

## ADOLESCENT ASSENT FORM TEMPLATE

### GENERAL REMARKS

This assent form template is intended to assist investigators to write assent forms that meet the UBC CREB's requirements for 14-18 year old participants. This form is based off UBC C&W REB's current template.

PLEASE NOTE that this template is primarily intended for children between the ages of 14 to 18 years who, in the context of a particular study, are deemed not competent to consent on their own behalf but who have the capacity to assent. A separate, age-appropriate, assent form should also be given to children between the ages of 7-13 years old who are not competent to consent on their own behalf but who have the capacity to assent. It is not expected that an assent form will necessarily be suitable for all children in these age-ranges. If a younger adolescent child (for example, 14 -15 years old) is unable to read the adolescent assent form, the younger assent form for 7-13 year olds may be used. The age range of 14-18 is a guideline and ultimately, the capacity to consent or assent to a particular study must be evaluated by the Principal Investigator.

This template can also be used for adult-aged participants who do not have the capacity to consent but who are capable of assent. In this case, references to children in the template should be omitted and amended.

***The template is a guide only. It is expected that some of the headings and related text may need to be changed or omitted depending on the nature of the study. Researchers should feel free to flag any issues or wording in a proposed assent form on which they would like REB input or advice.***

- Aim for no more than four pages in length using at least a 12 point font.
- Use either "participant" or "subject", but keep the use consistent throughout the assent form. The term "participant" is preferred in TCPS2 (chapter 2.A).
- Write the assent-section in the first person.
- For the footer version date, please enter date manually; do not use the auto insert date feature of Word as this will change to the current date each time the consent is opened
- **Use the provided section headings where they are relevant and appropriate**

**Letterhead:** Use appropriate letterhead. UBC CREB requires UBC and/or Hospital/Program Department Letterhead.

## Adolescent Information and Assent Form

### Title of Study

**Short Study Title:** Include a small, easily understood segment of the main study title or paraphrase the main study title briefly in easy to understand language (e.g. "Assent Form – Hematoblastoma Biology Study").

### WHO IS IN CHARGE OF THE STUDY?

Include the name of the principal investigator and co-investigator(s) and that s/he and her/his colleagues will be available to answer questions or deal with any problems that may arise. There is no need to mention the sponsor of the study.

**Sample Wording:**

*"The doctor in charge of the study is \_\_\_\_\_. He is being helped by \_\_\_\_\_. They will answer any questions I have about the study. If I am having an emergency and cannot talk to my parents or legal guardians, or if I am having any problems, I can call them at xxx-xxx-xxxx for help."*

### INVITATION

Include an invitation to participate. The assent form must invite, not ask, the participant to participate in the study. Any phrases that may inadvertently coerce (i.e. unduly influence their decision to assent) the participant (adolescent) into the study must be omitted. An example of such a statement is "They want me (need me) to help..."

**Sample Wording:**

*I am being invited to take part in this research study because I have been diagnosed with epilepsy and am being treated with an anti-seizure medication known as carbamazepine. The following pages explain the study so that I can decide if I want to take part or not. It is up to me if I want to be in this study. No one will make me be part of the study and no one will get mad at me if I don't want to be a part of this study.*

## DO I HAVE TO BE IN THIS STUDY?

This section should stress the voluntary nature of the participant's participation. What happens if I Decide to Withdraw My Consent to Participate?

### **Sample Wording:**

*I do not have to participate in this study if I don't want to. If I choose to participate, I can stop being in it at any time. The doctors and nurses will take care of me as they have in the past, regardless of whether I am in the study or not.*

*If I want to participate in this study, I will be asked to sign this form. My parent/guardian will need to sign a consent form before I am enrolled in the study; but I do not have to participate even if they sign the consent form. The researchers will not enrol me into the study unless I agree to do so.*

*I should take time to read the following information carefully and to talk it over with my family, and if I wish, my doctor, before I decide. I understand that I should feel free to talk to the study doctors if anything below is not clear. I can choose to be in the study, not be in the study, or take more time to decide. Even if I agree now to be part of the study, I can change my mind later. I can ask the study doctor or study coordinator any questions I may have at any time during my study participation.*

## WHY ARE WE DOING THIS STUDY?

Provide a brief, simple and accurate explanation about why the research is being done (i.e. background). For example, this can include non-technical information on the prevalence or incidence of a disease, on the problems associated with a disease, on the poor outcomes for other treatment methods, etc.

In addition to the above, when applicable, include the following key points:

- the standard/usual treatment(s) is/are for participants who are eligible for this study
- likelihood that standard treatment will have an effect on the participant.
- drug(s)/device(s) to be tested and an explanation as to their purpose. Designate drug names by "generic name" or "generic name (Trade name)". Exclusive use of drug trade names in consent forms is not allowed. Exception: Where a drug product contains multiple ingredients which make use of its generic name impractical, the trade name for the combination product may be used. Capitalize trade names only; do not capitalize generic names. Inform them if the drug is currently not used to treat this illness.
- if placebo controls are being used, explain what a placebo is (i.e. explain that a placebo is an inactive substance, that it looks identical to the test drug/intervention but that contains no therapeutic or experimental ingredients) and that they might be administered it and not the study drug.

- whether the research is being carried out for the first time in humans in general or children in particular;

**Sample Wording:**

*"I have a condition called epilepsy. Epilepsy is a condition of the brain also known as a seizure disorder. It is the name given when someone has multiple seizures.*

*"I have been treated with an anti-seizure medication known as carbamazepine, which has not completely stopped my seizures. I also have had my blood tested to make sure that the amount of carbamazepine in my blood is appropriate for me. My study doctors want to know if adding another anti-seizure medication to my carbamazepine treatment will better help prevent my seizures. This medication is called [drug name] and may work together with my carbamazepine to prevent or reduce the frequency of my seizures."*

*"In order for the researchers to better understand how well [medication name] really works, some participants will receive a placebo instead of [medication name]. A placebo is an inactive substance, which means that it will not have an effect on my brain or body. It looks identical to [medication name] but will not have any medication in it. The decision of whether I receive placebo or [drug name] will be made at random by a computer program (similar to tossing a coin). Neither I nor the study doctors and nurses will be aware of whether I am receiving [drug name] or placebo."*

**WHY ARE YOU INVITING ME TO BE IN THIS STUDY?**

This section should be distinguished from the "Why are we doing this study" section so that the participant can easily identify the specific goal(s) of this research project. The goal statement should specify exactly what the study hopes to find out. Please state how many participants are expected to take part in this study.

**Sample wording:**

*"I am being invited to be in the study to test if [medication name] will reduce the frequency of seizures during a period of six months in patients who have epilepsy like mine and are taking carbamazepine.*

**WHAT WILL HAPPEN TO ME IN THIS STUDY?**

Explain summarily and accurately what the participant will have to go through. Charts can be helpful to summarize procedures and time commitments, especially for complex or long-term studies. Include:

- A description, in simple and appropriate lay terms, of any therapies that will administered to the participant, and how

- For tissue sampling for this study: how much tissue will be taken and from where, how and when it will be taken; what will be done with it in the study; whether or not it will be stored and for how long (i.e. “kept frozen for many years”)
- If a voluntary donation of tissue and data to a tissue bank is also contemplated, then this should be referred to in the assent form and a separate, optional banking assent form should be included (please see the website for guidelines)
- If this main study is a tissue banking study, then the assent form should be consistent with the template available on the website (URL)
- The total amount of time that the participant will spend participating in the study and, if relevant the total number of visits to the research site (hospital, clinic, etc.) and how long each visit will be.
- If this is a long-term study and some of the participants are likely to reach the age of 19 and have the capacity to consent, then the researchers must have a plan to obtain their consent and refer to this in the consent form as well.

**Sample wording:**

*“If I choose to be in the study, I will come to \_\_\_\_\_ to see the doctors for one hour each week for 4 weeks (4 visits) for the first month, then once a month on or near the last day of each month for the following 5 months. On my third visit, I will receive [medication name], a [medication description], to take home and to start taking the next morning. During my fourth visit, the doctor will use a needle to take blood (5 mL or about 1 teaspoon) from my arm for some tests and to measure the level of drug in my blood, and I will provide a sample of urine for other tests. The doctor will take blood again (5 mL or 1 teaspoon) on each following monthly visit as well. If my doctor has any concerns during the study s/he may remove me from participation in the study and treat my seizures with the other available drugs”*

**CAN ANYTHING BAD HAPPEN?**

Explain in simple and appropriate lay terms any possible harm (i.e. side-effects or discomfort) that the participant might experience resulting from the study procedures appropriate for the child’s age, gender and maturity. The specific frequency and estimated of severity of the risks should be included. Note: if the study is minimal risk, retain this section heading, but indicate that there is nothing in the study itself that should cause anything bad to happen to the participant. If applicable, state any non-medical risks, such as emotional upset, loss of privacy or risks to future employment, or insurability. Also state what services/support will be offered in the event that the study procedures are or might be upsetting to the participant.

Also clearly indicate who should be contacted in case of adverse events, and list the telephone number(s).

**Sample wording:**

*“Sometimes medications can cause side effects, which can make people feel sick. Not much is known about [drug name] compared to many other drugs that people take, but they do know that some of the common side effects of [drug name] when given to adults were: headache (17 out of 100 people), sleepiness (15 out of 100 people), double-vision (5 out of 100 people), vomiting (5 out of 100 people), and diarrhea (2 out of 100 people).*

*One of the more serious side effects that have been seen with antiepileptic medications in general has been an increase in risk for suicidal thoughts. My complete truthfulness with the study doctor will be very important in making sure that no harm comes to me as a result of my participation in this study. I will make sure I tell the study doctor immediately if I feel or do any of the following:*

- *Talking or thinking about wanting to hurt myself or end my life*
- *Withdrawing from friends and family*
- *Becoming depressed or having my depression get worse*
- *Becoming preoccupied with death and dying*
- *Giving away prized possessions*

*“If I feel sick or if I notice any strange or bad feelings during the study, especially if they are unexpected or severe, I will let my parents or doctors know right away. I can call the doctor who is treating me: [name of doctor and telephone number in boldface] or the study coordinator, [name of the coordinator and phone number in boldface]. I can call at any time, day or night, to tell them.”*

**If applicable:**

**FOR GIRLS: ARE THERE RISKS IF I GET PREGNANT?**

If applicable, explain in simple and appropriate lay terms of any possible or unknown harm that may affect the participant’s pregnancy. If follow-up is required if a participant becomes pregnant, this should be mentioned as well.

*Please indicate to the parent(s)/guardian(s) and adolescent that if a pregnancy were to occur the researchers would respect the adolescent’s confidentiality and not disclose this to the parents/guardians without the adolescent's approval.*

**Sample wording:**

*“It is not very well known how [drug name] will affect a pregnancy or the developing baby. If I am getting my menstrual periods I must agree to undergo pregnancy testing using a blood or urine sample \_\_\_\_\_ times or more, depending on how long I am in the*

*study. If I am sexually active, I must use a study-approved birth control method and agree to try not to get pregnant during the study.*

*“It is important that I contact my doctors right away if I think I may be pregnant, if I have missed a period or it is late, or I have a change in my usual menstrual cycle (for example, heavier or lighter bleeding than usual, or bleeding between periods).”*

**If applicable:**

### **FOR BOYS: ARE THERE RISKS IF I GET SOMEONE ELSE PREGNANT?**

If applicable, explain in simple and appropriate lay terms of any possible or unknown harm that may affect a pregnancy if the participant gets someone else pregnant.

*“It is not very well known how [drug name] will affect a pregnancy or the developing baby. If I am currently sexually active, I must use a study-approved birth control method, and/or agree to not try to get someone else pregnant.”*

*“It is important that my partner contact the study doctors right away if she think she may be pregnant, if she has missed a period or it is late, or she has a change in her usual menstrual cycle (for example, heavier or lighter bleeding than usual, or bleeding between periods).”*

### **CAN I GET BETTER BY BEING IN THE STUDY?**

Explain that no one knows whether the participant will feel any better during or after the study, and that they may even feel worse. Also explain any benefits the participant may feel as well. Include any relevant information about the nature of the potential benefits (how important are these benefits?) and the likelihood of these benefits occurring, only to the extent this applies.

**Sample wording:**

*“No one knows whether or not I will benefit from this study. I may feel worse from participating in this study. However, by participating in this study, the study doctors hope the frequency of my seizures may be reduced.*

*“The study doctors hope that the information learned from this study can be used in the future to benefit other people with epilepsy.”*

### **ARE THERE ANY OTHER TREATMENTS FOR ME?**

If applicable, explain that the participant does not have to be a part of this study to receive treatment for their illness and that other treatments are available. Emphasize that they can ask

their doctor or their parents about any other treatments and therapies. If there are no other alternatives, state in simple and appropriate lay terms that no other treatment alternatives exist.

This section should be omitted for a study with no prospect of direct therapeutic benefit.

**Sample wording:**

*“Participating in this study is completely up to me. If I choose not to participate in this study or to withdraw at a later date, there are other treatment options that are known to reduce the frequency of seizures available for me: (List them) If I want to learn more about these other treatment options, I may contact the study team at any time or if I prefer, speak with my parents/legal guardian and family doctor.”*

## **WHO WILL KNOW I AM IN THIS STUDY?**

Explain, in simple terms, that the patient’s confidentiality will be respected and kept. Also explain how this will be done.

**Sample Wording:**

*“My privacy will be respected. Unless I allow them to, the study team will not tell anybody else I am or have been a part of this study. They will not release any information to anybody else that could be used to identify me, unless they are required to do so by law. For example, researchers are required to report if a participant is believed to be at risk for harming him/herself or others.*

*In order to protect my privacy, the study team will remove any information that may be used to identify me from any study documents, and instead of my name appearing on them, I will be identified by a specific study code number that applies only to me. Only this code number will be used on any research-related information collected about me for this study, so that my identity as part of the study will be kept completely private. Only Dr. \_\_\_\_\_ and his research assistants will have the ability to link this code number with my personal information, and the linking information will be kept in a locked cabinet in Room \_\_\_\_\_ of the \_\_\_\_\_ under the supervision and control of Dr. \_\_\_\_\_.”*

## **WHAT WILL THE STUDY COST ME?**

**When applicable**, begin this section with a general statement that research-related care and treatment will be provided at no cost to the participant.



***Sample wording:***

*“All research-related medical care and treatment and any related tests that I will receive during my participation in this study will be provided at no cost to me.”*

**Reimbursement**

**Stipulate** whether the participant will incur any personal expenses as a result of participation.

**State** whether their expenses will be reimbursed, which expenses, and how they should claim for reimbursement.

**Otherwise**, provide an explicit statement that there will be no reimbursement for study related expenses, if that is the case.

**Researchers** are encouraged to cover participants’ expenses such as parking, meals, travel, supportive care medications or other incidental costs over and above those needed for standard care they would not otherwise have been required to purchase.

**Remuneration**

**State** whether the participant will be paid for their participation (e.g. “I will not be paid for participating”).

**If participants** will be paid for participation, include the details of any honoraria/incentives to be provided.

**Such payments** must not be weighted toward the end of the study, as an incentive to complete participation.

**State** that payments will be pro-rated if the participant withdraws from the study, if this is the plan.

**WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?**

***Sample wording:***

If I have any questions or desire further information about this study before or during participation, or if I experience any side effects that were not outlined in this assent form, I can contact [insert PI or his/her representative] at (xxx) xxx-xxxx, ext. xxxx.

**WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A PARTICIPANT?**

***Sample wording:***

If I have any concerns or complaints about my rights as a research participant and/or my experiences while participating in this study, I should contact the Research Participant

Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at [RSIL@ors.ubc.ca](mailto:RSIL@ors.ubc.ca) or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

## **FUTURE STUDIES**

Include these statements or statements like these and checkboxes if you are interested in recruiting the participant for future research.

### **Sample Wording**

*There is a chance that during or after this study the study team will find other questions needing answers that require future studies. If I am willing to hear about these future studies I will mark the “yes” box. This does not mean that I will have to take part in a new study, just that the study team will let me know about it. If I do not want to be contacted about new studies I will mark the “no” box.”*

***Are you willing to be contacted by the researchers for future studies?***

**YES**   

**NO**

## ASSENT TO PARTICIPATE

This section of the consent form should start on a **new page**. A copy of the signed and dated assent form must be given to the participant.

**Sample:**

## SIGNATURE

### Participant Assent

*My signature on this assent form means:*

#### **Sample Wording (Check List):**

- *I have read and understood this adolescent information and assent form.*
- *I have had enough time to consider the information provided and to ask for advice if necessary.*
- *I have had the opportunity to ask questions and have had acceptable answers to my questions.*
- *I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.*
- *I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing the quality of care that I receive.*
- *I understand that I can continue to ask questions, at any time, regarding my participation in the study.*
- *I understand that if I put my name at the end of this form, it means that I agree to be in this study.*

*I will receive a signed copy of this assent form for my own records.*

*I agree to participate in this study.*

\_\_\_\_\_  
*Participant's Signature*

\_\_\_\_\_  
*Printed name*

\_\_\_\_\_  
*Date*