PARTICIPANT RECRUITMENT TOOLKIT

Resources to help study teams recruit & retain participants.

MICHR MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH
UNIVERSITY OF MICHIGAN

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PROMOTE YOUR STUDY

Promoting your study is key to the success of participant recruitment efforts. Social media is becoming a more popular place to promote your study. MICHR's Participant Recruitment Program offers many resources.

USING SOCIAL MEDIA

As health information on social media and online forums grows in popularity, studies are finding that the availability of social media tools is having a unique effect on people's social media behavior. Patients are using social media to connect with each other around a health topic, sharing information and knowledge with peers, and sharing their health concerns. This makes the use of social media in clinical research a great option for recruitment efforts.

According to the Centers for Disease Control (CDC), social media can connect millions of voices to:

- Increase the timely dissemination and potential impact of health and safety information
- Leverage audience networks to facilitate information sharing
- Expand reach to include broader, more diverse audiences
- Personalize and reinforce health messages that can be more easily tailored or targeted to particular audiences
- Facilitate interactive communications, connection and public engagement
- Empower people to make safer and healthier decisions

Is using social media right for your study? How do you use social media as a recruitment strategy?

Study teams can recruit using social media in two ways, organic or paid advertising. Targeted paid advertising allows for the placement of ads directly onto the pages of individuals who appear to meet the inclusion criteria for the study. This method can prove highly effective since you are casting a very specific recruitment strategy to individuals that Facebook has identified as meeting some of the criteria you are looking for in your volunteers. What method should you use? What works best? We can offer assistance answering these questions.

USING OUR U-M HEALTH RESEARCH PAGE TO PROMOTE YOUR STUDY

If you are not familiar with social media and not sure where to begin, we can help! The Participant Recruitment Program works closely with Michigan Medicine Communications and can assist with promoting your research study. We launch targeted social media campaigns on behalf of U-M study teams on both Facebook and Instagram using the main Michigan Medicine platforms. We can also assist with creating an organic approach to promoting your study by creating an image that can be posted on specified Facebook pages the study team identifies.

Our Staff Can Manage Your Facebook Advertising Campaign

Our service:

- Our team will manage your IRB approved advertising campaign on both Facebook and Instagram. All of our campaigns are pushed out from the main Michigan Medicine social media platforms.
- Our service of creating, launching, and monitoring the campaign is free.
- Our team will provide weekly analytics throughout the campaign.

How it works:

- Facebook owns Instagram which allows ads to run on both networks, simultaneously, with no extra cost.
- The user will be directly taken from your advertisement when clicking ‘learn more’ to either your study specific UMHR posting, a link to study information/online survey, or to a study specific website where they can then find more information regarding the study and decide if they would like to participate.
- Landing pages must have the following:
    - A brief, high-level overview of the study
    - Study contact information
    - Must be a URL (we cannot link to a pdf or other documents)

USING OUR U-M HEALTH RESEARCH PAGE TO PROMOTE YOUR STUDY

How it works (cont.):

- Campaigns can be targeted to users based off of location, gender, and age.
- Detailed targeting is also an option that can be discussed. This can be used to target users based off of topics, interests, employers, etc. that they have identified themselves through social media platforms. This may not be best for some studies, but can benefit based off of the audience you are trying to reach. For example, targeting parents of certain age children or a condition that has a large social media presence, such as MS or breast cancer, would be great uses of this mechanism.

Budget & Duration

- As each campaign will vary based off of study specifics, our team recommends the following budget:
    - $50/week for local campaigns (i.e. 50-mile radius of Ann Arbor)
    - $50-$60/week for statewide campaigns
    - $75-$100/week for national campaigns.
- Facebook uses a pay-per-click charging mechanism, which fluctuates given the competition for the target audience at any time. If a lifetime budget is set, the cost will be controlled and will never exceed that amount. The duration of the campaign should reflect within the set lifetime budget. For example, a local one-month campaign should have a lifetime budget of at least $200.
- Facebook charges at the end of every month and any time our account billing threshold is met. Depending on the amount of active campaigns we have at any time, you may receive multiple receipts per month. Facebook charges will be paid with Michigan Medicine's ad account and will then be reconciled back to the study's short code. Our team will send proper documentation of the charges to the study's short code holder when the account is charged.
- We recommend starting with a two-week campaign. This allows the campaign to learn the audience to optimize the amount of users that see and click on the ads.
- We advise to not make any changes to the ad in the first week to allow for the learning phase to be complete.

Please note: Budget, targeting, and duration will depend on study specifics and will be discussed prior to launching the campaign.

USING OUR U-M HEALTH RESEARCH PAGE TO PROMOTE YOUR STUDY

Ad Content:

- Our team will create a social media kit for your study, to be submitted to the IRB for approval. The social media kit will include multiple images and text options for the ads to avoid issuing an amendment in case changes need to be made throughout the campaign.
- The campaign should reflect the target audience and language should be focused on the study itself instead of the participants' attributes.
- Our team recommends using 1-3 images and 2-3 text options for each campaign. Facebook uses a mechanism that will push out the images/text that are receiving the most clicks and hold back the ones that aren't producing.
- A social media request form will need to be completed after receiving IRB approval and prior to launching the campaign.

USING YOUR OWN FACEBOOK PAGE TO PROMOTE YOUR STUDY

Organic is a method in which individual study teams create a Facebook page for their particular lab and then cultivate a following for that lab. This method is very slow as it takes time to build relationships and engage people. You entertain followers, educate them, and then inform them about study opportunities. This process is time consuming and will not pay immediate dividends if you are looking to enroll patients in a short amount of time.

Please note: Our team suggests using already established platforms to promote your study and would not recommend creating a study specific or lab specific Facebook page. We can assist with other organic approaches for recruitment.

U-M RESOURCES

Promoting your study is key to the success of participant recruitment efforts. Social media is becoming a more popular place to promote your study. MICHR's Participant Recruitment Program offers many resources.

STUDY COORDINATOR TRAINING

The Michigan Institute for Clinical & Health Research (MICHR) hosts the Research Basics for Study Coordinators series for study coordinators. The series is designed to introduce research coordinators who have less than two years of research experience or who are new to research at U-M to basic concepts in clinical research.

Topics include:

- Fundamentals of Data Management
- Good Clinical Practice and Essential Documents
- Conducting and Obtaining Valid Informed Consent

For more information, visit the Study Team page: www.michr.umich.edu/study-teams/

DATA OFFICE FOR CLINICAL & TRANSLATIONAL RESEARCH

The Honest Broker Office and the Research Data Warehouse have combined into one unit called the Data Office for Clinical & Translational Research. This unit offers the following assistance to study teams:

- Self-Service Data Tools: Support your new funding proposal, inform study design, and craft limited patient data searches. *Free*.
- Custom Data Request: Complex data pull that self-serve tools cannot address. *Fee for service*.
- Data Consultation: Consultation tailored to your needs and a deep dive into all patient health data resources available. *Free*.
- Data-Sharing Agreement: Assure privacy and security safeguards are in place when sharing patient health data with external collaborators.
- Further details are available here.

REQUIRED IRB TRAINING AND EDUCATIONAL RESOURCES

Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS)

- PEERRS training is required for every study team member.
- Learn more here.

Education

- IRBMED's Education Program was designed and developed through collaboration with members of the research community.
- Learn more here.

MICHART RESEARCH RESOURCES

The MiChart Research team provides a variety of services, including:

- Recruitment Alerts: Formerly called Best Practice Alerts (BPA), Recruitment Alerts are alerts the study team can receive through MiCHART (the electronic medical health record system at U-M) to alert the team of potential volunteers. Work with the MiCHART team to create the alert based on your eligibility criteria. Use this form to create your recruitment alert.
- Smart Forms for encoded data collection: Developed with application specialists with a focus on the data extract needs.
- Order Set Development: Research protocols ordering can be facilitated with order sets support. Useful inpatient or outpatient; infusion plans and therapy plans may also be provided. Please complete and submit: MiChart Research Orders Request Form.
- Study Team Support: Application staff are available for consultation to help streamline protocol execution and help in ordering process and procedures. • Study Build for Clinical Trials which have no Billing Calendars: Some studies do not have billable procedures yet have enrollment done in the Michigan Budget Enrollment Calendar Tool (MBECT). This service allows study teams to track enrolled subjects in the MiChart Application. • Reporting needs: All IRB-approved research studies must contact the Data Office for Clinical & Translational Research and complete formal requests via their process. For complete details, please visit: Data Office for Clinical & Translational Research Learn more here.

HUMAN SUBJECT INCENTIVE PROGRAM

The Human Subject Incentive Program (HSIP) office is responsible for all study payments at the University of Michigan. All incentives for study volunteers must come from the HSIP. Study coordinators will need training prior to using the system, so please plan accordingly.

Learn more here.

CLINICAL RESEARCH CALENDAR REVIEW & ANALYSIS OFFICE

The Clinical Research Calendar Review & Analysis Office (CRAO), which is a part of the Medical School Office of Research, was created to ensure items/services that research teams intend to bill to Medicare and other third-party payers are consistent with federal regulations. All clinical research that involves billable items and services is required to have a billing calendar, which must be submitted to CRAO.

Please plan accordingly if you will be using a billing calendar.

Learn more here.

FIND YOUR RESEARCH ADMINISTRATOR

Did you know that there is someone assigned to oversee your research projects and help you with questions about policies, processes, system and forms? Your research administrator can assist with all of these matters.

Find your research administrator here.

STAFFING AND BUDGETING

Proper budgeting and preparation can help study teams define reasonable and realistic accrual goals of study volunteers. There are several resources available at the University of Michigan to assist study teams prepare for successful recruitment for research studies.

The Clinical Trials Support Office (CTSO) is the central hub for the seven Clinical Trials Support Units (CTSUs), which support all clinical trials at Michigan Medicine. The CTSO acts as a liaison between study teams and other U-M research services to provide resources that support clinical trials.

Participant recruitment starts with your budget. Ensuring that you have enough funding to hire the necessary support staff to recruit, enroll, and retain your volunteers is critical to your success.

Find tips from the Office of Research on building a budget.

DATA DIRECT

DataDirect is a self-service tool that enables access to robust, up-to-date data on more than two million unique patients from across the UMHS enterprise to inform study design and determine feasibility of eligible patients for recruitment.

Learn more here.

REDCAP

REDCap is an electronic data capture (EDC) system that is secure, HIPAA compliant, and web-based. This easy-to-use, no-cost tool for University of Michigan clinical researchers is intended to replace Microsoft Excel and Access. Using REDCap's streamlined process for rapidly developing databases, you may create, design, and manage your research projects online. The Michigan Institute for Clinical & Health Research (MICHR) offers training on how to use REDCap.

Learn more about REDCap training here.

STUDY MANAGEMENT TEMPLATES

These templates assist study teams organize and maintain their study documents. These templates are designed to meet requirements for FDA regulated clinical trials. They may be useful, but not required, to organize study documentation for other studies as well.

www.michr.umich.edu/resources/study-management-templates

UMHealthResearch.org

This secure registry provides a database of studies being conducted at U-M, allows potential participants to view or sign up for research opportunities and enabling study team members to manage their IRB-approved study information.

ABOUT UMHealthResearch.org

The UMHealthResearch.org registry (previously UMClinicalResearch.org) provides a database of studies being conducted at U-M. It allows potential participants to view or sign up for research opportunities. The registry also holds profiles of over 28,000 potential volunteers who have given permission to be contacted if it looks like they may qualify to participate in a research project. Study team members are able to manage their IRB-approved study information and use the secure environment to connect with participants who may qualify for a study.

Studies must have IRB approval to post on UMHealthResearch.org for recruitment of study volunteers. Study teams must indicate their intention in their eResearch application in section 8-1.6 to post on UMHealthResearch.org. Exempt studies are available to post on UMHealthResearch.org.

Please contact our UMHealthResearch.org team at UMHealthResearch@umich.edu or 877.536.4243 for any questions you may have about your study.

TIPS FOR MANAGING UMHealthResearch.org

Engagement with the volunteers of UMHealthResearch.org (previously UMClinicalStudies.org) is critical. By connecting with volunteers in a timely manner, you are likely to have greater participation and retention.

- Be sure to make your posting as lay-friendly as possible. UMHealthResearch.org is an approved IRB recruitment tool and the IRB supports study teams writing their postings as simple and concise as they can.
- Carefully select the connector words when posting your inclusion exclusion criteria. Selecting these carefully will help you open your posting to all eligible volunteers.
- UMHealthResearch.org has built-in templates of messages that can be sent to potential volunteers when they hit the “I’m interested” button.
- You can also customize these templates for a more personalized message from your study team. Make sure that they are straightforward and easy to read and understand. For example, "Thank you for your interest, someone from our team will follow up with you soon."
- Use it for out-of-office replies. The biggest complaint we receive from volunteers is that they expressed interest in a study and never heard back from anyone. If no one is available to respond to volunteers, put a message in your template that explains that.
- Use it when your study enrollment is complete to follow up with findings from your research study.
- Learn more in our tips & tricks recorded webinar.

Please contact our UMHealthResearch.org staff at UMHealthResearch@umich.edu or 877.536.4243 for any questions or support you may need with your posting.

CLINICALTRIALS.GOV

ClinicalTrials.gov is a registry of clinical trials that is sponsored by the United States National Library of Medicine at the National Institutes of Health. Study teams at University of Michigan can link their UMHealthResearch.org (previously UMClinicalStudies.org) posting to a ClinicalTrials.gov posting.

ClinicalTrials.gov is not a lay-friendly website and linking your UMHealthResearch.org posting will provide the volunteer with detailed and easier to understand information on how to participate in your study.

Detailed instructions on how to link your ClinicalTrials.gov posting to our UMHealthResearch.org posting are available here.

RESEARCHMATCH.ORG

ResearchMatch.org is a national volunteer registry developed by Vanderbilt University that aims to serve as a complementary recruitment tool to help connect willing volunteers with researchers who are searching for appropriate volunteers to be placed in their research studies.

ResearchMatch.org will provide study teams with a national volunteer cohort that can assist teams searching for specific conditions with a broader volunteer base.

WRITING YOUR IRB APPLICATION

All study-specific communication materials need to be approved by the IRB, including recruitment materials and any information given to the participant during the study.

USING UMHealthResearch.org

ALL study teams with IRB approval at the University of Michigan are eligible to use UMHealthResearch.org. The UMHealthResearch.org (previously UMClinicalStudies.org) registry provides a database of studies being conducted at U-M. It allows potential participants to view or sign up for research opportunities. The registry also holds profiles of more than 34,000 potential volunteers who have given permission to be contacted if it looks like they may qualify to participate in a research project. Study team members are able to manage their IRB-approved study information and use the secure environment to connect with participants who may qualify for a study.

Studies must have IRB approval to post on UMHealthResearch.org for recruitment of study volunteers. Study teams must indicate their intention in their eResearch application in section 8-1.6 to post on UMHealthResearch.org in the IRBMED application.

HOW TO WRITE YOUR IRB APPLICATION TO DECREASE AMENDMENTS

When completing your eResearch IRB application for recruitment plans, it is important to think about all of your potential recruitment needs. Because IRB amendments often take time and can halt the progress of the study, we suggest thinking of all possible recruitment methods even if they do not seem relevant at the time. Preparing and thinking ahead will help to cut down on any amendments you may need to make during the recruitment and enrollment phase of your project.

We recommend ideas such as:

- Using social media (Facebook, Instagram, etc.)
- Community events (health fairs, sporting events, etc.)
- Using UMHealthResearch.org

(Please note: You will not be penalized by the IRB if you do not end up using every recruitment method you list.)

PLAN AHEAD TO ENSURE IRB APPROVAL FOR ALL OF YOUR RECRUITMENT MATERIALS

All study-specific communication materials need to be approved by the IRB through the eResearch application before public distribution. This includes not only recruitment materials but also any information given to the participant during the study.

Study-specific communication materials include:

- Poster
- Flyer
- Study brochure
- Physician-to-patient email
- Physician-to-patient letter
- Physician-to-patient card
- Print advertisement
- Radio advertisement
- TV advertisement
- Internet advertisement
- Social media advertisement
- Email campaign
- Direct mail campaign
- Patient portal
- Scripts

The IRB must review and approve both the context (copy, script) and the final layout (ad, flier, radio spot, news release, etc.) before to publication/distribution. Changes cannot be made to materials without IRB review.

Our Participant Recruitment program at MICHR can help you with review of these materials before they are submitted to IRB. Please contact us at michrrecruitment@umich.edu to learn more.

TIPS & TRICKS

All study-specific communication materials need to be approved by the IRB, including recruitment materials and any information given to the participant during the study.

IDENTIFYING YOUR AUDIENCE AND HOW TO CONNECT WITH THEM

In general, if you have a small, well-defined volunteer audience to reach, you may only need a letter, flyer, and/or brochure to distribute to current patients or to use in discussions during patient visits.

If you need to recruit a larger or more diverse volunteer audience, then you should consider a more comprehensive approach that combines several different types of communication channels, including advertising (typically paid), publicity, and social media (typically free).

Keep in mind that the more comprehensive your approach, the more time and budget you may need to develop and distribute the information or materials. In general, we do recommend using multiple techniques to reach participants to ensure you meet recruitment goals and to help develop a diverse cohort meeting your study criteria.

STAYING ON TARGET – RECRUITMENT TRACKING

How do you know if you are on track to recruit and enroll all of the participants required for your study? You first need to know your enrollment target, and then calculate how many volunteers you need to recruit each month to stay on track to successfully enroll that targeted number of volunteers. Create a tracking log where you track each volunteer you contact, screen and enroll. This will help you to identify if you are on track or behind with volunteer recruitment. Staying on top of your recruitment analytics is crucial to determine if you will reach your enrollment goals by your deadline.

Please visit the study team page for templates to organize and maintain your study documentation.

IN-CLINIC RECRUITMENT

Consider using the MiChart recruitment alerts. Submit a request for a MiChart recruitment alert.

These alerts will help you to identify potential study volunteers who meet your study criteria. You will need to set the criteria of your study beforehand.

Build a good working relationship with clinic staff. Arrange a meeting with the clinic administrator to discuss workflow and how you can easily assimilate into their world and not cause a burden to their efforts. Tell them about the criteria of your study and who you are hoping to recruit. If you engage them, the clinic staff can be your greatest champions.

Come prepared with information about your study. Flyers, brochures, or small informational cards are easy takeaways for potential volunteers.

Be passionate about your study when talking about it. If you believe in what you are trying to accomplish, volunteers will become excited as well.

COMMUNITY RECRUITMENT

Think of your target audience when thinking of ideas for recruitment. Your MICHR Recruitment team is always available to help you brainstorm ideas of where to recruit. Please contact us at michr-recruitment@umich.edu to find out more.

Below are several ideas for recruitment locations:

- Community Centers: Be sure to get approval from the center before you post flyers.
- Health fairs: Contact the organizer to set up a table (be sure to ask if there is a fee).
- Local support groups: If you are recruiting for a specific condition (let's use Multiple Sclerosis [MS] as an example), you may begin working with local support groups as a potential volunteer recruitment site. Be sure that this is a bi-directional relationship. The study PI could give a talk on MS and new or give a talk about management of MS. While this may seem time constreatmentsuming, it is important to build a relationship and, most importantly, trust with the patients in the group.
- Different stores: search around at local stores who allow for flyering. Be sure to check their policies for flyer posting as well.
- Contact the MICHR Recruitment program for a list of potential community venues which includes detailed information about policies for posting flyers.

RETENTION IDEAS

Recruitment and retention of volunteers is crucial to the success of clinical research studies. Recruitment and retention start on day one of your study. Nearly 80 percent of clinical research sites fail to finish on time. This is largely due to challenges related to recruitment and retention. Below are several ideas for recruiting and retaining study volunteers. The most important point to remember is study teams are building relationships with volunteers. Motivators for why volunteers participate will vary from volunteer to volunteer, and it is important to know why your participant decided to volunteer for your study, so ask them. Once you know what motivates a volunteer, you can make it a point to remember. Reinforce it throughout your interactions with them.

The most important thing you can do is elevate the status of your volunteer. What you need to reinforce with your volunteers is that without them, medical breakthroughs would not be possible.

Don't forget that your current volunteers could serve as helpful communicators about your study to other potential volunteers. Some options to engage them include:

Try to have in-person conversations

- Face-to-face communication is best when talking to volunteers.

Be timely

- Return volunteer phone calls as soon as you are able. If you are overwhelmed with requests, change your voicemail to say it may take 7-10 business days to respond to requests.
- Return messages on UMHealthResearch as soon as you can. If you are overwhelmed with requests, use our templates to create a message saying that it may take 7-10 business days. You can temporary deactivate your UMHealthResearch study. If you are out of the office and no other staff members are able to handle UMHealthResearch messages, you can also create a message that says all emails/phone calls will be returned once you are back. If your study has reached their numbers, and you are still receiving emails, be sure to send a request back to the volunteers thanking them for their interest.

Remember things about them

- Use volunteer files to write notes about each visit. While talking with the volunteer, ask questions that you'll be able to follow up on. For example, ask them if they are planning to go on vacation this year; if that happens to fall within your study timeline, ask them about it.

RETENTION IDEAS cont.

Be flexible

- Consider evening or weekend hours to accommodate study participants. Stay after hours one day a week to catch up on phone calls if needed.

Thank-you card

- These letters can be sent through email or direct mail and can be sent during the study process or after the study is completed.

Birthday card

- These can be sent by study staff.

Appreciation item or thank-you item

- Items include tchotchkes or trinkets that have your department logo branded on it. Be sure to include this in the IRB to ensure it is not considered coercive.

Travel and meal vouchers

- A note on compensation: It is important to consider all of these items when planning for compensation – parking, child care, travel to Ann Arbor or clinical research location, transportation.

Patient reminder service

- Ask patients how they would like to be reminded of their appointments. Options can include phone call, email, and text message.
- When communicating with volunteers, remember to give them your name, your contact information, and directions to your clinical research location.

Other Ideas

- Host an event to thank them for their participation and inform them of study progress.
- Include an easy way for current volunteers to forward or share study information to their friends/family who might be interested. Examples: postcards, brochures, web link within email
- Hosting an event that is open to the public to provide education about the specific condition of interest and current research/therapies to the community (for example, a talk at the Ann Arbor District Library).

FEEDBACK FROM UMHealthResearch.org VOLUNTEERS

We would like to share some of the best practices and feedback we have heard from clinical research volunteers. We hope you find this informative and helpful when recruiting and retaining volunteers.

- Use plain language.
- Think about how you would talk about your study to a friend or family member.
- Don’t include “goobledeegook” in posting.
- Make it as simple as possible.
- Don’t list too much information in the study section.
- Break up the text with bullet points.
- List it simply.
- I don’t need to know about the drug information.
- Too much detail in study criteria section.

U-M GUIDELINES FOR POSTING ON UNIVERSITY PROPERTY

Guidelines for posting on University of Michigan property can be found here.

POSTING AT MICHIGAN MEDICINE BEHIND THE GLASS

Michigan Medicine Volunteer Services coordinates the posting of flyers in the glass cases around the medical center campus (near the elevators). Flyers are posted for two weeks and are changed out at the first Sunday of the month, and then again mid-month on a Sunday, regardless of holidays. Flyer posting is coordinated on a first-come, firstserved basis. Call 647.7795 if you have questions.

Flyer guidelines for posting:

- 8 ½ “X 11”
- Portrait style only
- Must include phone and/or email contact information
- No tear-offs

Send 26 flyers via campus mail to:

April Lewis

Michigan Medicine Volunteer Services

L2616 Women’s

1500 E. Medical Center Drive

Ann Arbor, MI 48109-5237

MICHR PARTICIPANT RECRUITMENT PROGRAM SERVICES

The MICHR Participant Recruitment Program provides expertise, tools, and resources to facilitate participant recruitment in clinical and health research studies. We are committed to connecting research faculty, staff, community partners, and interested research participants to ensure successful research outcomes. Our aim is to assist study teams to be proactive and think upstream about their recruitment and retention needs, and to educate the community on research opportunities at the University of Michigan.

Recruitment Services

- UMHealthResearch.org: An innovative tool that connects research study teams to interested study participants. Study teams may query the database to specific inclusion/exclusion criteria based on participants' profile responses. Potential participants may review active study postings to assess their level of interest. Recruitment and retention consultation
- Study teams may request a consultation, ideally at the time of proposal development, to discuss diverse recruitment and retention strategies, estimated timelines and budgets, and letters of support for grant applications.
- Communication outreach, and community engagement: Program staff work in collaboration with the community to facilitate participation of underrepresented populations in research, reduce potential barriers to participation, increase public trust, and ensure that research opportunities are accessible to all interested individuals.
- Recruitment Material Creation: Our team can help with the creation of recruitment marketing materials, such as flyers, brochures, post cards, etc. at no cost. The study team is responsible for printing and dissemination of these materials.
- Social media recruitment: Our team can assist with promoting your study on social media platforms.

Please contact us at 877.536.4243 for additional information on community outreach events, recruitment education, and training opportunities. Study teams are encouraged to attend MICHR education and training opportunities to learn more about study participant recruitment strategies.

DESSIMINATION & FOLLOW UP

Sharing study findings can increase communication between volunteers and clinicians, increase volunteer satisfaction in their study participation, and lead to greater public understanding of research and willingness to participate in research.

WHAT IS FOLLOW UP?

In the spirit of building relationships with study volunteers, you may want to share the findings of your research with study volunteers. Sharing study findings can increase communication between volunteers and clinicians, increase volunteer satisfaction in their study participation, and lead to greater public understanding of research and willingness to participate in research.

Volunteers should always have the option of whether to learn the results, with a clear option to deny knowing the results. Many volunteers do not wish to learn the results of the study they've participated in.

If you are conducting a clinical trial for advanced cancer or other advanced disease, or if the study participant has passed away, you may want to ask the next of kin if they would like to be informed of study findings.

What is considered follow-up?

- Phone call
- Email
- Letter via direct mail
- Updates on website

WHY IS IT IMPORTANT TO PUBLICIZE YOUR RESEARCH FINDINGS?

There are good reasons that it is important to publicize U-M research, including the simple fact that your results reach a broader audience and this can increase the impact of your research. Additionally, we are able to provide the general public with key health information and tell them what we are doing with tax dollars supporting medical research. Publicizing research also gives positive recognition to Michigan Medicine and your funding source for supporting your research.

DOES YOUR STUDY LAUNCH/ RECRUITMENT HAVE NEWS VALUE?

A media relations specialist from the Michigan Medicine Department of Communication can work with you to assess whether your study is likely to generate interest among the news media that reach the general public or professionals in certain fields, or the members of the general public who follow our institution on social media. If so, they may decide to work with you to prepare materials that they will seek your input and approval on before dissemination.

Contact the Department of Communication at least two weeks in advance of the date of your clinical trials results are published or the date of your presentation at a major national media. Manuscripts or abstracts may be shared with U-M media relations professionals in advance. Under certain conditions, they can even be released by media relations professionals to select reporters under a press embargo – with the understanding that reporters will not post, broadcast, or print stories about your results until the time and date set by the journal you are publishing in or the meeting at which you are speaking. Information will be distributed publicly following the publication or presentation of results.

DOC selects and controls what is published on the Michigan Medicine newsroom, the Michigan Health Lab research and education news blog, the Michigan Health consumer-focused blog, and social media outlets. However, publication of stories by the external media is dependent on the editors and reporters receiving the press release or directly reading the results in the journal or a meeting program. Their coverage will vary widely based on the topic and findings, its appeal to a broad audience, the timing of a press release, and other news that may take precedence. U-M cannot control the outcome of interactions with the news media, but media relations staff can work with you to achieve the best possible outcome from media interviews and other interactions.

Examples of previous research press releases can be found on the UMHS newsroom, and the Michigan Health Lab blog has many kinds of research-focused stories. The Michigan Health blog has examples of stories aimed directly at health consumers. More information about and resources from the Michigan Medicine media relations and blog programs is available here.

COMMUNICATING CLINICAL STUDY OUTCOMES

Upon acceptance by a publisher, all publications of studies funded by the National Institutes of Health must be deposited in the PubMed Central repository and receive a designated identification number. Some journals submit publications to the database automatically, others do not. Investigators can ensure that their publication receives a PMCID number by contacting nihms-library-support@umich.edu. A copy of the final, accepted peer-reviewed manuscript is required to initiate the deposit process.

Information regarding NIH public access polices is located here.

REGISTERING YOUR STUDY ON CLINICALTRIALS.GOV

Applicable trials are to register and update the study posting on ClinicalTrials.gov to improve transparency with the public and to show others the type of research that is being done, in order to prevent duplication of effort. This NIH website provides further insight on the requirements by law under the Food and Drug Administration Amendments Act of 2007, including an interactive flowchart. Information regarding the obligation to register clinical trials as a condition of consideration for publication from the International Committee of Medical Journal Editors can be found on their website.

More information, including the definition of applicable trials, can be found on the University of Michigan Regulatory Affairs website. University of Michigan study teams should contact Diane Wilson, Regulatory Affairs Compliance Specialist, at 734.764.0634 or dleman@umich.edu with questions or for more information.

A media relations specialist from the Michigan Medicine Department of Communication (DOC) will work with you to assess whether your findings are likely to generate interest among the news media that reach the general public or professionals in certain fields, or the members of the general public who follow our institution on social media. If so, they may decide to work with you to prepare materials for dissemination.

WORKING WITH A PRESS RELEASE

What is a press release?

Press releases (also called news releases or news articles) are generally 1-2 page summaries of your research, written specifically for a lay audience. With the rise of the Michigan Medicine-run “brand journalism” approach, more and more of these articles and their associated videos, photos and illustrations are designed to appeal to the public as well as to act as invitations for coverage from journalists. No matter what they’re called, the most pertinent finding is usually featured in the headline and first few paragraphs. Information about funding source and any patent or licensing disclosures is included, as is a full list of study authors. One or two lead or senior researchers are typically quoted. The selection process for stories that will receive this treatment resides with the Michigan Medicine Department of Communication staff, mainly on the Institutional Positioning (formerly Public Relations) team and the Research & Advocacy Communications team.

or photos that can be used with the press release

Depending on the study findings, the timing and resources available, the media relations representative may also work with you to create a video or photos to accompany the article they write. Video will be posted along with the article, as well as to the Michigan Medicine YouTube page. Videos may vary from a simple 1-2 question recording of the study author, to a fully produced and narrated story including interviews with the study author and a participant. Decisions about video will be made by the media relations representative based on a number of factors.

WORKING WITH A PRESS RELEASE (cont.)

How are press releases distributed?

Press releases are distributed by the Department of Communication in numerous ways:

- Emailed by media relations staff to reporters in the U.S. and beyond, including print, radio, TV and online outlets. Reporters with an interest in covering health, medical and science news are targeted according to what they cover.
- Distributed through paid services that health reporters subscribe to, such as EurekAlert, Newswise, and PR Newswire.
- Posted to the Michigan Medicine newsroom. Press releases may also be posted to center and department websites, when appropriate.
- Modified for posting on the Michigan Health Lab blog.
- Emailed to communicators within the University of Michigan, including internal U-M and Michigan Medicine publications such as the University Record, Michigan Medicine Headlines, and Medicine at Michigan.
- Posted to Michigan Medicine Facebook and Twitter accounts, as well as any relevant center or department social media pages.

PREPARE TO TALK TO REPORTERS ABOUT YOUR STUDY

Following distribution of a press release, reporters may contact the Michigan Medicine Department of Communication to request interviews with the study authors. Study authors are encouraged to respond expediently to these requests, which are normally funneled through your media relations representative. The media relations representative will work with you in advance to prepare you for the interview experience. Additional media training may be available on request.

Read News Media guidance.

INVOLVING STUDY PARTICIPANTS IN COMMUNICATION EFFORTS

Participants Must Sign Michigan Medicine Consent Form

Because members of the public feel more connection to people who resemble them, it can be very effective to feature actual research participants in communication. For study teams, this can involve approaching participants to share their story in U-M-generated communication vehicles such as news releases, websites, ads, brochures, or social media posts or videos; you may also consider approaching them about interest from a reporter.

All participants who share their stories in this way must sign the UMHS HIPAA-compliant consent form available here.

Individuals who are currently considering taking part in a research study, but are not yet enrolled, should not be approached about potential participation in any communication efforts about that study.

Research participants who are currently in the treatment phase of a clinical study **may not be approached about communication activities until and unless the IRBMED has worked with you to ensure that the participant understands that they are under no obligation to participate in publicity activities**.

During the treatment phase, only filming and photography needed for research purposes is allowed. After photos or video are acquired, they may be included in communication materials that will be reviewed by the IRBMED, but only if participant consent for this use is secured.

After the treatment phase of the study has been completed, or in the case of studies that do not involve a treatment phase, research participants may be made available to the media – if they are willing to sign a UMHS HIPAA-compliant consent form and this form is filed with the research team and the individual's U-M electronic health record (if any).

INVOLVING STUDY PARTICIPANTS IN COMMUNICATION EFFORTS (cont.)

Contact IRBMED or DOC for further guidance

In some cases, reporters may wish to speak to a study participant about his or her experience. Participants will not be asked or expected to answer technical questions about the research, but rather will be asked to speak to their experience on the study – their personal motivation to participate, their relevant health information, what they personally did as part of the study and any side effects, inconvenience or benefit they personally received. This information is generally presented as one person's experience and is put in the greater context of overall study findings.

You will be asked to assist the media relations representative in identifying a patient/study participant who may be willing to speak to media. This may include making initial contact with the volunteer to determine interest. You may share patient information with a U-M media relations representative, who is protected under HIPAA. You may NOT share patient information with a media relations representative from outside U-M, nor with a reporter, without the U-M media relations person's assistance in obtaining patient consent. The U-M media relations representative will contact the patient to provide more details and to ensure patient signs a HIPAA release form.

PUBLISHING OR PRESENTING THE RESULTS OF YOUR CLINICAL TRIAL

Publishing results of your clinical trial in a peer-reviewed journal or presenting the results at a professional society meeting. If you are publishing or presenting the results of your clinical trial, please contact the Department of Communication office at 734.764.2220. Describe the topic your research is about, and note what your home department or division is, and you will be directed to the appropriate staff member. A list of contacts is available here.

If you need assistance performing additional literature sources or determining the best journal to submit your research to, you may consider working with the MLibrary Translational Research Liaison.