



Life's a Conversation.

## **APHASIA INSTITUTE RESEARCH & ETHICS COMMITTEE**

### **GUIDELINES for RESEARCHERS**

Through direct service, research, education, and training, the Aphasia Institute (AI) has pioneered programs and practices which help people with aphasia learn how to communicate in new ways and begin to navigate their own lives again.

We welcome requests from the research community for conducting and supporting research and *we will give priority to research that addresses issues of particular interest to people with aphasia. See some of AI's previously supported research here.*

The Aphasia Institute Research & Ethics (AIRE) Committee follows the recommendations of the *Tri-Council Policy Statement: Ethical conduct for Research involving Humans*<sup>1</sup> 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 Group<sup>2</sup>.

The AIRE Committee assesses research submissions with respect to:

- Alignment with our [mission and vision](#)
- 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.

### **INSTRUCTIONS: ETHICS REVIEW SUBMISSION FORM**

[Please label each submitted document clearly, both in the title and file name.](#)

#### **1. Important Information**

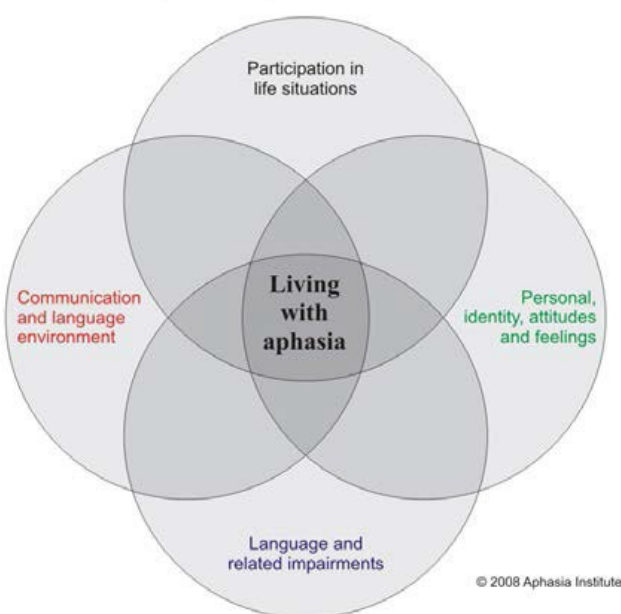
- The Principal Investigator signature is required on your submission
- The Principal Investigator or supervisor's CV must be attached.
- Prior ethics/scientific/scholarly review from the Research Ethics Board of a recognized institution **must** be attached.
- The Aphasia Institute should receive a copy of the final research report, abstracts, or resulting publications.

## 2. Specify A-FROM Target Domains

***Living with Aphasia: Framework for Outcome Measurement (A-FROM)***<sup>3</sup> is designed as a conceptual guide for thinking about outcomes in aphasia. The framework provides an integrated approach to outcome evaluation across diverse aphasia interventions. It was motivated by the need 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.

**Please specify the target domain(s) that your study will target:**

*(Relevant to Section B of the AIRE Committee Research & Checklist Form)*

<p>Living with Aphasia: Framework for Outcome Measurement (A-FROM)</p>  <p>© 2008 Aphasia Institute</p>	<p><b>Participation Domain</b></p> <p>Includes life situations specific to an individual (e.g. life roles, responsibilities, relationships, activities of choice, etc.)</p>
	<p><b>Language Impairments Domain</b></p> <p>Includes outcomes in the realm of language and cognitive processing (e.g. auditory comprehension, reading, speaking, writing, etc.)</p>
	<p><b>Environment Domain</b></p> <p>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.)</p>
	<p><b>Personal/Identity Domain</b></p> <p>Includes age, gender, culture and internal factors that vary as a consequence of aphasia (e.g. confidence, identity, etc.)</p>
	<p><b>Living with Aphasia Domain</b></p> <p>A dynamic interaction of multiple life domains, capturing elements of quality of life.</p>

### 3. Provide a Study Summary

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

### 4. Address Ethical Issues

#### a) 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

A draft consent form can be submitted in text format for initial AIRE Committee review. Upon *provisional* approval of the proposal, the informed consent must then be developed into an accurate communicatively accessible 'aphasia-friendly' pictographic format. 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.

Additional aphasia-friendly pictographs are also available through our free searchable image database at: <https://www.aphasia.ca/participics/>

**Note:** A frequent reason for either delay in approval *or* decline of a research proposal is due to the aphasia-friendly consent document and the quality of its communicative accessibility.

## **b) 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* AIRE Committee 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.

Alternately, you may request support from AI to create aphasia-friendly materials for your study for a fee. If this service is required, please send the following information to [research@aphasia.ca](mailto:research@aphasia.ca) to initiate your inquiry and fee discussion. See part (5a) in the Budget section below for more information about this process and related fees.

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. This is to ensure that ultimate participation and transparency of information for clients with aphasia. The AIRE Committee reserves the right to request that the revision feedback be incorporated into a new draft of the document(s).

## **5. Submit a Budget**

A budget detailing any hard or in-kind costs to the Aphasia Institute must be provided. The table below describes costs which may be involved, if a researcher requests support from the Aphasia Institute staff.

### **a) Creating Aphasia-friendly documents** (See also Section 4 above)

<b>Potential Services</b>	<b>Est. Fee</b>
<p>In order to make a request for AI to create aphasia-friendly materials for your project, <b>please submit:</b></p> <ul style="list-style-type: none"><li>• A document outlining the main points of the project</li><li>• A <i>draft</i> of your materials in aphasia friendly format (i.e. consent form in simple language). Drafts may also incorporate images from the free image database provided by the Aphasia Institute, at: <a href="https://www.aphasia.ca/participics/">https://www.aphasia.ca/participics/</a></li></ul> <p><b>If AI accepts your request, we will:</b></p> <ol style="list-style-type: none"><li>1) Work with a Graphic artist and/or source existing images in our image database</li><li>2) Graphic artist would create new images if they do not exist in the Aphasia Institute's current image database</li><li>3) Graphic artist would format the document to meet standards of accessibility, and AI staff would review the document</li><li>4) Aphasia Institute staff would liaise between the Researcher and the Graphic artist until the document is completed to the Researcher's</li></ol>	<p>Approx. \$3000 - \$3500</p>

satisfaction	
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### **b) AI Support for Participant Recruitment**

The Aphasia Institute strives to provide a number of services in-kind. The potential in-kind services listed below apply to our current online-service context. On-site visits by external researchers are not currently permitted.

However, services that require additional staff time may require a fee. For example, if the research involves detailed and/or sensitive eligibility requirements, the Aphasia Institute will evaluate on a case-by-case basis whether support of the proposal would be feasible in our current service context. Fees may increase at the discretion of the Aphasia Institute, based on complexity of the criteria and database assessments involved.

<b>Potential Services (<i>online context only</i>)</b>	<b>In-Kind</b>	<b>Fee Attached</b>
Setting up the first recruitment information session(s) between researchers and a group of potential participants. <ul style="list-style-type: none"> <li>In our current online service context, the group of potential information session participants can only be a general group of clients, attending the session voluntarily, based on flyers to be provided by the researcher, and with no prior pre-screening by Aphasia Institute staff.</li> </ul>	✓	
Being a staff liaison between the client participant and the researcher, for <i>basic</i> information exchange	✓	

<ul style="list-style-type: none"> <li>• (e.g., contact information for those who express interest at information sessions; directing participant to connect with researcher if further questions arise)</li> </ul>		
<p>Chart reviews</p> <ul style="list-style-type: none"> <li>• Chart reviews by external researchers are not currently permitted, and would require support from Aphasia Institute staff, based on consent by the client, and including a fee attached.</li> </ul>		Amount to be determined on a case-by-case basis

**Note:** Researcher would be expected to carry out any additional screening of participant(s) in one-on-one meetings organized independently of the Aphasia Institute.

Please refer also to the "Eligibility Criteria Form" (Research Submission Checklist item #4).

### **c) Training in Supported Conversation for Adults with Aphasia (SCA™)**

The AIRE Committee 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](mailto: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/health-care-providers/education-training/online-options/>

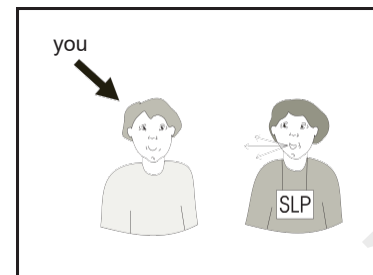
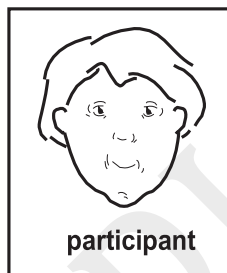
## **References:**

<sup>1</sup> 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).

<sup>2</sup> 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.

<sup>3</sup> 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.

# INFORMED CONSENT for RESEARCH



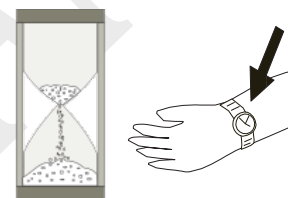
A Speech-Language Pathologist  
will talk to you and ask you  
questions about your life.

**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

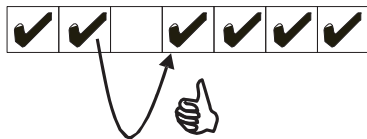


## Right to withdraw

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



You can skip a question



## Potential Benefits



- ✓ This will help research
- ✓ This will help:
  - Other people with aphasia in
    - the community
    - conversation groups
    - aphasia centres
    - hospitals
    - long term care homes

## Potential Risks

**X** 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**



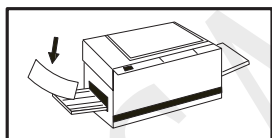
\_\_\_\_\_

**NO**



\_\_\_\_\_

**I have been given a copy of this form**



**YES**



\_\_\_\_\_

**NO**



\_\_\_\_\_

\_\_\_\_\_  
Signature of Participant

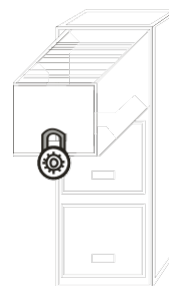
\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

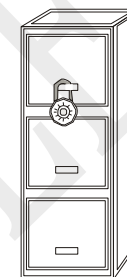
## Your Answers

↓  
In your **clientfile**?



**Staff** can look  
at it

↓  
**Research only**



**Only research**  
can look at it

**OR**

**It is your choice**

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



**YES**



**NO**

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Signature of Participant

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Date

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Signature of Witness

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Date