SKYLINE
INNOVATION

Voice Samples of Dysarthria from People with Parkinson Disease

This document is intended to help researchers confirm that their behavioural research consent forms provide for fully informed consent by participants. More detailed guidance on drafting behavioural consent forms is also available. Not every element is appropriate for all studies, but you may be asked to add additional details during the ethics review process if they are deemed necessary to ensure informed consent. Consent forms for survey-only studies will not require the same level of detail.

On page 1
Include letterhead details (department name, mailing address, department contact phone and email)

Provide full study title per Box 1.7.

List name and contact information (e.g. phone number and/or email) of the Principal Investigator (identified as “Principal Investigator”)

List names of co-investigators who will have direct contact with the participants and their data

Identify who the primary contact is and include contact information, e.g. phone number and email

If applicable, include a statement that the research is for a graduate thesis In the consent form body

If funded, include details of funders/sponsors
For-Profit Sponsor (Industry)

If actual or potential conflicts of interest exist for the researchers or sponsors, disclose the nature of the conflict and explain how it will be managed

Explain why the participant has been invited

Describe the study purpose in non-academic language

Describe the study procedures and total time being requested for participation
Make it clear that any participant questions will be answered by the researcher to ensure full understanding before consent is requested

Explain potentialrisks to participants (e.g., psychological, cultural, reputational, privacy, confidentiality) and describe procedures in place to minimize risk

If applicable, refer to any counseling or referralservices available to participants

Explain the degree to which participant identities will be protected, and how this will be accomplished. If participant identities will not be kept confidential, explain what may be disclosed, to whom, and why disclosure is necessary.

If focus groups are being used, include a statement that confidentiality cannot be guaranteed

Explain who will have access to the data and confirm that all identifiable data will be encrypted

If the research findings will be stored publicly, include a brief explanation about this

Describe reimbursement for participant expenses and/or remuneration being offered

Background & Introduction

Purpose of Study

Description of study Procedures

Number of Samples

Start Date and completion of study

Start: March 1st, 2022
Completion: December 31st, 2022

Participant (Inclusion/Exclusion Criteria)

The

Risk of Participation

There

Benefit of Participation
These

Costs
There will be no cost to participate in this study

Confidentially of Records
The company

Voluntary Participation
Taking part

Consent Process

Interested participant

Data Security

Each participant willrecord their voice reading from a preset script, short passage, or sequence of words. These recordings will be stored in a database which is encrypted and password protected. Each voice sample will have no personnel identifiers, making each sample completely anonymous

Dissemination

A final report

State clearly that participants may decline to consent and may withdraw from the study at any time without consequence

State if there are limitations on the time period during which data can be withdrawn (e.g. after identifiers have been removed)

If conducting research in schools, indicate how children whose parents/guardians do not consent will be occupied during the research activity (see Action Research Guidelinesfor details)

Include the required wording for the Research Participant Complaint Line in a separate paragraph: Sample Heading:Who can you contact if you have concerns or complaints about the study?

UBC Vancouver: “If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free 1-877- 822-8598.”

In the consent signature section

Include a statement that by consenting, participants have not waived any rights to legal recourse in the event of research-related harm(required if there is potential risk to participants or if study is DHHS funded)

Include a summary description of what the participant is consenting to

Include a statement of how consent is recorded (signature, checkbox, or verbal agreement)

Explain next steps following consent

Include a placeholder for signatory's name and date of consent

Many organizations use a variety of systematic methods to improve their functioning and performance. These activities may take the form of quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal education requirements. These activities are within the mandate of such organizations and are generally administered in the ordinary course of their operations.

Under the Tri Council Policy Statement on Ethical Conduct for Research Involving Humans, studies conducted for such purposes are distinguished from research requiring REB review. According to Articles 2.1 and 2.5 of the TCPS:

Research is "an undertaking intended to extend knowledge through disciplined inquiry or systematic investigation", whereas quality assurance and improvement studies, "when used exclusively for assessment, management or improvement purposes, do not constitute research".

Although QA/QI activities often look research-like, and may contain methods used in research studies (e.g. surveys, interviews, etc.), because the purpose of such activities differs from the intent of research, they are outside the scope of REB review. Although QA/QI studies may raise ethical issues that benefit careful consideration by the project team, the consent procedures for such studies generally depart from those required for research.

However, where one of the goals of such QA/QI activities is to "extend knowledge", they may fall under the TCPS definition of research and therefore require review.

As there is a high degree of uncertainty about where the line between research and QA/QI should be drawn, the following checklist provides an aid to help researchers determine whether their study requires ethics review.

Please note that an intent to publish your findings is not the litmus test for whether your study should be reviewed by the Behavioural Research Ethics Board.

Most journals ask for details of ethical approval or a statement that it was not required. If you wish to publish the results of a genuine QA/QI study, you would simply explain that under Article 2.5 of the Tri Council Policy Statement, QA/QI activities are not subject to institutional ethical review.