



Research Recruitment Guide

Fairview Health Support Services

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A Collaboration Among:

Fairview Research Administration

Fairview Research Recruitment Services

What is the purpose of this manual?

The “Research Recruitment Manual” is designed to guide you through the processes related to human subject research recruitment within the M Health Fairview system. The scope of this manual includes services provided by the Fairview Research Administration (FRA) and the Fairview Research Recruitment Services (FRRS) department.

The scope of this document does not include submission of research recruitment tools to the University of Minnesota IRB or other external IRBs. Research teams are required to follow all IRB policies concerning research recruitment tools and practices.

Who are the stakeholders in this research recruitment partnership?

- **Fairview Research Administration:** (FRA) The Fairview Research Administration department is your conduit to conducting clinical research at all Fairview Health System locations. FRA reviews all Fairview clinical trials through the ancillary review system and provides operation support to researchers.
 - Contact: research@fairview.org
- **Fairview Research Recruitment Services (FRRS):** FRRS was initiated in 2021 to provide an additional option for supporting research recruitment. The FRRS department provides services related to recruiting Fairview clinic outpatients and hospital inpatients.
 - Contact: researchscreening@fairview.org

How is this recruitment manual organized?

This document is organized to answer questions regularly received by investigative teams. We have displayed the content in study-based chronological order.

Who can I speak with about study logistics in a Fairview hospital or clinic?

Fairview Research Administration can assist you, please contact FRA Research@fairview.org.

Which Fairview hospital is the best for my inpatient recruitment?

You can start by contacting the Research Administration at Research@fairview.org. FRA can help you review the patient population at Fairview hospitals, make connections with the hospital medical leaders and support general study logistics in the hospital. Please see the appendix for a list of included Fairview hospitals.

Which Fairview clinics are the best for recruiting my study patients?

You can start by contacting Fairview Research and Recruitment Services at researchscreening@fairview.org. We can help you review the patient population at Fairview clinics and make connections with the clinic medical director, clinic manager and clinic providers. Please see the appendix for a list of included Fairview clinics.

How do I get started?

Fairview (FRA and FRRS) will act as an Honest Broker of the EHR data that is used for cohort identification and generating patient contact lists. To get started, please complete the Fairview recruitment intake form.

FRRS: [FRRS Intake Form](#)

When should I complete the FRRS Intake Form?

FRA and FRRS are pleased to assist you with study planning and recruitment support. We recommend that you complete the FRRS Intake Form after you have completed your protocol and are preparing for IRB submission.

Will Fairview consult with me about my study?

FRRS will meet with you to review the information in your intake form and plan a successful recruitment strategy. A study intake, initial consultation and set-up fee is assessed for all new and significantly modified studies. The initial set-up fee is waived when you elect to build a contact list with FRRS.

If your study continues recruitment activities > 12 months, an annual administrative fee will be applied. We will conduct a review of all recruitment efforts and provide you with a recruitment effectiveness report. The annual administration fee is applied to all studies.

Administrative Fees	
Start-Up Fee	\$500
Annual Administrative fee	\$250

Will Fairview review my study recruitment plan and tools?

Fairview Research Administration will review your recruitment strategy and tools during the required “ancillary review” process which will be assigned by the UMN IRB. Research studies cannot be implemented at a Fairview facility until the ancillary review process has been completed and all recruitment materials approved by FRA. FRA and FRRS representatives meet weekly to review your Intake submissions and ensure a timely turnaround.

Who can create a list of Fairview patients that meet my study criteria?

Both Fairview’s EPIC Analysts (FRRS) and CTSI’s BPIC can query the EPIC medical record to identify patients that are likely to qualify for your study. You can work with either FRRS or BPIC. The patient list from BPIC can only be utilized for US postal letters, this list cannot be used for MyChart messages.

You will need to work with FRRS if you intend to include the following patients in your recruitment plan.

- Historical HealthEast patient data
- Real-time daily patient information

Who can reach out to Fairview patients?

Only FRRS can directly communicate with patients. FRRS sends out all US postal letters and MyChart messages.

- FRRS can work with lists from FRRS or BPIC to send US postal letters.
- FRRS can work with lists from FRRS, BPIC or other sources for secured text messaging.
- FRRS can only work with FRRS reports to initiate MyChart messages.

Can I contact my own patients?

Yes! A provider may contact patients in which they have a direct treatment relationship to discuss study participation. The treatment relationship may also be extended to patients under the care of providers in the PI's department. FRRS supports patient recruitment throughout the Fairview network of 10 hospitals and 50 clinics. This guide is intended to help study teams understand the process of finding and communicating with patients in all Fairview facilities.

I would like to request a Fairview generated patient contact list; what are the next steps?

- We will coordinate a meeting with you and the Fairview EPIC analysts to ensure we extract a list of highly qualified patients from the Fairview EPIC.
- Once the query is complete, the data will be co-validated by FRRS and your team. FRRS will work with you to review the data and plan your patient communication strategy.
 - Time required: 2 weeks

FRRS Report Fees	
1 st Selection report	\$1,200
2 nd Selection report	\$700

How do I send US postal recruitment letters?

All research recruitment letters sent via US post will be printed, processed and mailed by FRRS.

You will be required to add the following paragraph to your recruitment letter and request IRB approval. The letter will be mailed by FRRS.

Adult patients:

At M Health Fairview, we are dedicated to helping researchers who look for new and better ways to deliver healthcare. We work together across our hospitals, clinics, and research teams to provide our patients the option to participate in research projects. Your medical records show that you may be able to take part in a new study. You are invited to contact the University of Minnesota researcher named below who will explain the study in detail and answer any questions you might have. The decision to participate is completely up to you. If you do not want to be contacted about future studies, contact the Fairview research office at 651.326.4450 or researchscreening@fairview.org and request that your medical record shows as Research Opt Out.

Pediatric patients:

At M Health Fairview, we are dedicated to helping researchers who look for new and better ways to deliver healthcare. We work together across our hospitals, clinics, and research teams to provide our patients the option to participate in research projects. Your child's medical records show they may be able to take part in a new study. You are invited to contact the University of Minnesota researcher named below who will explain the study in detail and answer any questions you might have. The decision to participate is completely up to you. If you do not want to be contacted about future studies, contact the Fairview research office at 651.326.4450 or (researchscreening@fairview.org) and request that your medical record shows as Research Opt Out.

US Postal Letters Batching Requirements/Restrictions	LABOR FEE	PRINTING/MAILING COSTS
First Batch (limit 250 recipients)	\$325	\$1.25 per page
Subsequent Batches (limit 499 recipients per batch):	LABOR FEE	
• 1-250 recipients	\$ 150	\$1.25 per page
• 251-499 recipients	\$ 200	\$1.25 per page

Can I send US postal letters myself?

Study teams are not allowed to send letters to Fairview patients (unless you are the treating provider). FRRS will send research recruitment letters and patients can contact the researcher at their discretion. All US postal letters, and accompanying mailed documents, must be approved by the appropriate regulatory and operational departments (including the IRB and FRA). Investigators and study teams may use patient identifiers to contact patients if they are the treating physician or are part of the treating physician's practice.

Should I send US postal recruitment letters or MyChart messages?

The response rate for US postal recruitment letters and MyChart messages have been studied. After reviewing the patient response rate for 14,000 MyChart messages and 6,000 US postal letters we have found the patient response rate to be very similar. As a general rule, you can expect a 10% patient response rate to either letters or MyChart messages.

Can I send both a US postal recruitment letters and MyChart messages?

Yes! In fact, our initial study of internal recruitment data would suggest that letters and follow-up MyChart messages are complimentary. A large study of Type 2 diabetes patients revealed an approximate 10% response rate to US postal letters, followed by another 10% response rate to MyChart messages that were sent to the same patients.

How do I send EPIC MyChart recruitment messages?

MyChart messages can be sent to adults who are actively using the patient portal feature and have agreed to be contacted about research studies. During COVID, the number of patients accessing this feature expanded by orders of magnitude, making this an excellent option for many research studies. While it is possible to send MyChart recruitment messages directly to 12–17-year-olds, the decision about whether to employ this method is made on a case-by-case basis.

MyChart study recruitment messages can only be sent to patients from a list created by Fairview EPIC engineers in the Fairview EPIC production database. It is not possible to import a list from another source (excel spreadsheet or BPIC list, for example) to send MyChart messages.

MyChart Pricing	First Batch	Subsequent Batches
Up to 499 recipients	\$550	\$200
Up to 999 recipients	n/a	\$300

Can I send MyChart messages myself?

Study teams are not allowed to send MyChart messages to Fairview patients. FRRS will send research recruitment MyChart messages and patients can contact the researcher at their discretion. All MyChart messages, and linked internet content, must be approved by the appropriate regulatory and operational departments (including the IRB and FRA). Investigators and study teams may use patient identifiers to contact patients if they are the treating physician or are part of the treating physician’s practice.

Can my MyChart message include an internet weblink?

Yes, MyChart messages may include a link a University of Minnesota or Fairview website. For example, study teams may include a link to a Red Cap screening tool. Links outside of the University of Minnesota or Fairview may be identified by EPIC as risky and fail.

Will I receive patient replies from MyChart messages?

Yes! FRRS will send MyChart messages that include a button titled “I’m Interested”. Interested patients that click on this button will automatically launch a message to your study coordinator (or designee). The EPIC MyChart messaging system requires the study PI and coordinator to have active EPIC accounts.

Can you send patients a text message about my study?

FRRS uses a secured, HIPAA-compliant text messaging system (Tiger Connect) to contact patients directly with a brief message about a study for which they might be eligible. The content of these text messages must be reviewed and approved by the IRB and FRA. Text messages can be sent directly to 12–17-year-olds, but determination will be made on a case-by-case basis.

Text Messaging	First Batch	Subsequent Batches
Up to 100 messages	\$550	\$275
Weekly small batches	First Batch	Subsequent Batches
Text list created by research team in batches of 10 patients or less	\$500	\$135

Can I call patients myself?

Study teams cannot contact Fairview patients directly. FRRS can make follow-up phone calls to prospective research subjects at the researchers request. Cold calling patients is not permitted, study teams should send an introductory IRB approved letter or MyChart message before patients are called. Study teams may use patient identifiers to call patients if they are the treating physician or are part of the treating physician’s practice after sending an introductory IRB approved letter or MyChart message.

Can someone help me conduct follow-up recruitment phone calls?

FRRS can follow-up direct mail, MyChart or text messages with a phone call using an IRB approved script. Intention to call patients must be disclosed in the initial letter or MyChart message. The number of hours needed for follow-up calls will be determined on an individual study basis.

- Cost: \$75 per hour

Can you send recruitment messages to M Health Fairview / UMN employees?

M Health Fairview and University of Minnesota employees are human subjects and all rules and regulations regarding study recruitment apply to our employees. The Fairview Research Administration office can help you design an employee recruitment strategy.

How can I design a recruitment strategy to meet my study Diversity, Equity and Inclusion goals?

M Health Fairview is committed to assisting researchers in reaching out to all Minnesota communities in support of their study and corresponding DEI recruitment goals. We are able to partner with our Fairview Community Engagement experts to design appropriate and effective recruitment tools. Additionally, we will assist your study team in navigating the M Health Fairview network to identify appropriate patients. Please contact FRRS for more information.

Can I send letters to patients who do not speak English?

You may use research recruitment US Postal letters or MyChart messages that are sent in a non-English language. FRRS has access to translators that can provide certified translations of your recruitment materials. FRRS can also identify non-english speaking patients in EPIC for your US postal mailings or MyChart messages.

Can you send US postal letters or MyChart messages to pediatric patients?

Research recruitment of pediatric patients is a complex and sensitive issue. Confidentiality protections encourage adolescents and young adults to seek the health care they need and safeguard their privacy when they receive services. The relationship between confidentiality of health information and consent for health care and research is important. The following policy is based on Minnesota State Statute (144.3 and 144.4), guidance from the Center for Adolescent Health and the Law, and Fairview policy.

US postal letters and MyChart messaging is not permitted for patients ages 0-17 for the following clinical categories:

- Contraception
- STD services
- HIV/AIDS services
- Pregnancy care
- Drug/alcohol abuse services
- Abortion
- Hepatitis B
- Tuberculosis

Patients age 0-11: US postal letters and MyChart messaging is allowed for patients ages 0-11. Within the EPIC framework, MyChart messages sent to patients ages 0-11 are routed by proxy to the patient's parent or guardian. The recruitment message should be sent to the patient's parent or guardian.

Patients age 12-17: US postal letters and MyChart messaging is allowed for patients ages 12-17 with the following limitations. MyChart messaging can only be sent to patients ages 12-17 that have designated a proxy in EPIC. MyChart messages will be sent to both the patient and the designated proxy. It is recommended that the recruitment tools should be sent to the patient and written with language addressed directly to the patient. However, the researcher should design a US postal letter addressing strategy based upon the patient profile and specific age of the intended recipient. For example, the researcher may have a different US postal letter for patients that are 12-15 versus 16-17. Recruitment services may be not permitted for studies involving mental health diagnosis (Minn. Stat. Ann 144.343). Researchers interested in pediatric mental health recruitment should contact Fairview Research Administration for additional information.

Can you send US postal letters or MyChart messages to patients with a sensitive clinical diagnosis?

US postal recruitment letters or MyChart messages may be sent to patients with a sensitive clinical diagnosis. This recruitment strategy will require advanced planning to ensure successful implementation and a patient response plan. Please contact FRA to initiate this planning, as early as possible.

Can I write my own EPIC Reporting Workbench report or SlicerDicer report to help with study recruitment?

Study teams may access clinical data through a variety of applications, including the AHC-IE, EPIC Reporting Workbench reports and EPIC SlicerDicer. Access to clinical data is allowed when researchers are preparing a research hypothesis, assessing whether sufficient patients would meet the eligibility criteria or similar purposes preparatory to research. Patient data used or disclosed during this review may not be removed from the data source in any form. Study teams cannot use patient identifiers to contact patients unless they are the treating physician or are part of the treating physician's practice.

Can someone conduct phone pre-screening of patients? How about scheduling?

Potential participants can be directed to FRRS who will pre-screen and schedule patients for their first study visit. Exact price to be determined on an individual study basis.

- Cost: \$75 per hour

Can someone conduct remote study consent of patients?

For certain types of non-acute studies, potential participants can be directed to call FRRS who can screen and consent patients using the UMN REDCap e-consent tool. Exact price to be determined on an individual study basis.

- Cost: \$75 per hour

I need to find clinic patients real-time, what are my options?

FRRS provides services to screen patients in any M Health Fairview clinic. We can review clinic patients based on inclusion/exclusion criteria on a daily basis. Patients are sent to study teams for review and follow-up with patients. Screening occurs Monday – Friday, from 8am to 4pm.

- Cost: Determined on a case-by-case basis

How do I screen hospitalized patients for my study?

FRRS provides services to screen patients in any M Health Fairview hospital. We will conduct daily reviews of hospital patients based on inclusion/exclusion criteria. Patients are sent to study teams for follow-up with patients. Screening occurs Monday – Friday, from 8am to 4pm.

- Cost: Determined on a case-by-case basis

Can you e-mail patients a study recruitment message?

The use of unencrypted e-mail for study recruitment is not currently allowed. FRA/FRRS are currently developing a process to use e-mail that meets all privacy and legal standards.

Can you create a customized study website?

FRRS provides customized website development services. The University of Minnesota supports no-cost website tools and hosting. FRRS can help you design and implement an interactive website and include links to the website in MyChart messaging.

- Development Cost: \$1,200
- Website hosting: Free! Sponsored by the University of Minnesota

Can you create a customized video for my study?

FRRS can assist you in creating a study video that can be hosted on your study website. FRRS will work with you to develop an engaging script, you will submit the script to the IRB for review. FRRS has capabilities of recording your video.

- Cost: Determined on a case-by-case basis

Can you help me with a social media campaign?

FRRS and the Fairview marketing department can support a social media-based recruitment campaign. Fairview will help you design a social media message that you can submit to the IRB for review. Fairview can run the social media communications and provide a link to your customized study website to help patients reach out to your study team.

Contacts

- Fairview Research Administration: research@fairview.org
- Fairview Research Recruitment Service: researchscreening@fairview.org

Appendix A: Hospitals and clinics are included in EPIC patient queries

Encounter: An encounter is defined when medical treatment is provided. A patient may receive >1 medical treatments (thus encounters) at a single location in a single day. The encounter valuations are provided for general comparison purposes only, and do not represent the number of patients seen in 2021.

<u>Fairview Clinic</u>	<u>Fairview Hospital</u>	<u>Patient Encounters 2021</u>
	M HEALTH FAIRVIEW UNIVERSITY OF MINNESOTA MEDICAL CENTER	384,346
	M HEALTH FAIRVIEW SOUTHDALE HOSPITAL	118,950
	M HEALTH FAIRVIEW LAKES MEDICAL CENTER	112,339
	GRAND ITASCA CLINIC AND HOSPITAL	102,583
	M HEALTH FAIRVIEW RIDGES HOSPITAL	97,964
	M HEALTH FAIRVIEW NORTHLAND MEDICAL CENTER	89,207
	RANGE HIBBING HOSPITAL	30,879
	M HEALTH FAIRVIEW ST JOHNS HOSPITAL	20,883
	M HEALTH FAIRVIEW WOODWINDS HOSPITAL	17,745
M HEALTH FAIRVIEW CLINIC FRIDLEY		55,702
RANGE HIBBING CLINIC		50,185
M HEALTH FAIRVIEW CLINIC MAPLE GROVE		48,610
M HEALTH FAIRVIEW CLINIC OXBORO		32,963
M HEALTH FAIRVIEW CLINIC BURNSVILLE		31,789

M HEALTH FAIRVIEW CLINIC ANDOVER	31,639
M HEALTH FAIRVIEW CLINIC ELK RIVER	26,981
M HEALTH FAIRVIEW CLINIC EAGAN	26,821
M HEALTH FAIRVIEW CLINIC NORTH BRANCH	25,523
M HEALTH FAIRVIEW CLINIC BROOKLYN PARK	22,707
M HEALTH FAIRVIEW CLINIC EDINA	22,646
M HEALTH FAIRVIEW CLINIC BLAINE	22,182
M HEALTH FAIRVIEW CLINIC MAPLEWOOD	21,993
M HEALTH FAIRVIEW CLINIC EDEN PRAIRIE	21,517
M HEALTH FAIRVIEW CLINIC APPLE VALLEY	19,899
GRAND ITASCA PROFESSIONAL BUILDING	19,737
M HEALTH FAIRVIEW CLINIC HIGHLAND PARK	18,576
M HEALTH FAIRVIEW CLINIC WOODWINDS	17,887
M HEALTH FAIRVIEW URGENT CARE OXBORO	17,106
M HEALTH FAIRVIEW CLINIC UPTOWN	15,682
M HEALTH FAIRVIEW CLINIC BETHESDA	15,618
M HEALTH FAIRVIEW CHILDRENS CLINIC	15,334

M HEALTH FAIRVIEW CLINIC CHISAGO CITY	14,325
M HEALTH FAIRVIEW CLINIC PRIOR LAKE	14,315
M HEALTH FAIRVIEW CLINIC SMILEYS	14,240
M HEALTH FAIRVIEW CLINIC NEW BRIGHTON	13,528
M HEALTH FAIRVIEW CLINIC HUGO	13,357
M HEALTH FAIRVIEW CLINIC ROSEMOUNT	13,215
RANGE MT IRON	13,185
M HEALTH FAIRVIEW CLINIC BASS LAKE	11,844
M HEALTH FAIRVIEW CLINIC PHALEN VILLAGE	11,469
M HEALTH FAIRVIEW CLINIC LAKEVILLE	10,759
M HEALTH FAIRVIEW GERIATRIC SERVICES	10,323
M HEALTH FAIRVIEW CLINIC ROGERS	9,615
M HEALTH FAIRVIEW CLINIC HEART CARE	8,662
M HEALTH FAIRVIEW CLINIC TAMARACK	7,114
MILL CITY CLINIC	6,830
M HEALTH FAIRVIEW CLINIC MIDWAY	6,431
M HEALTH FAIRVIEW CLINIC ROSELAWN	6,359
M HEALTH FAIRVIEW CLINIC RICE STREET	6,136

M HEALTH FAIRVIEW CLINIC OAKDALE	5,991
M HEALTH FAIRVIEW CLINIC VADNAIS HEIGHTS	5,585
M HEALTH FAIRVIEW CLINIC RIVERSIDE	4,649
M HEALTH FAIRVIEW CLINIC COTTAGE GROVE	4,387
M HEALTH FAIRVIEW CLINIC STILLWATER	3,064
PHILLIPS NEIGHBORHOOD CLINIC	554