



THE HARVARD CLINICAL
AND TRANSLATIONAL
SCIENCE CENTER

RESEARCH SUBJECT ADVOCACY

Informational Brochure User Guide

Supporting Conversations with Research Participants

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Scope: What are the Brochures?

Purpose: As more people participate in research, there is an increased need for appropriate supportive resources that help prospective participants understand what it means to take part in research and empower them to actively engage in conversation with the research team. The Research Subject Advocate (RSA) informational brochures were developed to meet this need by providing current and prospective participants with relevant information as well as a list of questions to ask when considering participating in a research study.

This guide is designed to introduce a library of available brochures and provide suggestions on how best to use them to support bidirectional communication between research teams and current and prospective participants.

Background: In 2001, the National Institutes for Health (NIH) mandated the Research Subject Advocate position. The RSA's role is to ensure safe and ethical conduct of human subjects research. With this mandate, many institutions instated Research Subject Advocacy programs, which function as a resource to the research community and to participants.¹

The New England Research Subject Advocacy Group (NE RSA) is a voluntary consortium, composed of health professionals collaborating to develop educational materials on health research, research participation, and common research procedures. The NE RSA is a partnership between the NIH Clinical and Translational Science Awards (CTSA) from Harvard University, Boston University, Tufts University, University of Massachusetts, Dartmouth University, and Yale University. This collaborative group is dedicated to sharing expertise and resources to inform the community about the importance of clinical research and to advance health research literacy. Together with stakeholders and advisory groups, the NE RSA has developed and distributed a growing library of freely available informational brochures.

All the brochures and additional materials are freely and publically available via the RSA page of the [Harvard Catalyst](#) website.

¹ *Clin Transl Sci*. Author manuscript; available in PMC 2015 August 01.

Intended Audiences

The brochures are not intended to be used as recruitment materials for a study; rather, they are informational resources to enable and improve communication between the research staff and research participants. Each brochure is written in plain language for lay audiences (including those that may have limited experience with or knowledge of research) and highlight the role of research participants in research.

These brochures were developed with three audiences in mind:

- Potential research participants
- Currently enrolled research participants
- Doctors, principal investigators, and research staff

This guide is designed to help research staff understand the genesis of the materials, including how they have been vetted, and provide guidance on how to use the materials to support their conversations with current and potential research participants. No prior training or education is required to use the brochures.

We encourage you to review the available brochures with your institutional review board (IRB) and/or human research protection (HRP) office and ask that they formally agree to the use and distribution of the brochures as an informational resource. The brochures are not designed to be used as a recruitment tool, thus they do not need IRB approval for each use, just a “blanket” approval that the brochures may be shared. A sample request for approval letter can be found in the Appendix section.

The following sections discuss the use of the brochures for each target audience.

Potential Research Participants and Community Members

Prior to engaging in any research activities, potential research participants should make sure they understand their rights as a participant, their role in the research study, the reason for the research study, any costs and compensation for participating, and the risks and benefits of participating in the research study. They should be given the opportunity to speak with a study investigator and/or research staff regarding their decision to participate in a research study. The research staff should inform the potential research participant that they have time to decide whether to participate, without any pressure. The brochures may be provided to support these discussions between potential participants and members of the study team.

For community members, the brochures are a valuable resource to support awareness around research participation and participant rights and protections.

Currently Enrolled Research Participants

Research teams should continue to ensure that participants understand their rights, their role in the research study, the reason for the research study, and the risks and benefits of the research study for the duration of the study. An enrolled research participant should be able to speak with the doctor and/or research staff at any time during the study regarding any concerns or questions. Each individual has the right to leave the study at any time for any reason. It is recommended that at each encounter with the participant, the research team should offer an additional opportunity to ask questions. The brochures may be provided to participants to support ongoing communication between participants and members of the study team.

Doctors, Principal Investigators, and Research Staff

This tool has been developed to assist in communication about research participation to potential and current research participants. We encourage researchers to contact their IRB/HRPs to receive feedback on the brochures and the approach.

If your IRB has not yet agreed to accept the distribution/promotion of the *Research Subject Advocacy brochures* as an informational resource, you should contact them requesting review and approval. A sample letter of request can be found in the Appendix section. **To increase the impact of the brochures, we recommend that you determine the brochure(s) best suited to the potential or current research participant, based on their knowledge, experience, or understanding of participating in research, the research study being considered, and any other information you believe would be beneficial.**

Brochure Development

The NE RSA is charged with developing collaborative materials for community members and prospective research participants. The group accomplishes these goals through the development of materials and resources to support the communication between researchers and participants.

The NE RSA is fortunate to be able to draw upon diverse expertise not only within exceptional teaching hospitals, including those with specialized areas of research and care, but also in the community. The development and review of the materials include input from local content experts, IRBs, and plain language specialists. Graphic designers are contracted to format the layout, branding and messaging of the materials. The brochures are freely available to download in high and low resolution for professional and on-demand printing. In addition, professionally printed copies of the materials can be requested by emailing regulatory@catalyst.harvard.edu.

The primary anticipated use of these brochures is to support and empower communication between research teams and participants before, during, and after the initial informed consent process. The materials provide concise information about each topic as it pertains to research and research participation. Each brochure provides information, visuals, and a series of questions to think through and to ask before deciding whether to participate in a study and at any time over the course of a study. The information provided is not study-specific. Rather, brochures are written to be applicable across a range of studies, yet specific enough to give readers a solid foundation for conversations with researchers and staff, their doctors, families, or others. Materials emphasize the voluntary nature of research, while also describing constraints imposed by the research process.

Development: Vetting the Brochures

The areas of focus for each brochure have been identified through conversation and consultation with stakeholders and advisory groups that include researchers, research staff, research administrators, CTSA leadership, past research participants, and community members. The NE RSA then develops responsive materials through iterative and collaborative drafting and revision in consultation with area content experts. Experts in health literacy at The Center for Information and Study on Clinical Research Participation (CISCRP) are contracted for plain language review, helping transform technical jargon into scientifically accurate, non-promotional language, validated at a 6th-8th grade reading level.

Subsequently, all materials are independently evaluated by The Harvard Catalyst RSA Advisory Board, comprised of leaders from community development organizations, members of a local community ethics committee, partnering hospital research nurses, research coordinators, researcher/staff educators, other RSAs, health disparities experts, a community engagement liaison, and an expert in cultural competency in research. The Board has served as an auditing committee for tactical guidance in the drafting of surveys, programmatic evaluation, the development of materials and resources, and in identifying potential resources for educational outreach efforts.

Finally, all resources are reviewed and revised once more by content experts and specialists in health literacy and plain language, as well as by institutional communications departments. After content and design are finalized, resources are posted to the NE RSA websites, professionally printed, and promoted. Brochures are then professionally translated into over a dozen languages.

Note: Materials are informational, and not focused on recruitment to a specific clinical research study. Nevertheless, all draft documents are provided to participating institutions' human research protection programs for review and comment before being finalized. As informational materials, the IRBs determined that the brochures do not require specific IRB review and approval for use and distribution.

Use of the Brochures

This guide is a resource for principal investigators and research staff seeking resources to support conversations with potential research participants and ensure participants' understanding of the research being conducted and their role in the study. The guide describes ways to use the brochures, sample language to describe the brochures to IRBs, and a sample script to help guide use of the brochures with potential research participants.

Overview of the general brochure outline:

- Definition and explanation of the brochure topic
- What is the involvement in research?
- What are the risks?
- What are the benefits?
- Additional important points to consider specific to the brochure topic
- Participating in research is a choice
- Sample of questions (typically 10-15) potential research participants may want to ask specific to the brochure topic

Whenever possible, it is recommended to review and select the brochure(s) based on the research participant's experience and knowledge about the research being conducted. The use of the brochure(s) will provide additional information and assist research participants in applying the information learned.

The brochures are designed as stand alone resources but may be combined to cover many areas of research based on the research participants' needs (see "Using the Brochures in Combination"). They can be accessed/shared by a principal investigator or research staff, a doctor, or potential research participants. The brochures have a space on the back for research staff to include study-specific contact information. By arrangement, non-member institutions that wish to use the materials may request access to the native files to include their logos and/or appropriate contact information.



Using the Brochures in Combination

A catalog of different brochure combinations is in development. This collection of example combinations will be openly accessible to both researchers and potential research participants to help ensure the most beneficial learning experience. We recommend providing a participant with the “Should I Be a Research Subject” brochure along with other brochures relevant to the research.

Some examples include:

- Research study involving a blood draw and specimens that will be stored in a biobank:
 - Blood Draw for Research
 - Giving Samples and Information for Research
- Social Behavioral Research study using a survey
 - Social, Behavioral, and Educational Research
 - Participating in a Survey
- Research study involving imaging
 - MRI/PET/CT Scan for Research
 - Incidental Findings in Health Research
- General questions about research – these brochures may be helpful to add to any of the above combinations
 - Health Research v Health Care
 - Meet the Research Team

Facilitator Guidance

The brochures may be used by a variety of facilitators, including researchers and research staff who have experience communicating with potential research participants. The facilitation notes provide descriptive content, relevant definitions, and discussion questions intended to deepen the participants' understanding of the material. The materials and activities in this manual can be implemented and altered at the discretion of the facilitator. Allowing 10-20 minutes for reviewing the brochures will allow sufficient time for questions and discussion. You may share the brochures with potential research participants, as well as their family members or support networks.

Brochures can be selected either individually or in combination to meet your protocol-specific concerns, with individuals' designated roles and study-specific obligations in mind. Brochures should be used to provide appropriate context for the research study and assist (potential) research participants' in applying the information. The active engagement of potential research participants, and their ability to apply the information provided in the brochures to gain a better understanding of their role in research, is a primary aim of these materials and vital to their successful application as part of the research process.

Brochure Library

Brochures Available

<ul style="list-style-type: none">• Blood Draw for Research• Conflicts of Interest (COI) in Research• Genetic Research• Giving Samples and Information for Research• How is Health Research Different from Health Care?• Incidental Findings in Health Research• Meet the Research Team• Participating in a Survey	<ul style="list-style-type: none">• Research Data: How is my information protected and used?• Research Participant Registry• Research Subject Bill of Rights Scans for Research (CT)• Scans for Research (MRI)• Scans for Research (PET)• Should I Be a Research Subject?• Social and Behavioral Research	<ul style="list-style-type: none">• Surrogate Decision-Making in Health Research• Stem Cell Research• Transcranial Electric Stimulation (tES) in Research• Transcranial Magnetic Stimulation (TMS) in Research• Using Telemedicine in a Research Survey• What is a Clinical Trial?• What is involved in a Drug Research Study?
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Brochures Available in Translation

All of the brochures are currently available in English and most are available in an additional 15 languages. These languages were selected based on the 2008 Commonwealth of Massachusetts Department of Public Health report, "Interpreter Services in Massachusetts Acute Care Hospitals," which outlines those languages most frequently spoken in the Commonwealth, and those most frequently encountered in area hospitals.

We currently offer our brochures in the following languages:

English	Haitian Creole	Russian
Albanian	Italian	Spanish
Arabic	Khmer/Cambodian	Traditional Chinese
Cape Verdean	Korean	Vietnamese
French	Polish	
Greek	Portuguese	

Attribution, Sharing and Adapting the Training Tool

We encourage you to:

- **Request** – email us (regulatory@catalyst.harvard.edu) and request the materials
- **Share** – copy, distribute, and transmit the work
- **Adapt** – adapt the work to suit your needs
- **Contribute** – share your sample informed consent language

Under the following conditions:

- **Attribution:** We encourage the broad dissemination of this tool. In freely using the materials or when citing this tool, we require that you acknowledge the developers of the materials (see citation language below).

With the understanding that:

- **We might contact you:** We are interested in gathering information regarding who is using the materials and how they are using it. We may contact you by email to solicit information on how you have used the materials, or to request collaborations or input on future activities
- **When reusing or distributing, make clear the above terms:** For any reuse or distribution, you must make clear to others the terms of this work. The best way to do this is to include a link to the web page containing the materials.
- **When adapting:** Please share with us improvements to the tool so we may learn and improve our materials as well.

Citing the Brochures

When using, adopting, or adapting our brochures, please make sure to use the following citation language that represents all the institutions that have collaborated on the development of the materials over the years:

Citation language (for written materials): *This material is the work of the New England Research Subject Advocacy Program, with contributions from member institutions' affiliated universities and academic healthcare centers. This work was conducted with support from the National Center for Advancing Translational Sciences, National Institutes of Health, through: Boston University Clinical and Translational Science Institute, under award number 1UL1TR001430; the Dartmouth Clinical and Translational Science Institute, under award number UL1TR001086; Harvard Catalyst | The Harvard Clinical and Translational Science Center, under award number 8UL1TR000170-05; Tufts Clinical and Translational Science Institute, under award number UL1TR001064; UMass Center for Clinical and Translational Science, under award number UL1-TR001453; and the Yale Center for Clinical Investigation, under award number UL1TR000142. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health.*

Shortened citation language (included in the brochures): *This material is the work of the New England Research Subject Advocacy Group, with contributions from the affiliated universities and academic healthcare centers of member institutions. For more information see: <http://catalyst.harvard.edu/regulatory/language.pdf>.*

Contact Us

We welcome any feedback or questions you may have. Please email us at regulatory@catalyst.harvard.edu.

Appendix A - Script

The following script example is a high level suggestion to integrate the brochures into a discussion with a potential participant.

When to use: 1. Before or after reviewing the informed consent, allowing additional time for the individual to consider joining the research study and providing resources that may help with or trigger additional questions. 2. When a (potential) research participant asks for more information before or during participation in a study. 3. When providing information to patients who have expressed interest in participating in research.

Example: *This/these brochure(s), titled <insert brochure title(s)> is intended to give you a general overview of <insert topic(s)>. For our study, we want you to understand <highlight the key facts about the brochure, such as the topic, risks and benefits, how participating in research is a choice and participants can leave a study at any time for any reason>. The questions on the back are there to highlight additional aspects of research participation. We will do our best to answer any of these questions, or other questions you may have. <Brochure(s) topic> was written and approved by content experts, Human Research Protections and Institutional Review Boards, as well as this research team. This/these brochure(s) are designed as an educational tool for potential/enrolled research participants like you to help you understand the research process, your rights, and important questions to consider and ask when thinking about joining a research study.*

*Please note, this/these material(s) is just a general educational tool, it was not written specific to this research study, so make sure to ask questions at any time throughout the research process. If you decide to enroll in the research study, you can ask the research team questions at any time, before, during, or after the study. Participating in research is **your** choice.*

If you find this resource beneficial, you can find similar educational resources including videos and podcasts on the Harvard Medical School website, Harvard Catalyst. All materials are free and available to the public.

The Harvard Catalyst website is: <http://catalyst.harvard.edu/services/rsa>

Appendix B – Sample Letter to HRPP/IRB Office

Dear Human Research Protections Administrator/IRB Office:

We request approval to post/distribute **Research Subject Advocacy Brochure(s)** [NAME OF BROCHURE (S)] for our potential research participants who will be considered for [NAME OF RESEARCH PROJECT/PROTOCOL NUMBER]. A link to the brochures can be found on the Harvard Catalyst Research Subject Advocacy Program (<http://catalyst.harvard.edu/services/rsa>).

<Research Subject Advocacy brochure(s)> is/are designed as informational resources to support communication between researchers and potential research participants. The brochures are not intended to be used as a recruitment tool. The brochure(s) is/are designed as an informational tool not specific to research studies. The content considers research participants who have some research experience, working knowledge of research methods, or limited experience with research, addresses the brochure specific research topics in plain language, and gives sample questions to ask, specific to the research topic.

Ideally, <the Research Subject Advocacy brochure(s)> will not only help potential research participants understand the importance of research participation, but will also empower them to ask questions and gain a better understanding of the research topic and key issues to be aware of when participating in a research study.

<Research Subject Advocacy brochure(s)> was/were developed by the New England Research Subject Advocacy (NE RSA) Program. The group is charged to increase clinical research awareness and enhance clinical research capacity and sustainability through established partnerships and networks of community members, leaders, and organizations in New England; collaborative development of educational materials for diverse, underrepresented populations otherwise underexposed to clear, high quality information about clinical research is a key aspect of the group's fulfillment of its charge.

This letter request the review and approval of the following brochures:

- <List which brochures you are requesting review, if all list all the titles>

The brochure(s) will be shared/distributed by <NAME OF CONTACT/LOCATION THE BROCHURES WILL BE LISTED; DATES THE BROCHURES WILL BE SHARED BEGINNING AND END; IF THE RESEARCH STAFF CONTACT INFORMATION WILL BE LISTED ON THE BROCHURES>. [DISCUSS ANY ADDITIONAL VETTING/REVIEW THAT HAS BEEN DONE].

Sincerely,

<Your name and signature; contact information>

<Attach PDF's of the brochures for review>