

APHASIA INSTITUTE QUALITY, RESEARCH AND ETHICS COMMITTEE

RESEARCH GUIDELINES

Vision

There are no barriers to living successfully with aphasia

Mission

Give hope to people with aphasia and their families by developing and sharing innovative solutions that reduce language barriers to full life participation

The Aphasia Institute welcomes requests for conducting and supporting research and will give priority to areas of particular interest to people with aphasia (e.g., long-term support for individuals living with aphasia, group treatment, use of volunteers, pragmatics/ functional communication, issues around competence, life participation and quality of life).

In developing our guidelines, the Aphasia Institute's Quality, Research and Ethics Committee (QRE) has followed the recommendations laid down in the *Tri-Council Policy Statement: Ethical conduct for Research Involving Humans*¹ and the guidelines for *good Clinical Practice* developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Expert Working Group².

The QRE assesses research submissions with respect to:

- Alignment with the mission and mandate of the Aphasia Institute
- Scholarly merit
- Risk of harm
- Impact on the Aphasia Institute

Research with the aim to reduce language barriers to full life participation will be given preference.

¹ The *Tri-Council Statement: Ethical Conduct for Research Involving Humans* is the document that describes the policies of Canada's three major federal research granting bodies: the Medical Research Council (MRC), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC).

² The ICH is a partnership between the European, Japanese, and American pharmaceutical industries and the applicable regulatory authorities. *Good Clinical Practice* (GCP) is an international standard of scientific and ethical quality that applies to the designing, recording and reporting of research that involves human participants.

ETHICS REVIEW SUBMISSION FORM INSTRUCTIONS

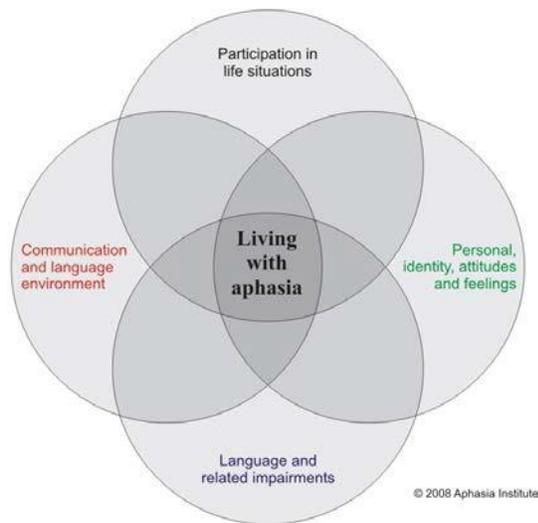
A. General Information

- The Principal Investigator signature must be obtained **after** all sections of the form is completed.
- The Principal Investigator or supervisor's CV must be attached.
- Prior ethics/scientific/scholarly review from the Research Ethics Board of a recognized institution **must** be attached.

B. Study Information – target domains

*Living with Aphasia: Framework for Outcome Measurement (A-FROM)*³ is designed as a conceptual guide for thinking about outcomes in aphasia. The project is an attempt to address the lack of an integrated approach to outcome evaluation across diverse aphasia interventions. It was motivated by the inability to capture the important but often elusive outcomes of interventions that focus specifically on making a difference to the everyday lives of people with aphasia and their families.

Living with Aphasia: Framework for Outcome Measurement (A-FROM)



Participation Domain

Includes life situations specific to an individual (e.g. life roles, responsibilities, relationships, activities of choice, etc.)

Language Impairments Domain

Includes outcomes in the realm of language and cognitive processing (e.g. auditory comprehension, reading, speaking, writing, etc.)

Environment Domain

Includes aspects of external context that might facilitate or impede language, communication or participation of people with aphasia (e.g. physical environment, social environment, political environment, etc.)

Personal/Identity Domain

Includes age, gender, culture and internal factors that vary as a consequence of aphasia (e.g. confidence, identity, etc.)

Living with Aphasia Domain

A dynamic interaction of multiple life domains, capturing elements of quality of life.

C. Study Summary

- Include the full title as it appears on the protocol
- Ensure that the summary is described in lay language.
- A separate study protocol **must** be attached.
- Please include a clear timeline for the research to take place.

³ Kagan, A., Simmons-Mackie, N., Rowland, A., Huijbregts, M., Shumway, E., McEwen, S., Threats, T., & Sharp, S. (2007). Counting what counts: A framework for capturing real-life outcomes of aphasia intervention. *Aphasiology*, 22(3), 258 – 280.

D. Budget

- A budget detailing your study costs to the Aphasia Institute, if any, must be identified.) Estimates in the tables below describe what costs may be involved, if a researcher requests support from the Aphasia Institute regarding staff time or aphasia-friendly documents, and if the researcher plans to hold recruitment and/or information sessions at the Aphasia Institute (on-site or online).
- Please specify which costs will and will not be covered by your institution/grant, or if there will be other elements of support requested that are not listed below.

i) Budgeting for support in creating Aphasia-friendly documents (See also Section E)

	Description	Estimated Fee
STEP 1	<p>If researcher would like to request the Aphasia Institute to create aphasia-friendly materials for their project, they should submit:</p> <ul style="list-style-type: none">• Key documents outlining the main points of the project• A <i>draft</i> of your materials (e.g. consent form) in aphasia friendly format (i.e. simple language). Drafts may also incorporate images from the free image database provided by the Aphasia Institute, at: www.participics.ca	
STEP 2+	<p>Estimated fee includes the following steps:</p> <ol style="list-style-type: none">1) Aphasia Institute staff would work with a Graphic artist and/or source existing images in our image database2) Graphic artist would create new images if they do not exist in the Aphasia Institute's current image database3) Graphic artist would format the document to meet standards of accessibility, and Aphasia Institute staff would review the document4) Aphasia Institute staff would liaise with the Researcher to ensure they are satisfied with the document, and provide feedback to the Graphic artist from the researcher5) Aphasia Institute staff would liaise between the Researcher and the Graphic artist until the document is completed to the Researcher's satisfaction	\$3000 - \$3500 range

ii) Budgeting for staff support during recruitment

- Once a research project and associated documents are approved by the QRE, the following steps may take place in the recruitment process. The Aphasia Institute is able to provide a number of services in-kind, whereas other services may take up more staff time, for which a fee would be attached.

	Description of possible service by Aphasia Institute	In-Kind	Fee Attached
STEP 1	<p>Setting up the first recruitment information session between researchers and a group of potential participants, with 2 alternatives:</p> <p>a. If the group of potential participants is a general group of clients, attending the session voluntarily, based on flyers to be provided by the researcher</p> <p>b. If it is a pre-selected group according to study criteria – then the fee attached would be based on a database assessment of the possible number of active clients who may be eligible for the study</p>	✓	✓ (\$100 per 10 eligible clients)
STEP 2	Setting up rooms for first screening meetings between researcher and participant, if researcher will be screening participant themselves; (and support for setting up rooms for future meetings if needed)	✓	
STEP 3	Being a staff liaison between the client participant and the researcher, for <i>basic</i> information exchange (e.g., collecting forms, directing participant to connect with researcher)	✓	
STEP 4	<p>Chart review for further information on client participants:</p> <p>a. If on-site visits are permitted by the Director of Finance & Operations, the researcher may conduct the chart review themselves at the Aphasia Institute, based on consent by the client</p> <p>b. If on-site visits are <i>not</i> permitted by the Director of Finance & Operations, any chart review conducted by Aphasia Institute staff would have a fee attached</p>		✓ (\$100 per 10 eligible clients)

iii) Budgeting for training in Supported Conversation for Adults with Aphasia (SCA™) prior to interacting with participants with aphasia

- The Aphasia Institute QRE board requires researchers who will be interacting with participants with aphasia to attend a training session in Supported Conversation for Adults with Aphasia (SCA™). Please contact training@aphasia.ca or (416) 226-3636 ext. 123 for training information. Fees for the SCA™ training course are posted at <https://www.aphasia.ca/home-page/health-care-professionals/knowledge-exchange/>. The course pre-requisite is a Certificate of Completion of the SCA™ eLearning module available for free at <https://www.aphasia.ca/communityhub/>

E. Ethical Issues

Informed Consent

- The informed consent form must clearly state:
 - i. that research participants have the right to withdraw from participation at any time for any reason without adversely affecting their ongoing care
 - ii. that research participants have the right to choose whether to disclose information obtained from the research pertaining to the care/services they receive at Aphasia Institute to staff members
 - iii. how confidentiality will be maintained
 - iv. how data will be retained
 - v. when it will be destroyed
 - vi. the researcher's plans for any follow-up studies
- The initial consent form can be submitted in text format for initial QRE review. Upon *provisional* approval of the proposal, the informed consent must be developed into an accurate communicatively accessible 'aphasia-friendly' pictographic format. However, the more information a researcher can provide at the initial submission, the more the review process could be expedited – such as examples of how the researcher *may* translate the information into aphasia-friendly format. *Final* approval would be granted after this aphasia-friendly informed consent form is reviewed and approved. Please see the attached consent form for an example. Aphasia-friendly pictographs as well as the sample aphasia-friendly consent form below are also available at www.participics.ca

Aphasia-friendly Materials

- Due to the nature of aphasia, **all relevant study materials** will need to be translated into aphasia-friendly pictographic material upon *provisional* QRE approval of the study. Researchers who wish to create accessible documents on their own can follow the example provided in the following pages re: an aphasia-friendly informed consent. Final aphasia-friendly consent/materials created by an external research team would be reviewed by Aphasia Institute staff experts, who would recommend if revisions are needed – to support ultimate participation and transparency of information for clients with aphasia. The QRE reserves the right to request that the revision feedback be incorporated into a new draft of the document(s).
- *Understanding the complexity of the development process and need for experience, the Aphasia Institute can sometimes assist with creation of an aphasia-friendly research form and related study materials. However, our capacity is limited. If you require this service and we are able to help, fees are determined on a project-by-project basis based on cost-recovery. (See also Section D re: 'Budgeting for support in developing Aphasia-friendly documents')*

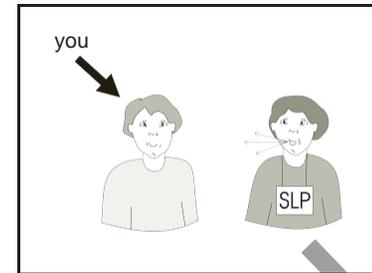
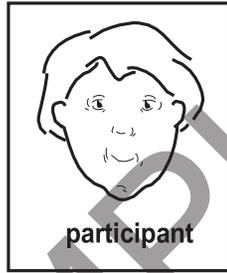
If this service is required, please send the following information to research@aphasia.ca to initiate your inquiry and fee discussion:

- Your *key document(s)* with all main points
- Your *draft* consent form and related materials in aphasia-friendly format (i.e. simple language). Drafts may also incorporate images from the free image database provided by the Aphasia Institute, at: www.participics.ca

Intellectual Property

- The Aphasia Institute should receive a copy of the final research report, abstracts, or resulting publications.

INFORMED CONSENT for RESEARCH



A Speech-Language Pathologist
will talk to you and ask you
questions about your life.

Participant : _____

Investigator : Aphasia Institute, Toronto ON
416-226-3636

Project Title : How to create a
pictographic consent form

Funded By : Aphasia Institute



How long?

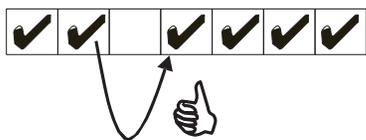
60 minutes

Right to withdraw

- ✓ You can stop at any time
- ✓ It is your choice
- ✓ It is ok to stop



You can skip a question



Potential Benefits



Stop

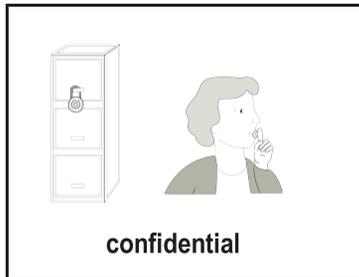
- conversation groups
- aphasia centres
- hospitals
- long term care homes

Potential Risks

✗ There is NO danger in participating in this study



✓ Everything is confidential



Project Consent

Do you have any questions?



YES



NO

Do you understand?

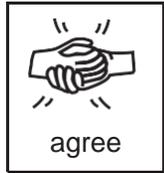


YES



NO

I agree to participate in this research project



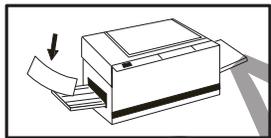
YES



NO



I have been given a copy of this form



YES



NO



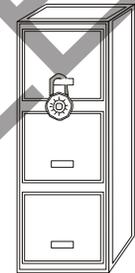
Your Answers

In your client file?



Staff can look at it

Research only



Only research can look at it

OR

It is your choice

Signature of Participant

Date

Signature of Witness

Date

Do you want your answers to be
in your client file?



YES



NO

Signature of Participant

Date

Signature of Witness

Date