



Life's a conversation

APHASIA INSTITUTE QUALITY, RESEARCH AND ETHICS COMMITTEE

Submission Checklist

Send submission or questions to: Aphasia Institute
Attn: Lisa Chan, Research & Development Coordinator
73 Scarsdale Road, Toronto ON M3B 2R2
Ph.: (416) 226-3636 Ext. 33
Fax: (416) 226-3706
E-mail: research@aphasia.ca

The following outlines the requirements for submission of a research proposal to the Aphasia Institute Quality, Research and Ethics Committee. Please ensure the following is included.

- Application form
 - An abstract and/or lay summary should be included
 - All fields must be completed
 - Principal Investigator/supervisor's CV should be appended
- Prior Ethics/Scholarly Review approval letter and review comments from the Research Ethics Board of a recognized institution
- Protocol (The application form is **not** a substitute for the protocol)
 - Should not exceed four (4) pages
 - Double-spaced in a 12-point, non-compressed font
 - Word document (*.doc) or Portable Document Format (*.pdf)
- Include a clear timeline for the research
- Include a budget detailing the costs to the Aphasia Institute.
 - Please specify which costs will and will not be covered.
- Informed Consent Forms
 - The initial consent form can be submitted in text format to ensure an accurate translation into a communicatively accessible 'aphasia-friendly' format.
 - Upon provisional approval of the proposal, the informed consent must be developed in a communicatively accessible 'aphasia-friendly' pictographic format. Please see the attached consent form for an example of what to include.
 - For questions regarding participants' rights and ethical issues, include these on the form or send questions to the Research & Development Coordinator (contact above), who will liaise with the QRE Chair.
- Recruitment materials
 - Please submit all posters, advertisements, flyers, or scripts that will be used for recruitment.
 - The materials can be submitted in text format. If conditional approval is granted, the materials will have to be converted into aphasia-friendly format.



APHASIA INSTITUTE QUALITY, RESEARCH AND ETHICS COMMITTEE

Important Dates for 2018/2019

Deadlines for Submissions	Meeting Dates
Mon. November 6, 2017	Mon. December 4, 2017
Mon. January 8, 2018	Mon. February 5, 2018
Mon. March 12, 2018	Mon. April 9, 2018
Mon. May 14, 2018	Mon. June 11, 2018
Mon. August 13, 2018	Mon. September 17, 2018
Mon. October 15, 2018	Mon. November 12, 2018
Mon. January 7, 2019	Monday February 4, 2019

The schedule is subject to change at the discretion of the Quality, Research and Ethics Committee.

Please contact Lisa Chan at (416) 226-3636 ext. 33 or research@aphasia.ca for more information.



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APHASIA INSTITUTE QUALITY, RESEARCH AND ETHICS COMMITTEE

ETHICS REVIEW SUBMISSION FORM

A. GENERAL INFORMATION

PRINCIPAL INVESTIGATOR INFORMATION

Title:		Name:	
Department:		Institution:	
Telephone:	Fax:	E-mail:	
Street Address:			
City:	Province:	Postal Code:	
Signature of Principal Investigator:			Date:

CO-INVESTIGATOR(S) INFORMATION

1.	Title:	Name:	Institution:
2.	Title:	Name:	Institution:
3.	Title:	Name:	Institution:

KEY CONTACT INFORMATION

Title:		Name:	
Department:		Institution:	
Telephone:	Fax:	E-mail:	
Street Address:			
City:	Province:	Postal Code:	

PRIOR ETHICS/SCIENTIFIC/SCHOLARLY REVIEW

Attached

Relevant correspondence from the REB of a recognized institution **must** be attached for consideration.

B. STUDY INFORMATION

INDICATE THE PRIMARY NATURE OF YOUR PROPOSAL (please select one)

<input type="checkbox"/> A. Intervention Study	<input type="checkbox"/> C. Explanatory Research (e.g., identification of needs, descriptive analysis)
<input type="checkbox"/> B. Assessment Study	<input type="checkbox"/> D. Other (please specify):

INDICATE THE DOMAINS TARGETED (Please select all that apply)

<input type="checkbox"/> Participation e.g., relationships, roles, activities	<input type="checkbox"/> Personal Factors e.g., identity
<input type="checkbox"/> Environment e.g., perception of barriers	<input type="checkbox"/> Aphasia Severity e.g., ability to read

PLEASE ALSO INDICATE OUTCOME DOMAIN (For intervention studies ONLY)

<input type="checkbox"/> Participation e.g., change in relationships, roles, activities	<input type="checkbox"/> Personal Factors e.g., change in identity
<input type="checkbox"/> Environment e.g., change in perception of barriers	<input type="checkbox"/> Aphasia Severity e.g., change in ability to read

INDICATE THE DATA SOURCE FOR YOUR STUDY (please select all that apply)

<input type="checkbox"/>	Person with Aphasia:
<input type="checkbox"/>	Family, Caregiver:
<input type="checkbox"/>	Speech-Language Pathologist:
<input type="checkbox"/>	Other (e.g. Nurse Ratings – please specify):

C. STUDY SUMMARY

TITLE:

SCIENTIFIC/TECHNICAL ABSTRACT (if available – Max ¼ page)

LAY SUMMARY (Max ½ page)

D. ETHICAL ISSUES

All documents that will be viewed by the participant **must** be included in the submission.

Informed consent form – text	<input type="checkbox"/> Attached
Recruitment materials	<input type="checkbox"/> Attached



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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

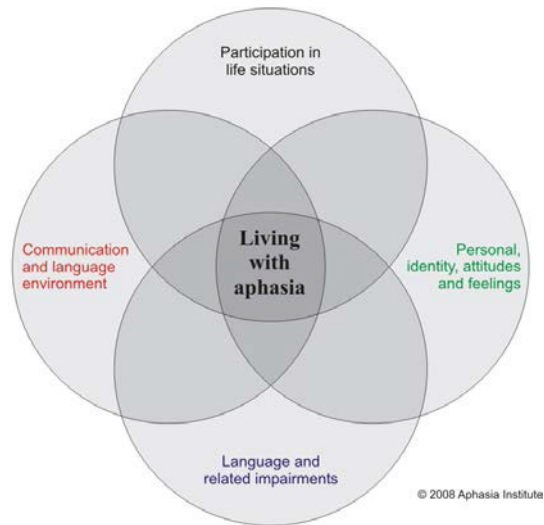
A. General Information

- 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 (staff time, travel costs, etc.) must be identified. Please specify which costs will and will not be covered by your institution/grant.

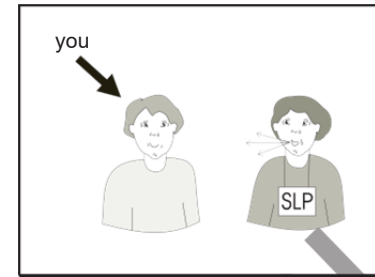
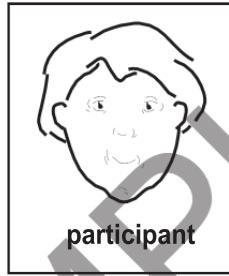
E. Ethical Issues Informed Consent

- 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 to ensure an accurate translation into a communicatively accessible 'aphasia-friendly' format. Upon provisional approval of the proposal, the informed consent must be developed in a communicatively accessible 'aphasia-friendly' pictographic format. Please see the attached consent form for an example. Aphasia-friendly pictographs are also available at www.participics.ca.

Aphasia-friendly Materials

- 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 Marisca Baldwin at (416) 226-3636 ext. 23 or training@aphasia.ca for training information.
- Due to the nature of aphasia, **all relevant study materials** will need to be translated into aphasia-friendly pictographic material upon QRE approval of the study. 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 Pictographic Resource Team at the Aphasia Institute is available to provide the necessary assistance in order to translate all study materials into aphasia-friendly pictographic format. The fees for these services will be determined on a project-by project basis. If such services are required, please contact Lisa Chan at (416) 226-3636 ext. 33 or research@aphasia.ca.
- **Intellectual Property**
The Aphasia Institute should receive a copy of the final research report, abstracts, or resulting publications.

INFORMED CONSENT for RESEARCH



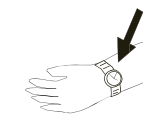
A Speech-Language Pathologist will talk to you and ask you questions about your life.

Participant : _____

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

Project Title : How to create a
pictographic consent form

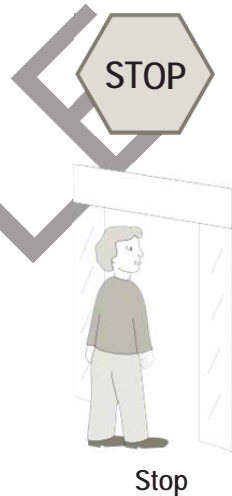
Funded By : Aphasia Institute



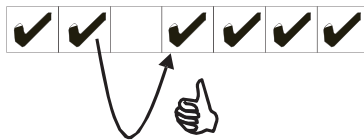
How long?
60 minutes

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



- ✓ 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

✗ 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



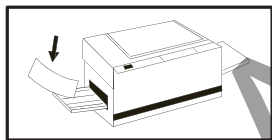
YES



NO



I have been given a copy of this form



YES



NO



Signature of Participant

Date

Signature of Witness

Date

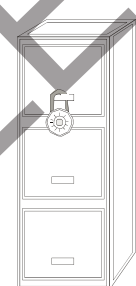
Your Answers

In your **client file**?



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

Signature of Participant

Date

Signature of Witness

Date