The Christ Hospital Health Network	**Institutional Review Board** **LOCAL CONTEXT REFERENCE SHEET**

Federalwide Assurance (FWA) number: FWA00000702

IRB Registration number: IRB00001448

Accreditation: AAHRPP reaccreditation June 19, 2018

Point of Contact:	**Steve Roberts, MD** **IRB Chairman**

State and Local Institutional Information

Legally authorized representatives who can provide consent for research participants:

The term legally authorized representative may include a person properly appointed by an advanced directive (such as a living will or declaration) or a durable power of attorney for health care, certain court appointed guardians, and next of kin identified below in certain circumstances. Documentation of a person's status as a legally authorized representative for a research subject is required and must be carefully evaluated to determine the validity of the appointment and scope, if any, of authority granted to make decisions regarding procedures involved in the research. For example, the existence of a durable power of attorney for health care or advance directive for health care may not create a legally authorized representative for any or certain kinds of research decisions. The Hospital's General Counsel's Office shall be consulted by the IRB and investigator if there are any questions related to legally-authorized representative consent.

Please describe any institutional policies, procedures or generally accepted ways you operationalize obtaining surrogate consent for adult individuals with impaired decision-making capacity:

Because decision-making capacity is task specific, some decisionally impaired individuals remain capable of making informed decisions for themselves regarding research participation. The capacity to obtain informed consent should be assessed in each individual, for each research protocol being considered. The determination of cognitive impairment does not automatically confer decisional incapacity on affected individuals. Especially in the earliest stages of cognitive impairment, many people with cognitive impairment remain capable of making a wide variety of decisions, including deciding whether or not to participate in research.

Procedures should be developed to enhance the possibility that subjects can consent for themselves. The setting in which consent is sought and the person seeking consent should be conducive to promoting a potential subject's ability to comprehend and appreciate what is being asked. Because there are no generally accepted criteria for determining competence to consent to research, the investigator must propose criteria for assessing potential subjects, and the criteria must be reviewed by the IRB. Criteria for determining competence vary according to the degree of risk or discomfort presented by the research procedures and the extent to which therapeutic gains can be anticipated.

There have been several approaches proposed to assess a subject's ability to give informed consent. Whatever approach is taken it is essential to document the plan in detail in the research study protocol. Examples may include:

- A screening standard mental status examination, such as the MINI-Mental Status Exam (MMSE). A MMSE score less than 24 suggests impaired cognitive ability and would require further assessment of the potential research subject's decision making capacity, or exclusion of that subject from the research.

- The development of a decision-making capacity assessment tool that is specific for the research project.

- A post-consent quiz documenting the subjects' knowledge of critical elements in the informed consent form (i.e., nature of the illness being studied, voluntary nature of participation, ability to withdraw at any time, consequences of withdrawing, possible risks and benefits of participation, procedures involved, time required, confidentiality, and whom to call with any questions).

- The study investigators may ask a physician/psychologist outside the research team to evaluate the potential subject's decision-making capacity.

3) Risk with No Direct Benefit

Research protocols that do not hold out a reasonable prospect of direct benefit to the participating subjects, and that expose subjects to more than a minor increase over minimal risk, should be offered only to those subjects who either retain decision making capacity or those who have indicated in an advance directive that they would be willing to be enrolled in such studies. Guardian or next of kin consent is rarely appropriate in these situations.

4) Limiting Risks

Investigators must include in the protocol a description of appropriate psychological or medical screening criteria to prevent or reduce the chances of adverse reactions to research. Investigators may need to be consulted to ensure that proposed research procedures will not be detrimental to the subject's non-research program or treatment plan. Consideration should also be given to the effects of separation from supportive family or friends, which may be a significant risk for this population.

5) Assent

Despite the fact that consent may be obtained from a legally authorized representative, the feelings and expressed wishes of an incompetent subject should still be respected. Participation in research is essentially an optional activity and even an uninformed or uncomprehending refusal should usually be respected. In the case of research involving more than minimal risk, the objection of an adult subject with limited decision-making capacity to provide assent should be binding, except in rare cases when the IRB makes and specifically documents that the intervention is expected to provide a direct health benefit to the subject and the intervention is available only in the context of the research.

Age of Majority in the state:

In Ohio, the legal age for consent is 18 years of age.

Special characteristics of your clinical site, your institution or the community:

We are a community hospital; a HIPAA-Covered entity; all research conducted The Christ Hospital must be reviewed by TCH IRB. TCH may rely on external IRBs for agreed upon protocols.

Conflict of Interest

Describe how the HRPP addresses conflicts of interest (COI) in the conduct of human research activities such as how information about potential conflicts of interest are identified, reviewed and processed by the IRB/HRPP in reviewing human research protocols:

Conflict of interest for all investigators and research staff who are directly involved in the treatment or evaluation of research subjects is reported to the IRB prior to initial IRB review and any changes in COI status since last review are reported during continuing review. If any COI is disclosed, the IRB determines whether or not a conflict exists. If the IRB determines that a conflict exists, the convened

board will decide on a management plan. This may include, but is not limited to: reduction or elimination of the conflict, disclosure of the conflict in the informed consent document, separation of financial and research decisions, additional research oversight, modification of role in the research, etc.

Specify if the IRB or another institutional committee receives COI disclosures:

Each protocol submitted to the IRB for review must be accompanied by the Disclosure of Financial Interest form. The form must be submitted by all investigators and research staff who are directly involved in the treatment or evaluation of research subjects in the study. The IRB may require that researchers submit any additional information it believes necessary to make a determination regarding potential COI.

TCH Informed Consent Language:

The following must be addressed in the informed consent form for research in which TCH is relying on another IRB. Ensure that the items below are tracked in your submission for ease of review.

1. Ensure that The Christ Hospital Principal Investigator (first and last name) and a 24-hour emergency contact number is listed on the first page of the consent document.

2. Ensure language included in the case of research-related injury, including source of funds for payment of treatment costs, if applicable.

3. When HIPAA Authorization is required, ensure HIPAA language is included in the ICF. When it is not included in the ICF, the following language may be used in the ICF to replace the use of a standalone HIPAA authorization form:

   "HIPAA Authorization
   The federal Health Insurance Portability and Accountability Act (HIPAA) requires your permission in order to use health information about you that is created or used as part of this research. This permission is called an Authorization. Your research record, related information from your medical records, results of laboratory tests, and both clinical and research observations made while you take part in the research will be used. This information will be recorded on case report forms that will be maintained and stored in a confidential manner in the research office.

   Your health information will be used to conduct the study, to monitor your health status, to measure the efficacy of the testing protocols, to determine research results, and possibly to develop new tests, procedures, and commercial products. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure regulations, policies, and study plans are being followed. You can see a copy of your study records only after the study ends to ensure the reliability of the study.

   To meet regulations or for reasons related to this research the study investigator may share a copy of this consent form, your study information, and medical records that identify you with the following people or groups: the study sponsor or designee(s), the IRB or its designee(s), and federal and state agencies (such as the FDA, DHHS, NIH, and other US and non-US government bodies that oversee or review research).

   Your health information may be further shared by the groups above. If shared by them, the information will no longer by covered by this Authorization. These groups are committed to keeping your health information confidential.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can cancel this Authorization, at any time, in writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. Standard medical care and any other benefits to which you are otherwise entitled will not be affected. Cancelling your Authorization only affects uses and sharing of information after the study investigator gets your written requests. Information gathered before then may be used and given to others.

If you sign this informed consent form, you are giving authorization for the use and disclosure of your health information for purposes of this research study. You do not have to give this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you chose not to sign this form. However, you will not be able to participate in the study."

4. Ensure there is contact information for subjects to have a pathway to address concerns.
   TCH preferred language- "For questions regarding your rights as a research participant or to discuss problems, complaints, or concerns about a research study, please contact The Christ Hospital Patient Relations Department at 513-585-1200."

5. If a local (TCH) investigator has a financial interest in this research, ensure that IRB-approved required disclosure is inserted, as applicable, by reviewing IRB

6. The informed consent form signature page must include a signature and date line for the participant or legally authorized representative, if applicable, as well as the person obtaining consent.