

RESPONDING TO RESEARCH REQUESTS



A guide for leaders of community-based Down syndrome organizations

MAY 2022

BEFORE YOU BEGIN

Down syndrome research is becoming more prevalent and as the field advances, your organization may become increasingly involved in the research process. As “gatekeepers,” the decision to open your community to research opportunities is an important one for every organization. It is never too late to step back and think about how your community can/should be actively involved in research, and what community education may need to take place beforehand.

Your leadership should consider what role you want your organization to play in Down syndrome research, and what level, and with what partners. What does your community want to do, and how can you/your staff facilitate the connection between scientist and community member? Does your organization plan to charge researchers for access to your channels? To what degree do you want to be involved in scientific research?

There are many ways to support a research project:

- Recruit participants for research studies, trials, surveys by sharing study information on your social media channels, in your newsletters, at your events, etc.
- Distribute a lay-language summary covering a study and study impact, study findings and make reports to your community
- Influence a study/survey before it happens by representing your community and experiences on a study design committee, or by informally discussing DS and family-related priorities with a researcher
- Refer scientists to other Down syndrome-related experts in the field via your network

FIRST STEPS WHEN RESPONDING TO AN INQUIRY

You receive an inquiry from a researcher who wants you to share their study/trial/survey with your community. What do you do?

- I. **Make an initial response:** don't wait to respond. It is good to reply to an inquiry with a “This message has been received and we're considering it...” so that the researcher doesn't continue to follow up with additional inquiries.

Suggested language for initial response to inquiries:

- a. *Thank you for your interest in the [ORG NAME] community! We are always open to collaborating with (researchers/institutions/organizations) working in the Down syndrome field. As you can imagine, we receive many requests to partner on projects and we recently established a process to help us evaluate opportunities like this one. I am going to forward your message to our team, and someone will get back to you within [five working days, two weeks, etc.].*
- b. *Thank you for reaching out. [ORG NAME] is open to collaborating with researchers, scientists, and academics to connect them to our community. However, please be*

advised, [ORG NAME], does not sell or share member information with researchers, vendors, or any other outside entity. Each proposal is carefully reviewed by [committee, advisory group, staff, etc.] for content, ethics, and feasibility, and to determine long-term impact on the wider community. We require [X, Y, X] so we can fully understand this project and your request: [link to checklist or similar].

- II. Ensure the researcher has provided **sufficient information** for you to evaluate their request. Have they sent you adequate information? If not, ask for it:
 - Contact information and credentials of the requestor or the individual who will be the main point of contact for questions
 - A thorough explanation/description of the study/trial/survey. This may be through a protocol summary or more detailed information sharing.
 - Proof of regulatory oversight (IRB, ERB, etc.) and approval of any materials they ask you to distribute, including images, outreach language, and social media language
 - Outline of participant inclusion parameters
 - Timeline components of the request (project anticipated start or end date), and
 - Any other relevant information
- III. Evaluate the request using one of the suggested **Vetting Checklists (below)** or create your own that suits your community. Make a process that is efficient and easy for you. For example, create an online form or survey link that automates your checklist and automatically alerts you to a new request.
- IV. In addition to a Vetting Checklist, here are overall **principles** to keep in mind:
 - Is the researcher connected to a respected academic, government, or healthcare institution?
 - Are there other sponsors/partners associated with this study whose mission does not align with yours?
 - Are the risks for participation clearly iterated (in family-centered language) and are the risks minimal?
 - Do the inclusion parameters align with your community profile (if you serve mainly adults and the study is pediatric, etc.)?
 - Is there an easy way for interested individuals to contact the study and receive a real-time response?
 - Were people with Down syndrome and/or their caregivers included in the study design? If not, was expertise from the DS clinical community included?
 - Is the language around the study/trial/survey factual and not sensational? Does the study promise anything outrageous or improbable?
 - Are the study materials and outreach collateral written with Down syndrome language that aligns to your community values?
 - Is participant information de-identified and aggregated? If not, what is the reasoning?
 - Is compensation for participation commensurate with the time invested?
 - Is compensation directly benefitting the participant?
 - Is the timeline for identifying participants reasonable (is it too short for you to meaningfully contribute)?

REQUESTING MORE INFORMATION FROM A RESEARCHER

It is okay to say, “this sounds interesting, but we **need more information**” to a researcher. Especially once you have established your own internal protocols, you should communicate that process to any potential partner. Recommended language:

Thank you for your inquiry and we are interested in learning more about your project. Our organization has established determination parameters to help us choose partners whose projects will best suit and impact our community. In order for us to consider your request, we require more information.

Please submit the following documents [share checklist, form, or other]

Please indicate when would be a good date/time for a brief phone call to discuss your project with [a member of our advisory committee, our designated staff person, etc.].

REJECTING A REQUEST FROM A RESEARCHER

It is also okay to say, “**No thank you**” to a researcher and still be open to working with them in the future. Recommended language:

Although we see value in a potential partnership with (org/project), unfortunately not every project can be accommodated due to constraints of time, space, and resources. I’m writing to let you know we cannot grant your request because of:

- *timeline conflicts. We do not have any available space on our channels during the time period you requested. (Option to request a different timeline that we can accommodate)*
- *subject matter conflict. We are already promoting a similar “ask” to our community, and do not want to confuse or dilute messaging.*
- *limited resources. We don’t have the staff available at this time to re-edit, co-brand, or develop content to promote your project.*

We encourage you to reach out to us again in the future with requests earlier in your development process as we do our best to support researchers like you doing work in the DS community.

ONCE YOU HAVE ESTABLISHED PARTNERSHIP WITH A RESEARCHER

When a decision to participate has been made, **further exploration of the process and the dissemination of information** must take place. It is recommended every organization:

- Request final review of any materials before they are shared to the community
- Request periodic updates – especially if recruitment is involved – in order to ascertain if the community is responding. This could be a call with the researcher or a simple email update.
- Request the researcher (and your team) set aside time after the study to ensure the researcher has: thanked participants, and communicated with families about study updates, study reports, etc.

SAMPLE VETTING CHECKLIST (adapted from DSACT of Austin, Texas):

	Yes	No	n/a
Criteria			
Project has a benefit to the Down syndrome community			
Identification of the condition, disease or goal under study			
Researchers use current, family-focused and positively-positioned terminology in recruitment, consent, and explanation materials			
Researchers do not use of outdated terms or concepts (e.g., individuals with Down syndrome are always happy, “special” people, “angels”, vulnerable, etc.)			
Study/trial/survey includes correct references to current, respected resources			
Study/trial/survey has been approved by IRB, ERB			
Study/trial/survey has adequate privacy protections in place (e.g., anonymizes participant data, or clearly states reason for not doing so)			
Any compensation is simply stated, commensurate to effort, and is not overly emphasized			
Study/trial/survey does not claim that participating will improve, cure, or treat any condition			
No person can be excluded from participating based on being a member of a protected class, unless there is a clearly stated reason (such as studying a particular age group)			
For medical or treatment-related research: a medical doctor well-versed with Down syndrome research has reviewed and approved the project and this MD's credentials and contact information are included in project materials			
Researcher has submitted: Contact information and credentials of the requestor or the individual who will be the main point of contact for questions			
Researcher has submitted: A thorough explanation/description (including time commitment) of the study/trial/survey			
Researcher has submitted: Copies of trial/study process, consent forms, participant-facing materials and/or entire survey content			
Researcher has submitted: Proof of regulatory oversight (IRB, ERB, etc.)			
Researcher has submitted: Outline of participant eligibility parameters, along with any pre-screening criteria			
Researcher has submitted: Timeline components of the request (project anticipated start or end date)			
Researcher has submitted: Any other relevant information, including IRB-approved images, video, outreach language, and social media and digital channel language, as well as communications intended to be seen/received by health care professionals, other materials intended for a “non-participant” audience (e.g. board)			
Researcher has submitted: Contact information and credentials of the requestor or the individual who will be the main point of contact for questions, along with an explanation of how they will manage follow-up			

OTHER ASPECTS TO CONSIDER:

- Preparing your community to be “research ready” is an important step in the process. Bringing research-related language, facts, and materials into your organizational culture can help raise awareness and increase readiness for participation. LuMind IDSC has a suite of Research Awareness resources that are available to all affiliates for co-branding and broadcast.
- Some organizations establish permanent advisory councils to address research-related issues. The Massachusetts Down Syndrome Congress (MDSC) offered to share their materials and process with any organizations seeking to formalize their approach.
- Aligning your organization with local clinical partners is also a good option toward sharing the decision-making burden. Having a network of trusted clinical and research partners is a good way to build knowledge.
- Larger organizations may have the resources to add a part-time or full-time staff member to vet and coordinate community-facing research activities. There are several job descriptions that can be shared if your organization is looking to that avenue.

For more information, guidance, or tools, please contact:

- Kate O’Neill (koneill@lumindidsc.org)
- Angela Britton (abritton@lumindidsc.org)

We’re very grateful to our partners at Massachusetts Down Syndrome Congress and Down Syndrome Association of Central Texas for sharing their resources and processes for this project.