**Verbal Consent telephone script Template**

**Version Date: May 3, 2018**

Verbal consent can be obtained in minimal risk studies where written consent is not feasible (e.g., administering a survey over the phone). Verbal consent is generally obtained over the phone; it should not be used when obtaining consent in person. Participants should be provided with information regarding the purpose of the research, the time involved, a summary of the risks and benefits, contact information for questions about the research, and contact information for rights as a research participant. When obtaining verbal consent, consent must be documented in writing by the person obtaining consent. A verbal consent log should also be used to keep track of all potential participants contacted (see [templates](http://my.sickkids.ca/research/clinical-research-services/research-ethics/Pages/Forms-and-Templates.aspx) section of REB website).

For more information on verbal consent, including a full list of what documents the REB requires for verbal consent, see the REB’s [website](http://my.sickkids.ca/research/clinical-research-services/research-ethics/Pages/Consent---Homepage.aspx). If you are unsure if your study can use verbal consent, please contact your REB coordinator.

**How to use this template:**

This template includes sample language for obtaining verbal consent and a form for documenting verbal consent. It is intended to serve as a **guide**. Depending on the nature of the study, you may need to provide different information and details than are stated in the template.

*GREY Highlighted text*: General instructions for the section

**BLUE text:** Guidance and example language. To be deleted/modified as relevant prior to REB submission.

**PURPLE text:** Headings and options.

**BLACK text:** SickKids approved template wording and/or examples that should not be altered without justification

Note that SDM refers to surrogate decision maker (e.g., parent, guardian, for participant that does not have capacity to consent on own behalf)

Use of “you” or “your child” should be modified depending on who is providing consent, the participant or SDM.

**Verbal Consent Script**

Title of Research Project

**Participant name:** **Person calling:**

**Date Called:**Click here to enter a date. **Time Called:**

**Introduction**

Could I please speak to [name of participant/SDM]?

**If respondent asks who the caller is:**

*If speaking to someone other than the potential participant or SDM, limited information about the study should be provided as information about the study could reveal personal health information.*

My name is [name of caller] and I am calling from SickKids about a research study.

**If potential participant/SDM maker is unavailable:**

*Do not leave a message regarding call back information as this may reveal personal health information.*

Is there a better time to call back? Date/time:

**If potential participant/SDM indicates they are not interested:**

Thank you for your time. Goodbye.

**If potential participant/SDM is available:**

Is now a good time to talk?

If no: Is there a better time to call back? Date/time:

I am calling from [department or relevant group] at SickKids. You are receiving this call because you are/your child is a candidate for a research study on [describe the main object of the study, e.g., a study on juvenile rheumatoid arthritis].

*Include the following as relevant:*

* You are being contacted because you had previously indicated [describe when (e.g., when you participated in study X)] that you were interested in being contacted about future research.
* You were sent an information letter about this study [state time frame (e.g., a month ago)].
* Your contact information was obtained from [describe where/from whom contact information was obtained].

Are you willing to hear more about the study?

[ ] Yes [ ] No

If no: Thank you for your time. Goodbye.

If yes proceed to study information.

**Study Information**

*All information that is normally included in a consent form should be described. Follow the outline below as applicable and insert all relevant information.*

If the phone call is being recorded:

Please note that this phone call is being audio recorded for [explain why the phone call is being recorded].

You are a candidate for this research because [state main inclusion criteria/why the participant is being considered for the study].

The goal of the research study is to [state main study objectives, e.g., to understand patient perspectives on care].

This study is being conducted by researchers at SickKids [list other research institutions as applicable] and will include approximately [target number of participants] participants from [list sites].

**Research Activities:**

*All research activities must be described. What each activity entails, how long it will take, and the timing of the activities should be described.*

Participation in the study involves [describe research activities, see examples below].

**For surveys/questionnaires:**

Completion of [number of] survey(s)/questionnaire(s). The survey/questionnaire asks questions about [describe survey content] and takes about [length of time] to complete. The survey/questionnaire is administered [explain how the survey/questionniare will be administered; e.g., over the phone right now/in future, online via a link that will be sent to their email address, in paper via mail that will be sent to their home address with a postage paid return envelope].

**For interviews:**

Completion of [number of] interview(s). The interview involves questions about [describe interview content] and takes about [length of time] to complete. The interview can be done [explain how the interview will be conducted; e.g., over the phone right now]. [Describe how the interview will be recorded: e.g., The interview will be audio-recorded and transcribed verbatim; The interview will not be audio-recorded but I will take notes on your answers.]

**For review of medical records:**

Review of your/your child’s health records at SickKids. Information about [list types of information that will be collected from health records] will be collected from your/your child’s health records. No identifiable information will be collected from your/your child’s records.

Do you have questions about the activities this study involves?

[ ] Yes [ ] No

If yes: Have all your questions been answered?

[ ] Yes [ ] No

**Potential risks, harms, discomforts:**

*All potential harms, risks and discomforts must be described. This includes potential emotional harm from sensitive survey/interview questions.*

Do you have questions about the potential risks of this study?

[ ] Yes [ ] No

If yes: Have all your questions been answered?

[ ] Yes [ ] No

**Potential benefits:**

You will not benefit directly from this study. OR You may benefit directly from this study [describe how participants may benefit directly].

The results from this study may [describe societal benefits of study, e.g., improve understanding of patient experiences].

Do you have questions about the potential benefits of this study?

[ ] Yes [ ] No

If yes: Have all your questions been answered?

[ ] Yes [ ] No

**Reimbursement**:

If no payment/reimbursement:

You will not be paid or reimbursed for being in this study.

If compensated:

As a token of our appreciation, you will be given $XX <if providing gift card, provide category of stores or specific store name> for your participation in this study. The gift card will be sent to you by mail after completion of the survey/questionnaire/interview.

If recognized:

In recognition of your participation, you will be given a certificate of participation and/or # volunteer hours. The certificate of participation will be sent to you by mail after completion of the survey/questionnaire/interview.

Do you have questions about reimbursement?

[ ] Yes [ ] No

If yes: Have all your questions been answered?

[ ] Yes [ ] No

**Confidentiality Information**

We will respect your privacy. No information about you will be given to anyone or be published without your permission, unless the law requires us to do this.

Indicate how identifiable information will be protected:

All information collected about you will be “de-identified” by replacing your identifiable information (i.e., name) with a “study number”. Only the “study code key” can connect the information collected about you to your identity. The study code key will be safeguarded by the SickKids research team and will not be available to the (Sponsor/Funding agency/Coordinating centre). Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

If de-identified/coded study data will be shared outside of SickKids, include the following:

De-identified study data will be transferred to [the sponsor; local/national/international research collaborators/industry partners]. Study data is being shared so that [explain reason for data transfer].

If data will be sent outside of Canada:

Any study data and sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. All information will be transferred in compliance with all relevant Canadian privacy laws.

Representatives of the SickKids Research Ethics Board and/or Research Quality and Risk Management team may look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines.

The research team will keep any personal health information about you in a secure and confidential location for (# of years) years and then destroy it according to SickKids policy. *SickKids policy recommended standard is 7 years for non-regulated studies. However, sponsor, publishing journal or professional affiliation standards for record retention should apply when necessary.*

Do you have questions about how your privacy will be protected?

[ ] Yes [ ] No

If yes: Have all your questions been answered?

[ ] Yes [ ] No

**Participation Information**

This study is voluntary. You can choose if you want to participate and you can change your mind at any time during the survey/questionnaire/interview and you can choose not to answer specific questions. Whether or not you participate in the study will not have any effect on the care you or your family receive at SickKids/on your employment/training at SickKids. If you don’t want to participate in the study anymore [explain how to withdraw – e.g., you can let me know over the phone now or email me later to ask to have your data withdrawn].

Do you have questions about the voluntary nature of participation in this study?

[ ] Yes [ ] No

If yes: Have all your questions been answered?

[ ] Yes [ ] No

**Contact Information**

In case you would like to know more about your rights as a research participant or have any other research ethics questions, here are some contact numbers that are good to have. Do you have a pen and paper ready?

For questions regarding your rights as a research participant, you can contact the manager of the SickKids Research Ethics Board at 416-813-8279.

For questions regarding the study, you can contact [provide research contact information]

**Questions**

Do you have questions about anything that we’ve talked about so far?

[ ] Yes [ ] No

If yes: Have all your questions been answered?

[ ] Yes [ ] No

**Consent**

Are you ready to decide if you want to participate or not? If you need time to think about the study or want to talk about it with someone else, we can arrange to talk at a different time.

**If participant/parent wants additional time or wants to talk again, ask about best time to call back -** date/time:

Do you want to participate in this study?

[ ] Yes [ ] No

If no: Thank you for your time. Goodbye.

If yes: Please confirm that you have been informed regarding the information about this study and are giving your consent to be a part of it.

[ ]  Verbal Consent

Name of person providing consent:

Name of person obtaining consent:

Time:       Date: DD/MMM/YYY

**Next Steps**

If survey/questionnaire/interview will be done via phone, determine date/time for survey/questionnaire/interview or proceed immediately to survey/questionnaire/interview.

Would you like to do the survey/questionnaire/interview now or at a later date?

If later, date/time:

If survey/questionnaire/interview will be done online, describe how information will be sent to participants.

We will send you an email with the link to the web-based survey/questionnaire/interview. To do that, we’ll need your email address. Please be assured that your email address, like all your other information in this study is confidential. We will not share it with anyone else.

What is your email address? *Document email address on telephone log or master linking log. Do not include here.*

If survey/questionnaire/interview will be done in paper, describe how information will be sent to participants.

We will need your mailing address in order to send you the paper version of the questionnaire/survey. We will give you a pre-paid envelope which you can use to send it back to us when it is completed. What is your mailing address? *Document mailing address on telephone log or master linking log. Do not include here.*

If participants will be sent reimbursement via mail:

We will need your mailing address in order to send you a gift certificate/certificate of appreciation/letter of volunteer hours. What is your mailing address? *Document mailing address on telephone log or master linking log. Do not include here.*