### COMPOUND AUTHORIZATION AND CONSENT 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**

*Template Dated 7/24/2023, Biomedical Research*

*Select the appropriate name of the institution engaged in research above and delete the rest or add your own.*

**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.]*

*The ‘Research Study Summary’ is required for all non-exempt research studies approved after January 21, 2019 unless they are FDA or DOJ regulated and non-federally funded. It should include ‘a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension’.*

**Research Study Summary:**

* We are asking you to join a research study.
* The purpose of this research study is to *[Insert the purpose of the study.]*
* Study procedures will include: *[Insert summary of study procedures.]*
* *[Number of visits]* visits are required.
* These visits will take *[Number of hours]* hours total.
* There are some risks from participating in this study. *[Insert summary of the study risks.]*
* The study may have no benefits to you.*[Describe benefits of the study to others. If there are expected benefits to subjects, revise the sentence and describe the benefits.]*
* There are other choices available to you outside of this research.*[Describe alternative procedures or treatments outside of the study. If none, you can delete the entire bullet point.]*
* Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
* If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

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

We are asking you to take part in 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.]* participants to be part of this research study.

**Who is paying for the study?**

*[List all organizations/entities providing monetary support for the study, regardless of whether funds are received directly or through another organization (such as a cooperative group or foundation.)*

**Who is providing other support for the study?**

*[List any organizations/entities providing non-monetary support only, such as a free study drug.]*

**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.*
* *If appropriate, explain whether or not the investigational study agent has or has not been approved for use or treatment in the United States for the participant’s condition.*

**What are you asking me to do and how long will it take?**

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.*

**What are the risks and discomforts of participating?**

* *Identify all reasonably foreseeable risks or discomforts associated with the study, and describe how they will be managed.*
* *If available, include a brief statement about the safety and tolerability of the drug in previous studies or clinical experience.*
* *Risks should be listed in hierarchical order, from most likely to least likely to occur.* *Use categories of* ***Most Common****,* ***Common****,* ***Uncommon****, and* ***Rare but Serious****. Where such information is available, the consent form should state the likelihood of risks occurring. For example, “most participants in a similar study had headaches and felt nauseous,” or “10 out of 100 people who took drug X felt dizzy.”*
* *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 know about new risks or important information about the study?**

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

*If the study is likely to generate clinically relevant research results, include a statement whether clinically relevant research results, including individual research results, will be disclosed to subjects,* ***and if so, under what conditions****.*

**How can the study possibly benefit me?**

* *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.*

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

The benefits to science and other people may include a better understanding of *[Describe benefits of the study to others.]*

* *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).*

**Are there any costs to participation?**

If you take part in this study, you will not have to pay for any services, supplies, study procedures, or care that are provided for this research only (they are NOT part of your routine medical care). However, there may be additional costs to you. These can include costs of transportation and your time to come to the study visits. You or your health insurance must pay for services, supplies, procedures, and care that are part of your routine medical care. You 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 your time coming to the study visits.

*For studies with billable services, add the following:*

*Your study doctor, a member of the study team, or a member of the research billing team will be glad to answer your questions about whether services or tests performed during the course of a research study will be billed to your insurance provider or to you, or about any bills that you may receive during your participation in a research study. Please call the research billing team at 1-877-TRIALS0 (1-877-874-2560) with any questions. You may also contact your insurance provider directly.*

**Will I be paid for participation?**

You will be paid for taking part in this study. *[Describe form of payments and the amounts, and any reimbursements.]* You are 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 (including direct monetary payment, payment in the form of a gift, or reimbursement for costs such as travel, parking, childcare, etc.), and the conditions for receiving this compensation. If using Bank of America card, use the language from the Consent Glossary document.*
* *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 are my choices if I decide not to take part in this study?

Instead of participating in 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.
* Receive comfort care only, without any treatment for your disease.
* *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 will you keep my data safe and private?**

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.

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…’.

***NOTE:*** *The next 4 sections starting with ‘What Information Will You Collect About Me in this Study?’ through ‘What if I change my mind?’ refer to HIPAA Authorization.* ***Do not remove any of the sections and only tailor the suggested areas for the study.***

**What Information Will You Collect About Me in this Study?**

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

*Describe in detail the information to be used and where it comes from, e.g., your entire medical record from YNHH, information from your record including how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth, etc. Examples are provided below.* ***Delete and add as needed.***

* Research study records
* Medical and laboratory records of only those services provided in connection with this Study.
* The entire research record and any medical records held by[the name of institution or hospital created from: [start date] to: [end date] \_\_\_\_\_\_\_\_
* Records about phone calls made as part of this research
* Records about your study visits
* Information obtained during this research regarding
  + - HIV / AIDS test results
    - Hepatitis infection
    - Sexually transmitted diseases
    - Other reportable infectious diseases
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Diaries and questionnaires
    - The diagnosis and treatment of a mental health condition
    - Use of illegal drugs or the study of illegal behavior
    - Records about any study drug you received
    - Records about the study device

In next section, ‘*How will you use and share my information?’,* you must include the entries for **DHHS, Yale HRPP, PI, co-investigators and research staff**. Other examples are provided below. **Delete and add as needed.**

**How will you use and share my information?**

We will use your information to conduct the study described in this consent form.

We may share your information with:

* The U.S. Department of Health and Human Services (DHHS) agencies
* Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
* The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about [the new drug product or device] involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
* The study sponsor or manufacturer of study drug/device
* Drug regulatory agencies in other countries
* Governmental agencies to whom certain diseases (reportable diseases) must be reported
* Health care providers who provide services to you in connection with this study.
* Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
* Principal Investigator of the study
* Co-Investigators and other investigators
* Study Coordinator and Members of the Research Team
* Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

**Why must I sign this document?**

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

[If study involves blinding include the following: However, this is a single/double blinded treatment study and if you sign this permission form, you will not be allowed to look at or copy your study related information until after the research is completed.

**What if I change my mind?**

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to [Name and the address of the PI:] at the Yale University, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

**Who will pay for treatment if I am injured or become ill due to participation in 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.***

**What if I want to refuse or end participation before the study is over?**

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

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 will happen with my data if I stop participating?**

*Participants should be informed whether they will have the ability to withdraw their data from the research once it is collected. Unlike tissue samples, which often can be withdrawn and destroyed, data derived as part of the research usually will not be covered by an option for withdrawal. If data or samples will be unable to be withdrawn (for example, if they have been de-identified), participants should be told in the consent form.*

**Who should I contact if I have questions?**

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

If you have questions later or if you have a research-related problem, you can call the Principal Investigator 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](mailto: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.*

**Authorization and Permission**

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 Consent Printed Name |  | Person Obtaining Consent Signature |  | Date |

***When applicable add:***

* *If enrollment of cognitively impaired individuals is approved for the study, add lines for legally authorized representative or surrogate, as well as a line for the description of their relationship to the participant.*
* *If use of short forms is approved for the study, add Interpreter box below. Otherwise, remove it prior to submitting to the IRB.*

|  |
| --- |
| Complete if the participant is not fluent in English and an interpreter was used to obtain consent.  Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language.  This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.  Print name of interpreter: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of interpreter: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_  An oral translation of this document was administered to the participant in \_\_\_\_\_\_\_\_\_\_\_\_\_ (state language) by an individual proficient in English and \_\_\_\_\_\_\_\_\_\_\_\_ (state language).  Print name of impartial witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of impartial witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_  See the attached short form for documentation. |