research-Participation**

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University Hospitals
MacDonald Women's Hospital

Contact Us

1-440-995-3810

MCTU@UHhospitals.org

UHhospitals.org/Research

11100 Euclid Avenue, Cleveland, Ohio 44106

University Hospitals
MacDonald Women's Hospital

Research & Clinical Trials

WHAT IS CLINICAL RESEARCH?

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- The treatment may not be effective for the participant.
- The study may require more time and attention than would a non-study treatment, including more trips, treatments, hospital stays or complex dosage requirements.

University Hospitals Department of Obstetrics and Gynecology (OB-GYN) is actively involved in research studies for women's health. Obstetrics focuses on caring for and maintaining a woman's overall health during maternity and Gynecology focuses on women's bodies and their reproductive health. It includes the diagnosis, treatment and care of women's reproductive system.

What studies are available right now?

The OB-GYN department has experience conducting research trials for the following conditions:

- Fibroids
- Endometriosis
- Chronic Pelvic Pain
- Heavy Menstrual Bleeding
- Menopause
- Female Sexual Health
- Contraception

To find out about research studies that may be available to you:

Call 1-440-995-3810, email MCTU@UHhospitals.org, or visit UHhospitals.org/Research to search for studies, or ask your doctor about studies that may be available

To gain a better understanding of research and informed decisions before participating in research studies, visit:
hhs.gov/About-Research-Participation