**KESSLER FOUNDATION**

INSTITUTIONAL REVIEW BOARD

### CONSENT TO PARTICIPATE IN A RESEARCH STUDY

*Please remember that this consent form is for the person participating in the study and not for a research professional. Do not cut and paste from the protocol, but rather write the consent form in accessible language at the 8th grade English level.*

*Please DO NOT change the margins of this document as sufficient space is needed for applying the IRB approval stamp on each page.*

*All instructions (shown in red italicized text) should be removed before submitting this form for IRB review.*

***Sections marked with \*\*\* should be removed for studies that fall into either of the following two categories:***

1. *Intervention studies in ADULT participants that meet criteria for “limited IRB review.” Revised Federal Regulations indicate that a “limited IRB review” should be made available for “benign behavioral interventions” in ADULT participants. According to the regulations, such interventions are “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing…Examples would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.”*
2. *Other studies that have a similar risk profile as that described above (harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects and the investigator has no reason to think the subjects will find the procedures offensive or embarrassing). Observational studies in which the primary risk is that of a breach of confidentiality likely fall in this category, unless data collected are of a highly sensitive nature.*

*Please contact the IRB with any questions you may have about whether your study meets criteria to use the abbreviated consent form content.*

**TITLE OF STUDY:** *Insert research study title.*

**RESEARCH STUDY #:** *Insert IRB protocol number, if already assigned.*

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, am being asked to consent to participate in a research study led by Dr(s).\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Other persons who work with *him/her/them* as study staff may be asked to help *him/her/them*. I understand that taking part in this study is completely voluntary; I do not have to be part of this study unless I choose to be. I am free to leave the study at any time if I change my mind. All research studies carried out at Kessler Foundation are covered by the rules of both the Federal Government and Kessler Foundation.

The Information provided may contain words I do not understand. I will ask the study doctor or the study staff to explain any words or procedures I do not understand.

The table below contains a brief summary of key information about this research study. Additional information can be found throughout this document.

*The summary table below is intended to highlight the most important information a participant needs to know before consenting to participate. Investigators are strongly encouraged to limit the length of this table so that it does not go beyond page 2 of the consent form.*

|  |
| --- |
| **Study Summary** |
| Why is this research being done? | *Briefly state the purpose/objectives of the research* ***in lay language using 8th grade English. Avoid technical terms and language when at all possible.*** |
| How long does the study last? | *A brief statement of the Duration of the study should be given here.* The study will take me *(include the number of visits, actual time for each visit and the total period of time the study will take in weeks/months.)* |
| What will happen during this research study? | *A brief summary of the procedures of the study should be given here. More details of the Procedures can be added in a separate section, below).*While I am part of this study, I will be asked to \_\_\_\_. |
| What risks are associated with participating in this study? | *A brief statement of the major risks and discomforts to the subject while participating in the study should be given here. A more detailed description of Risks and Discomforts can be given later in this document.*  |
| What are the benefits of participating in this research study? | *Describe the benefits (if any) that a subject or others may expect from this research.*The benefits of participating in this study may be:*(Describe potential benefits, to the individual and to society in general, that might result from the research. If the individual participant will receive NO DIRECT BENEFIT, this must be stated.)*However, I may receive no personal benefit from taking part in this study.*OR*I will receive no direct benefit from taking part in this study, but the information obtained from this study may help the researchers to better understand \_\_\_\_\_\_.  |
| What other options are available to me if I choose not to participate in this study?  | Participation in this study is completely voluntary. If I choose not to participate in this study, there will be no effect on my medical care, employment status, or access to benefits to which I am otherwise entitled. |

**The following sections offer more detail about the study.**

**WHY IS THIS RESEARCH BEING DONE?**

*Briefly explain in lay language using 8th grade English the reason why the study is being done. What problem is it trying to solve? What new information will it provide?*

 **WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?**

While I am a part of this study, I will be asked to do the following:

*Describe in lay language using 8thgrade English, step by step* ***(in first person)****, what will happen to the participant. This description should include, but not be limited to, such items as:*

1. *The overall design of the study written in lay language.*
2. *Methods and probability of assignment, randomization, controls and placebos.*
3. *Brief summary of blinding procedures, if applicable.*
4. *Procedures to be performed, including frequency and follow-up. (Distinguish between assessments done before and after the intervention and the intervention itself.)*
5. *Distinction between those procedures that are experimental and those that are part of standard care.*
6. *Medications (including placebo) to be administered and the method, dose, and frequency of administration.*
7. *Number, frequency and duration of visits, or time required of participants already on site.*
8. *Specimens to be collected, including frequency and size/amount.*
9. *Specific requirements of the research participant, e.g., post-treatment follow-up, diary cards, questionnaires, etc.*
10. *If pregnancy is an exclusion criterion, ensure that pregnancy testing is mentioned in the procedures.*

*If participants will be audio and/or video-recorded, please add the following statement and signature lines:* I will be *(specify type of recording, audio and/or video)*-recorded during the study, so that the researchers may collect all the information they need correctly. I will indicate below my willingness to be recorded for purposes of this research study:

[ ] **Yes**, I agree to allow *(specify audio and/or video)* recording of my study sessions.

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ *Participant unable to sign due to arm impairments or consent by telephone*

[ ] **No**, I do not agree to allow *(specify, as above)* recording of my study sessions.

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ *Participant unable to sign due to arm impairments or consent by telephone*

*\*\*\****HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?**

*State the total number of participants to be enrolled in the study, the number for each site if a multicenter study, and the number in each arm of the study. State any specific requirements of the participant for inclusion in the study (e.g., age, sex).*

Up to \_\_\_\_\_ people will take part in this study.

*\*\*\****WHO QUALIFIES TO PARTICIPATE IN THIS STUDY?**

*Provide a summary, in lay language, of the criteria for enrollment in this study.* ***Please do not list the same items under both inclusion and exclusion. For example: Inclusion – between 18 and 80 years old – Exclusion – younger than 18 and older than 80.***

*State if any criteria will be determined at screening and describe these criteria in terms that a lay person can understand. For example, do not include details of blood levels of chemicals or numerical scores on tests.*

*\*\*\****WHAT MIGHT MAKE ME INELIGIBLE FOR THIS STUDY?**

If any of the items listed below are true for me, I will tell the researcher. To ensure my privacy, I do not have to say which item or items apply to me. If I choose to tell the investigator which items are true for me, the information will not be shared with anyone.

*List study exclusion criteria in* ***lay*** *language.*

*If pregnancy is an exclusion, the following statement should be included:* Because of potential risk to the fetus, women of child bearing potential will be required to have a pregnancy test before they can enroll in this study. If I am female, and have a positive pregnancy test, I will not be enrolled.

*\*\*\****PARTICIPATION IN GENETIC STUDIES: *(remove If not applicable)***

The genetic studies described are for research purposes only. Therefore, you will receive no results from this study (except as described below).  It is not the purpose of this study to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. The research tests are not being used as diagnostic tests for any disease or illness. Your participation in this study is not a substitute for your regular medical care or check-ups.

*\*\*\****CONFIDENTIALITY OF GENETIC INFORMATION: *(remove If not applicable)***

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against anyone based on his/her genetic information. This law generally will protect me in the following ways:

        Health insurance companies and group health plans may not request my genetic information that we get from this research.

        Health insurance companies and group health plans may not use my genetic information when making decisions regarding my eligibility or premiums.

        Employers with 15 or more employees may not use my genetic information that we get from this research when making a decision to hire, promote, or fire me or when setting the terms of my employment.

        All health insurance companies and group health plans must follow this law as of May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

        Be aware that this new Federal law does not protect me against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**WHAT RISKS ARE ASSOCIATED WITH PARTICIPATING IN THIS STUDY?**

The study described above may involve the following risks and/or discomforts:

*For each procedure/intervention, describe the potential, immediate and long-term discomforts, hazards, and risks - include physical, psychological, social, and reproductive risks. If the incidence or duration of these risks or discomforts is known, it should be stated.*

 *(If applicable)* If I become pregnant during the course of the study, I will notify the principal investigator of this fact as soon as possible since the risks to the fetus or me are unknown.

There also may be risks and discomforts that cannot be foreseen.

*\*\*\****WHAT WILL HAPPEN IF THE RESEARCHERS LEARN NEW INFORMATION ABOUT THE STUDY?**

During the course of the study, I will be told about any new findings that might affect my willingness to remain in the study.

**WHAT WILL BE DONE TO PROTECT INFORMATION ABOUT ME?**

Every effort will be made to maintain the privacy of my study records.

***Protected Health Information*** *(If the study does not involve the use or creation of PHI, delete this heading.)*

*If the study does not involve the use or creation of PHI, delete this paragraph:* The researchers would like to use information about my health as well as information that identifies me. This information is referred to as “Protected Health Information” and is given special protections under The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996. The researchers must obtain my approval to use Protected Health Information.

If I participate in this research study, information that will be used and/or released may include the following:

*State what protected health and/or research information will be used/disclosed for the study using lay terminology. You must include all protected health and/or research information to be used for the research study. Examples include (remove or revise as needed to correctly reflect the data used or collected in the study):*

* Information from my medical records, such as my diagnoses, medications or other treatments I am receiving, laboratory test results, images (such as x-rays or other scans), reported symptoms, ability to function, and other observations made by health professionals as part of my medical care.
* Questionnaires about how I am feeling physically or emotionally
* Results of tests of my physical or mental function
* Results of laboratory tests or physical examinations given for purposes of the research study
* What study medications I have been prescribed, my use of the prescribed medication, and whether I am experiencing any problems that could be related to the study medication
* Other observations made by researchers during the course of the research study

Protected Health Information such as my name, address, date of birth, etc., that is stored electronically is kept in the REDCap system that includes all the protections of my health information required by HIPAA, including requiring users of my information to be pre-approved by the study director and a mechanism that will remove any information that identifies me in research data that is shared with other institutions. Access to study data will be limited to the members of the study team and will require study team members to submit 2 different access codes to use this data. REDCap/SIMS also tracks access to, and changes made to any study records. Kessler Foundation does not permit Protected Health Information to be kept electronically in documents that do not hide information that can identify me. Hard copy documents that contain my name, phone number, address, date of birth, etc., are kept in locked cabinets that only members of the research team can access.

*If no PHI is being used or created, replace the paragraph above with this version:* Information such as my name, address, date of birth, etc., that is stored electronically is kept in the REDCap system that includes all the protections of my health information required by HIPAA, including requiring users of my information to be pre-approved by the study director and a mechanism that will remove any information that identifies me in research data that is shared with other institutions. Access to study data will be limited to the members of the study team and will require study team members to submit 2 different access codes to use this data. REDCap/SIMS also tracks access to, and changes made to any study records. Kessler Foundation does not permit Protected Health Information to be kept electronically in documents that do not hide information that can identify me. Hard copy documents that contain my name, phone number, address, date of birth, etc., are kept in locked cabinets that only members of the research team can access.

***Sharing Protected Health Information*** *(If the research study does not involve use or creation of PHI, change this heading to “Sharing Research Information”)*

My health *(replace “health” with “research” if no PHI is being used or created)* information may be shared with people and researchers at this institution and associates of the sponsor(s), university, clinic or hospital who help with the research. The researchers may share this information with other people or organizations who are in charge of the research, others who are helping the research study to be done, those who pay for the research, or those who make sure that the research is done properly.

The study team may share a copy of this approval form and records that identify me with the following people or organizations:

* The Institutional Review Board - a committee that reviews research studies for the protection of the people who participate in research.
* Auditors from Kessler Foundation, the sponsor *(list name)* or government agencies responsible for the conduct of research to make sure the researchers are following regulations, policies, and study plans.
* Members of the study team, including *(insert study team member names)*
* *(If applicable)* The Finance Dept. of the Kessler Foundation, who will prepare subject payments for participation in the study
* Other organizations: *List all study-specific agencies, divisions, companies, labs, etc. who may see research data or PHI-if none, state 'NONE' or select/remove from following:*

FDA (United States Food and Drug Administration) - the government agency that reviews all research information for approval of new drugs and treatments for the public. *(REMOVE if not applicable)*

DHHS (Department of Health and Human Services) - the government agency that oversees and funds research involving human beings. *(REMOVE if not applicable)*

I have the right to look at my study information at the study doctor's office and to ask (in writing) for corrections of any of my information that is wrong.

*Language for blinded study-REMOVE if not applicable* Because this is a blinded study (neither I nor my doctor will know if I am receiving study drug or placebo, a sugar pill), I may not see my study information or request corrections to my study information until the study is completed.

If the findings from the study are published, I will not be identified by name. My identity will remain private unless its release is required by law.

***Removing Approval***

I can change my mind at any time and remove my approval to allow my information to be used in the research. If this happens, I must remove my approval in writing. Beginning on the date I remove my approval, no new information will be used for research. However, researchers may continue to use the information that was provided before I withdrew my approval.

If after signing this form, I want to remove my approval, I can contact the person(s) below. He/she will make sure the written request to remove my approval is processed correctly.

*(Insert Contact Person Name, their Title, Address, Phone and Fax numbers-include ONLY names associated with the study team)*

***Approval Expiration***

This approval has *(state time it will be kept, should match what is stated elsewhere - if there is no expiration or indefinite, state "no expiration date").* However, as stated above, I can change my mind and remove my approval at any time.

Questions should be directed to the research staff person who is reviewing this form with me. I can also call the Kessler Foundation Privacy Board – *John DeLuca, Ph.D., ABPP at (973) 324-3572.*

**WHERE ELSE CAN I FIND INFORMATION ABOUT THIS STUDY? *(remove If not applicable)***

*The following section should be included in the consent form if this is a clinical trial. IRB Policy 5036 requires that all IRB approved trials be registered on the web site <ClinicalTrials.gov>. The definition of a clinical trial is any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome. Medical intervention, as used here, means any intervention used to modify a health outcome.*

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/). This web site will not include information that can identify me. At most, the Web site will include a summary of the results. I can search this Web site at any time.

**WILL IT COST ANYTHING TO PARTICIPATE IN THIS STUDY?**

Taking part in this study may incur the following (increased/decreased) costs to me. Some of these costs may be covered by my health insurance provider.

*Indicate who is to bear the expense of tests, procedures, hospitalization, etc., done solely for research purposes. If participation increases/decreases the cost to the subject, so state.*

*OR*

There will be no cost to me for my taking part in this study.

**WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?**

*Include this statement if subjects are to be paid or reimbursed for participation. Specify the dollar amount and the payment schedule or other forms of reimbursement. Address the matter of prorating payments if the participant withdraws or if the investigator terminates the study.*

I will receive $\_\_\_\_\_\_\_\_\_\_\_ for taking part in this study according to the following schedule:

Note: If I receive $600 or more in a calendar year from Kessler Foundation for participation in research, I will have to provide my social security number to Kessler Foundation before I can be paid due to United States tax laws. I have the option to provide my social security number to the research team now, or wait until it is required for payment and provide it at that time. As described above, many actions will be taken to ensure that the confidentiality of my social security number is protected.

*\*\*\** **WHAT WILL HAPPEN IF I AM INJURED IN THIS STUDY?**

*(Choose the appropriate paragraph below)*

*FOR RESEARCH INVOLVING NO GREATER RISK OF PHYSICAL INJURY THAN THAT ENCOUNTERED IN EVERYDAY LIFE:*

Medical treatment will be arranged for me by the Principal Investigator for any physical injuries suffered as a direct result of my taking part in this study. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical treatment. All claims for out of pocket medical expenses for my medical treatment should be made to the Principal Investigator. I understand there will be no cost to me for the treatment. No financial payment will be provided to me other than my out of pocket medical expenses for physical injuries that happened as a direct result of my taking part in this study.

*FOR RESEARCH ON VOLUNTEERS INVOLVING MORE THAN MINIMAL RISK (for unsponsored research and sponsored research where the sponsor does not agree to reimburse subjects’ out of pocket medical expenses for care for study-related physical injuries ):*

If I take part in this study, I will be exposed to certain risks of physical injury. Medical treatment will be arranged for me by the Principal Investigator for any physical injury that occurs as a direct result of my taking part in this study. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical treatment. I understand that I will be responsible for any part of the treatment cost not paid by my insurance or managed care provider. No financial payment is offered to me in the event of physical injuries that happened as a direct result of my taking part in this study.

*FOR RESEARCH ON VOLUNTEERS INVOLVING MORE THAN MINIMAL RISK (for industry-sponsored research where the sponsor agrees to reimburse subjects’ out of pocket medical expenses for care for study-related injuries):*

If I take part in this study, I will be exposed to certain risks of physical injury. Medical treatment will be arranged for me by the Principal Investigator for any physical injury that occurs as a direct result of my taking part in this study. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical treatment. (*Name of sponsoring company*) will provide payment for the reasonable costs of medical treatment for the amount that my health insurance, managed care provider or other third party payer does not cover. All claims for costs resulting from medical treatment and not paid by my insurance should be given to the Principal Investigator, who will send the claims to (*Name of sponsoring company*) for payment made directly to me. No financial payment will be provided to me other than my out of pocket medical expenses for physical injuries that happened as a direct result of my taking part in this study.

**CAN I CHANGE MY MIND ABOUT PARTICIPATING IN THIS STUDY?**

I understand that taking part in this study is my choice, and I may refuse to take part, or may stop taking part in the study at any time without penalty or loss of benefits to which I am otherwise entitled. I also understand the investigator has the right to withdraw me from the study at any time.

*Describe the medical consequences (if any) of the participant’s decision to withdraw from the research. Indicate the procedures for an orderly termination of participation by the subject.*

**WHO CAN I CONTACT FOR MORE INFORMATION?**

If I have any questions about my treatment or the research procedures, I can contact:

*List the name, phone number, and office address of the investigator or other responsible individual who can be contacted by the participant in the research activity.*

*The principal investigator may include this paragraph if he/she believes it is applicable to this study:* If I have medical questions pertaining to this study, there is an on-call resident physician available at the Kessler Institute of Rehabilitation, who can be reached at 973-731-3600. I am aware that this on-call resident physician is not part of the study team and will not be familiar with the study but will be able to direct my study-related medical questions to the appropriate member of the study team.

If I have concerns only regarding my **rights as someone taking part in a research study**, I may contact Donna Servidio, IRB Manager, at 1-800-648-0296, extension 6972.

I will receive a copy of this consent form if I agree to take part in this research study.

**WILL INFORMATION ABOUT ME BE USED FOR OTHER RESEARCH STUDIES IN THE FUTURE?**

*Federal regulations require that consent documents address the use or non-use of data or biospecimens in future research studies. Select the option below that is most appropriate for your study.*

*Option 1 – No Future Use: If data or biospecimens collected in this study will not, under any circumstances, be used for purposes of any future research studies, include the following statement:* Information and *(if samples are used, specify type - blood, urine, etc, otherwise remove “and samples”)* samples collected in this study will be used for the purposes of this research study only. They will not be made available to researchers for use in future research studies. *Note: Many funding agencies now require researchers to make data available for future use by the research community. If that is the case for the sponsor of your study, do not choose Option 1.*

*Option 2 – Projects Involving Data Repositories: In some cases, the study to which the participant is consenting involves future use of data as an integral part of the study itself (examples include the Spinal Cord Injury and Traumatic Brain Injury Model Systems or other projects involving collection of data specifically for purposes of future use). In such cases, delete the section of this template labeled “USE OF INFORMATION COLLECTED IN THIS STUDY FOR FUTURE RESEARCH” and address use of data elsewhere in consent form (in discussion of procedures, confidentiality, or other appropriate sections). Include a description of how data may be used in the future, whether it will be used in identifiable form, and whether and how participants will be given the option to provide authorization for the use of that information.*

*Option 3 – Other Projects in Which Future Use Is Possible: Include the following section:* The information and *(specify type - blood, urine, etc – as applicable)* samples collected in this research study may be useful in future research studies.

In some future studies, the researchers may want to use my information and samples *(delete all references to samples from here forward if not applicable)* in a way that identifies me. This means that the researchers would have access to my name, contact information, medical record number, or other identifying information, and would know that I am the person who provided the information or samples. If, in the future, researchers wish to use information or samples *(if applicable)* that can identify me, they will be required to obtain my specific permission, in writing, for the use of my information or samples.

In other cases, researchers may want to use my information or samples in a way that does NOT identify me. In this situation, the researchers do not have access to my name (or other identifying information) and would not know that I am the person who provided the information or samples. In this section, I am being asked whether it is acceptable to me for researchers to use information or samples that do not identify me without asking for my specific permission at the time of the future research study.

[ ] **Yes**, I agree to allow information or samples collected in this study that do not identify me to be used in future research without my specific permission.

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ *Participant unable to sign due to arm impairments or consent by telephone*

[ ] **No**, I do not agree to allow information or samples collected in this study that do not identify me to be used in future research without my specific permission.

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ *Participant unable to sign due to arm impairments or consent by telephone*

*Option 4: If the options above do not fit the ways in which data may or may not be used in your study, you may compose new content for this section that addresses:* *(1) whether data may be used in the future (2) whether it may be used in identifiable form and (3) whether and how participants will be given the option to provide authorization for the use of that information.*

## SIGNATURE OF PARTICIPANT *(remove If consent will always be completed by phone)*

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Participant Name: Signature:

Date:

**SIGNATURE OF INDIVIDUAL PROVIDING SURROGATE CONSENT IF PARTICIPANT IS COGNITIVELY IMPAIRED *(remove if not applicable or if surrogate consent will always be completed by phone)***

I, (*name of surrogate*) , as the (*relationship to patient*)

 of (*name of patient*) , do consent to the above person taking part in this research study. I further state that all good faith effort has been made to contact all others in my level of priority to review this decision with them, and that no one has another opinion as to the above named person taking part in this study.

Signature: Date:

**SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL *(remove If consent will always be completed by phone)***

To the best of my knowledge, the participant, , (or his /her parent/legal guardian) has understood the entire content of the above consent form, and comprehends the study and its risks as well. The participant’s questions and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator Name: Signature:

Date:

## SIGNATURE OF WITNESS *(remove If consent will always be completed by phone)*

I was present when the researcher(s) described the study to the participant (or his/her parent or legal guardian) and I am a witness to the fact that the participant (or his/her parent or legal guardian) consented to participation in this study.

Witness Name: \_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date:

**VERBAL CONSENT IF THE PARTICIPANT LACKS UPPER LIMB FUNCTION TO COMFORTABLY WRITE (OR IF CONSENT IS OBTAINED VIA TELEPHONE) *(remove If not applicable)***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is unable to sign the consent form due to [check one]:

[ ] impaired arm function, or

[ ] consent being completed by telephone.

I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.

Signature of Investigator or Responsible Individual:

Name: Signature:

Date:

Signature of Witness:

Name: Signature:

Date:

*Complete if consent obtained by telephone:*

Would the participant named above like to be contacted for future research? [check one] ❒ Yes ❒ No

Would the participant named above like to be contacted for donation purposes? [check one] ❒ Yes ❒ No

**VERBAL CONSENT VIA SURROGATE IF CONSENT IS OBTAINED VIA TELEPHONE *(remove If not applicable)***

I certify that I have carefully explained the purpose and nature of this research to the participant’s surrogate in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has stated agreement with the following:

“I, (*name of surrogate*) , as the (*relationship to patient*)

 of (*name of patient*) , consent to the above person taking part in this research study. I further state that all good faith effort has been made to contact all others in my level of priority to review this decision with them, and that no one has another opinion as to the above named person taking part in this study.”

I am signing this consent form to document that that the above-named surrogate has given his/her consent to for the person named above to participate in this research study.

Signature of Investigator or Responsible Individual:

Name: Signature:

Date:

Signature of Witness:

Name: Signature:

Date:

Would the participant named above like to be contacted for future research? [check one] ❒ Yes ❒ No

Would the participant named above like to be contacted for donation purposes? [check one] ❒ Yes ❒ No

**SIGNATURE OF READER/TRANSLATOR IF THE PARTICIPANT DOES NOT READ ENGLISH WELL *(remove if not applicable)***

The person who has signed above, , does not read English well. I read English well and am fluent in *(name of the language)* , a language this person (his/her parent/legal guardian) understands well. I have translated for him/her (his/her parent/legal guardian) the entire content of this form. To the best of my knowledge, he/she (his/her parent/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and that these questions have been answered.

Reader/

Translator Name: Signature:

**ATTACHMENT – POLICY ON SUBSTITUTED (SURROGATE) CONSENT (*remove if not applicable*)**

**2.3 Individuals Able To Provide Effective Surrogate Consent for Participation In Research Studies**

**2.3.1** The following individuals may be considered capable of providing surrogate consent, in the following descending order of priority:

(1)      the guardian of the subject who has the authority to make health care decisions for the subjects;

(2)      the health care representative of the subject pursuant to an advance directive for health care;

(3)      the spouse or civil union partner, as applicable, of the subject;

(4)      the domestic partner, as defined in section 3 of P.L. 2003, c.246 (C.26:8A-3) of the subject;

(5)      an adult son or daughter of the subject;

(6)      a custodial parent of the subject;

(7)      an adult brother or sister of the subject;

(8)      an adult grandchild of the subject;

(9)      an available adult relative with the closest degree of kinship to the subject.

**VERIFICATION OF SPOUSE OR DOMESTIC PARTNERSHIP STATUS**

*(remove if not applicable)*

With respect to an individual from whom an investigator seeks to obtain surrogate consent to enroll a subject in a research study, and who claims to be a spouse or domestic partner but has a different last name than the subject, the investigator is responsible for verifying that such individual qualifies as a spouse or domestic partner for purposes of this policy. Spouse or domestic partnership status shall be verified by obtaining three (3) of the following pieces of supporting documentation:

|  |  |
| --- | --- |
| 1. Joint mortgage or lease  | ( ) |
| 2. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary under a life insurance policy | ( ) |
| 3. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary of retirement benefits  | ( ) |
| 4. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary under a will | ( ) |
| 5. Joint ownership of an automobile, joint bank account or joint credit account  | ( ) |
|  |  |
| Notwithstanding the foregoing, an individual may verify that he or she is the spouse of the subject by providing a valid marriage certificate without the need for the investigator to obtain copies of three of the above-listed documents.  | ( ) |
| In the case of a same-sex domestic partnership, domestic partnership status may be demonstrated by obtaining a copy of an Affidavit of Domestic Partnership from a Local Registrar of Vital Statistics in any municipality in the State of New Jersey (without the need to obtain copies of three of the above-listed documents), under which each domestic partner confirms joint responsibility for each other’s common welfare and the sharing of financial obligations. | ( ) |

Copies of the documents obtained as part of the process of verifying spouse or domestic partnership status shall be maintained in the research records, along with a copy of this Verification form which contains check-offs for each document that has been obtained and which has been signed and dated by the investigator and the spouse/domestic partner.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Investigator Print Name |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Spouse/Domestic Partner Print Name |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Investigator |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Spouse/Domestic Partner |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |