### ADOLESCENT ASSENT FOR PARTICIPATION IN A RESEARCH STUDY

**YALE UNIVERSITY**

**YALE UNIVERSITY SCHOOL OF MEDICINE**

**YALE-NEW HAVEN HOSPITAL**

**YALE-NEW HAVEN HOSPITAL: SAINT RAPHAEL CAMPUS**

**YALE-NEW HAVEN HOSPITAL: SMILOW CANCER CENTER**

**CONNECTICUT MENTAL HEALTH CENTER**

**YALE UNIVERSITY SCHOOL OF PUBLIC HEALTH**

**YALE UNIVERSITY SCHOOL OF NURSING**

*Select the appropriate name of the institution engaged in research above and delete the rest or add your own. Add the IRES IRB# to the header of the document. Replace the version date of the template in the footer with your selected versioning method for your research documents. For ideas, see* ***Researcher Guide: Consent Version Control and Tracking*** *in the Help Center section of IRES IRB.*

**Study Title:** *[Insert the title of the study.]*

**Principal Investigator (the person who is responsible for this research):** *[Insert name and mailing address.]*

**Phone Number**: [*[Insert the PI’s phone number].*

**24-Hour Phone Number**:*[If appropriate, insert the 24-hour phone number. Otherwise, delete the entry.]*

**INSTRUCTIONS:**  This template is designed to provide guidance in the development of an adolescent assent form for subjects ages 13 - 17. It is recommended that the information presented in the assent form closely matches the information in the parental permission/adult consent form. Should the subject present with a lower mental age, for whom this assent form might be too difficult to comprehend, a child assent form can be used instead.

*Italicized sections* include suggested text and further instruction and guidance. Note that sections shown in square brackets must be edited for each specific protocol. Not all sections will apply to every protocol. Therefore, delete sections that do not apply, as well as this and other instruction paragraphs, prior to submitting the form(s) to the IRB.

**Why am I here?**

* We are asking you to join a research study.
* The study will look at [*briefly describe the purpose of the study*].
* It will take [*state number of visits, in days or number of hours as applicable*]*.*
* This assent form explains the research study and your part in the study.
* Please read it carefully. Take as much time as you need.
* Please ask the study staff questions about anything you do not understand.
* You can ask questions now or anytime during the study.
* If you join the study, you can change your mind later.
* You can quit the study at any time.
* We will also ask your parents to allow you to be in the study.

**Why is this study being offered to me?**

We are asking you to join a research study because *Explain briefly why the prospective participant is eligible to participate.]*. We are looking for*If appropriate, state the approximate number of participants and/or research sites involved in the study.]* total people to be part of this study.

**What is the study about?**

The purpose of this study is to *[Insert the purpose of the study.]*

* *Explain the purpose of the research in one or two sentences.*
* *For investigations to establish safety or efficacy of a test article, insert a statement indicating that the purpose is to test safety and/or how well the drug works in the participant’s condition.*

**What will happen during the study?**

If you agree to take part in this study, this is what will happen: *[describe the study procedures clearly, in roughly chronological order.]*

* Describe the procedures using simple, lay language, short sentences and short paragraphs. The use of subheadings may help to organize this section and improve readability.
* Define and explain medical and scientific terms in ordinary language (for example, the amount of blood to be drawn should be given in terms of teaspoons, tablespoons or ounces). A medical or scientific term, drug name, etc. may be used throughout the consent form once it has been introduced and explained in lay language.
* Explain and distinguish any procedures that are experimental from those that are part of the participant’s standard clinical care. Describe assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.
* For research involving randomization of participants into different groups, specify (and explain) the randomization procedures.
* For research involving the use of placebo, clearly define the term placebo.
* For research involving interviews, surveys, questionnaires, etc., clearly describe the purpose and content of the instruments. It may also be helpful to provide a representative sample of the types of questions participants will be asked.
* For research involving review of participant’s medical record, the consent form should explain what types of information will be collected, and why.
* When relevant, any plans to return information to participants, to their medical records, to primary care physicians, or others must be made explicit in the consent form.

**Pregnancy testing in minors**: If your study involves pregnancy testing, add the section below. Ensure that the parental permission includes adequate language in the Confidentiality section. The parental permission template includes the suggested language.

**What you need to know about pregnancy testing:**

* We will ask you to have a pregnancy test before you start this study [Or add other timepoints when pregnancy testing will take place.]. Only you will be told the results.
* If you are pregnant, we will also advise you to get care for your pregnancy and to get the support of an adult.
* You will be asked not to be in the study or you will be removed from the study if your pregnancy test is positive.
* You need to know that your parents may ask you why you cannot be in the study or why you were asked to leave the study.
* If there is any chance that you are pregnant or you might become pregnant during the time of this study, please think really carefully about whether you want to be in the study.
* It is okay if you decide that you do not want to be in the study or to stay in this study. You do not need to give a reason for not being in the study.

**How long will I be in the study?**

You will have [*enter number of visits]* visits that will take about *[enter time for visit in minutes, hours, etc.* each.

**What are the possible risks of the study?**

* *Identify all reasonably foreseeable risks or discomforts associated with the study using laymen terms. For help identifying easy explanations, you can refer to the following resources:*
	+ *Kids' Medical Dictionary:* [*https://kidshealth.org/en/kids/word/*](https://kidshealth.org/en/kids/word/)
	+ *NCCN Informed consent Language Database:* [*https://www.nccn.org/icl/default.aspx*](https://www.nccn.org/icl/default.aspx)
	+ *University of Iowa’s ‘Medical Terms in Lay Language’ page:* [*https://hso.research.uiowa.edu/medical-terms-lay-language*](https://hso.research.uiowa.edu/medical-terms-lay-language)
* *Refer to the* ***Consent Glossary*** *for descriptions of risks associated with certain research procedures.*
* *When relevant, risks to pregnant women or to a fetus should be explicitly stated.*
* ***For studies taking place at the YNHH-Saint Raphael campus:*** *the reproductive risks section of the consent document should instruct study participants to practice "family planning methods" acceptable to the study investigator.” The terms “contraception” and “birth control” may not be used unless specific contraception is required to be in the study.*
* *In addition to physiological risks/discomforts, describe any psychological, social, legal or financial risks that might result from participating in the research.*
* *For standard of care treatments, e.g. approved drugs or drug combinations for use in the participants’ condition, do include foreseeable risks if the sponsor chose the drug regimen as part of the protocol. There is no regulatory requirement to include risks associated with drugs prescribed by the participant’s physician as part of clinical care e.g. this is the exact drug or drug regimen the participant will receive as a patient regardless of whether the patient enrolls in the study. Most standard of care treatments, however, will be sponsor or investigator chosen as part of the research protocol (protocolized) and are therefore, based on FDA opinion, research-related risks. In these cases, foreseeable (usually most common) and rare but serious adverse events associated with each agent and possible risks associated with combinations should be included or statement that combined risks are unknown.*
	+ ***Example 1****: A patient previously prescribed a particular drug by his/her physician is invited to take part in a registry study about this drug that involves a research questionnaire and blood draw. In this case, the research-related risks are associated with the questionnaire and blood draw only and not the drug. Since the drug is not a research-related risk, there is no requirement this drug’s foreseeable AEs be included in the research consent form and preferable they are not included in an effort to condense the consent form to focus only on relevant risks of the research.*
	+ ***Example 2****: A participant is randomized to two different drugs each used in the study as per its approved label. The drugs are mandated by the protocol and thus risks associated with the drugs are research-related risks even if the participant could have received either drug clinically. Risks associated with these drugs should be included in the consent form.*
* *In some cases, the investigator may determine that the risks of drugs prescribed as part of clinical care be included in the consent form as research-related risks if, for example, there is concern that combination of the participant’s clinically prescribed drug with drugs that are part of the protocol may increase the risk of an AE.*
* *For studies involving investigational drugs or devices, the consent form should describe a means whereby information about the drug or device may be obtained in emergency situations.*
* *For research involving genetic or related testing, participants must be informed of any risks associated with the genetic information that may result. See the* ***Consent Glossary*** *for the sample language. Such risks could include reduced access to or reduction of benefits or entitlements (e.g., insurance, educational opportunities, employment, etc.); stigmatization; psychological distress in response to information; or detection of biological relationships within a family.*

**How will I learn any new important information about the study?**

We will tell you and your parents if we learn any new information that could change your mind about taking part in this study.

**How can the study possibly benefit me or other people?**

The study might benefit you by *[Describe potential benefit for the subject]*.

* *Describe any benefits that can be reasonably expected to result from the research directly to the participant (e.g., improved health outcomes).*
* *If appropriate for Phase 1 dose escalation or other early phase trials in which safety, not efficacy is the primary outcome, indicate that the subject is not likely to personally benefit but the research may help other patients with (state condition under study) in the future.*
* *If there is no likelihood that subjects will benefit directly from their participation, this should be stated.*
* *Financial rewards for participating in research are not considered benefits and should not be included in this section.*
* *Please note that, by definition, the benefits of research are unproven. Therefore, subjects should be told that participation “may,” rather than “will” yield benefit.*

The study might help other people by helping us understand more about *[Describe what the study is hoping to learn]*.

* *Describe any benefits that can be reasonably expected to result from the research to the population the participant represents (e.g., a better understanding of the participant’s condition that may lead to new treatments), or to society at large (e.g., general advancement of scientific knowledge).*

**Will it cost any money for me to be in the study?**

If you take part in this study, you and your parents will not have to pay for anything being done for the study only (things NOT part of your routine medical care). There might be additional costs to you or your family. This might include costs of transportation and your time coming to the study visits. Your health insurance must pay for services, supplies, procedures, and care that are part of your routine medical care. Your parents will be responsible for any co-payments required by your insurance.

*[Alternative wording if there are no costs to participants:]*

You will not have to pay for taking part in this study. The only costs include transportation and coming to the study visits.

**Will I be paid if I join the study?**

You will be paid for taking part in this study. *[Describe form of payments and the amounts, and any reimbursements.]* You may be responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

* *Describe any compensation that will be made to participants such as:*
	+ ***Stipends:*** *A payment that a research participant may receive as compensation for his/her participation in the research (direct monetary payment, payment in the form of a gift);*
	+ ***Reimbursements:*** *When a research participant is reimbursed for actual expenses incurred during his/her participation in a research study (for mileage, parking, childcare, lodging, or meals)*
* *If using Bank of America card, use the language from the* ***Consent Glossary*** *document.*
* *Explain the conditions for receiving this compensation (for example, residing more than 50 miles from the study site in order to receive reimbursement for mileage, etc.).*
* *Explain if payment will be prorated for participants who do not complete the study.*
* *Explain if payment is conditional on completing the study.*
* *If participants are not paid, state that and remove the statement about taxable income.*

**What other options do I have?**

If you don’t want to be a part of this study, you have some other choices.

You could:

* Get treatment without being in a study. *[Describe whether the same treatment is available without participating or other alternative treatment options might be available and advantageous to participant]*
* Take part in another study.
* *This paragraph is a required element of informed consent for all research involving treatment or therapeutic intervention. Certain non-treatment protocols may also require a section detailing appropriate treatment or procedures that are available outside of the research. Investigators may also choose to state that the only alternative is to decline participation in the study. If the section does not apply to your study, you may omit this entry and delete the heading.*
* *Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that a reasonable person would want to know in order to decide whether or not to participate in the study. Alternatives should include medically recognized standard of care available outside the study (standard of care involving off-label uses of drugs and 510k cleared devices should be also be offered if available, clinically, outside the study). Risks and benefits of these should be discussed.*
* *Please note that alternatives are not limited to curative procedures. For chronic or terminally ill subjects, alternatives may include procedures for symptom management, improving the ability to function, or comfort care.*

**How do you protect my information?**

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

Describe the methods used to safeguard the confidentiality of participants’ data, for example:

* coding data or samples with numbers (include how long the link between the numbers and the data will be stored, who will have access to the link);
* storing research materials in locked cabinets,
* password-protecting data stored on a computer, etc.
* *If using* ***focus groups****, add Focus Groups language from the* ***Consent Glossary****.*

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

One of the following statements must be included:

(1) That identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (2) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

If you do not plan on sharing information for future research revise the last statement starting with ‘We will also share…’.

**What will happen if I get hurt because I joined the study?**

* *This section is a required element of informed consent for all research presenting greater than minimal risk. It should also be used for minimal risk research that presents the potential for physical harm. If this section does not apply to your study, delete it.*
* *Yale expects the for-profit entities sponsoring the research to cover the cost of treatment of injuries sustained as a direct result of participation in the research.*
* *Yale does not normally provide any form of compensation for injury or lost income. In studies sponsored by a non-profit entity (e.g., investigator’s own funds, federal funding, or a private non-profit organization), participant or his/her insurance can be billed for cost of treatment.*
* *See the sample language in the* ***Consent Glossary.***

##### Do I have to be in this study?

No, being in this study is up to you. You can say no now if you already know that you do not want to join the study. You can say yes now and if you change your mind later, you can leave the study at any time. If the study involves treating you, your study doctor may need to help you safely stop treatment first. Just tell the study staff that you no longer want to be part of it. The researchers may still use the information they had already collected about you before you withdrew from the study.

There will be no negative consequences regardless of what you decide to do. Your decision will not change the care you receive or benefits that you would normally get.

The researchers may withdraw you from participating in the research if necessary.Describe conditions when that can be true - e.g. because of development of serious side effects.

*If there are medical needs required by the participant upon withdrawal, these should be stated. Any follow-up procedures or assessments accompanying the withdrawal should be clearly explained. Tailor the statement about the ability to withdraw from participation to the specifics of the study. For example, in a study on an experimental device or surgery, the subject who has received the intervention can withdraw from the follow-up portion of the study, but the device will not be removed and the surgery cannot be undone.*

**What if I have questions?**

Please feel free to ask us about anything you don't understand.

If you have questions later or if you have a problem with the study, you can call the doctor in charge of the study at *Insert the PI’s phone number.*

If you have questions about your rights as a research participant, or you would like to speak with someone other than the Principal Investigator or study team to discuss problems, concerns, or questions, or to obtain information or offer suggestions you can call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov)*,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

*Remove the paragraph about Clinical Trials if the study does not meet the definition of a clinical trial and is not registered.*

**Documentation of Assent**

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Participant Printed Name |  | Participant Signature |  | Date |
| Person Obtaining Assent Printed Name |  | Person Obtaining Assent Signature |  | Date |