IRB Guidance for obtaining consent from a Legally Authorized Representative (LAR or Surrogate) or permission from a Parent or Legal Guardian during the COVID-19 pandemic.

Note: This guidance posted in both PDF and WORD format, so that signature lines can be copied from this document and placed in the consent form.

When planning for surrogate consent, please work with hospital administration before making plans to reach out to family members who are not able to be with their loved ones, to ensure contact is done in the most respectful manner.

For the purposes of Downstate Policy IRB-01, a *legally authorized representative (LAR, personal representative or legally empowered representative or surrogate)* is an individual, judicial, or other body authorized under applicable law to provide consent on behalf of an adult prospective research participant for the research participation of an adult who is cognitively impaired and unable to provide consent. A *LAR* is an individual authorized to provide permission on behalf of a prospective research participant to be involved in the research.

Base the designation of a *LAR* in individual cases on the presence or absence of a power of attorney, living will, or health care proxy (as above).

The informed consent process must comply with institutional policy. For research at Downstate, this includes Policy CONS-01. Only one person from the list below, from the class of highest in priority may authorize the research when persons in prior classes are not reasonably available. The surrogate must be willing and competent to act. The person who is designated may designate another person on the list to be surrogate, as long as no one in the class higher in priority objects. However, if one surrogate does not provide consent, the investigator must honor that decision and not seek consent from another surrogate on the list.

- Healthcare Agent (legal guardian) with authority to provide consent to healthcare decisions (highest priority)
- Guardian authorized to decide about health care, pursuant to Article 81 of the NYS Mental Hygiene law
- Spouse or domestic partner (provided there is no legal separation)
- Adult child (son or daughter)
- Parent
- Adult sibling (brother or sister)
- Close adult friend (must be 18 years or older and present a signed statement of relationship to a patient/participant) (lowest priority)

For Kings County Policy, see: NYC H+H Kings County Human Subject Research Protections Program

For more information on obtaining consent from COVID-19 patients refer to the IRB guidance for "Eliminating hazards associated with COVID-19". The latest COVID-19 guidance materials are posted at: https://research.downstate.edu/covid-19-updates.html

When requesting parent or legal guardian permission for a child, add the following at the beginning of the consent form:

If you are providing permission for a child to be in the study, the terms "you" and "your" refer to your child.

When obtaining consent from a surrogate for a cognitively impaired adult, add the following at beginning of the consent form:

If you are deciding if an adult can be in this study, the terms "you" and "your" refer to the adult who cannot make the decision. Please consider the wishes and beliefs or the best interests of this person. If the participant's ability to make decisions is regained after you give your permission for him/her to be in the study, he/she will be asked to provide his/her consent.

BELOW ARE THE SIGNATURE LINES THAT MAY BE USED TO OBTAIN SURROGATE CONSENT AND PARENTAL/LEGAL GUARDIAN PERMISSION. DELETE THE ROW(S) FROM THE TABLE IF NOT APPLICABLE (I.E., LINES PERTAINING TO CHILDREN, INDEPENDENT CONSENT MONITOR, AND INTERPRETERS)

SIGNATURES:

You have read this document and were told of the risks and benefits and a member of the research team answered questions to your satisfaction. A member of the research team will answer any future questions. You voluntarily agree to join the study and know that you can withdraw from the study at any time without penalty. You do not waive any legal rights by signing this form.

You will receive a signed copy of this document.

_____ **Print the Name of the Child (Under the age of 18 only)** ☐ Check if the Child is a Ward. *When enrolling a Ward, an Independent Consent Monitor must sign this consent form below.*	_____ **Signature of the Child providing assent (ages 13-17 only)**	_____ **Date Signed**
_____ **Print Name Minor** Check type of minor: ☐ *Emancipated Minor** ☐ Married Minor** ☐ Pregnant Minor** **An emancipated minor is defined as either a person 16 years or older and living independently from his/ her parents or a minor who is a parent him/herself.* ***An Independent Consent Monitor must also sign this consent form below.*	_____ **Signature of Minor**	_____ **Date Signed**
_____ **Print Name of Parent or Legal Guardian**	_____ **Signature of Parent or Legal Guardian**	_____ **Date Signed**
_____	_____	_____

Print Name of 2nd Parent or Legal Guardian (if applicable) or check one of the boxes below: ☐ Not applicable because the 2nd parent/legal guardian is not reasonably available, deceased, unknown, or incompetent. ☐ Not applicable because only one parent has legal responsibility for the care and custody of the child.	**Signature of 2nd Parent or Legal Guardian (if applicable)**	**Date Signed**
_____ **Print Name of Independent Consent Monitor** (Required when enrolling a Minor without Parental Permission or when enrolling a Child who is a Ward) An Independent Consent Monitor may not be a member of the research team.	_____ **Signature of Independent Consent Monitor**	_____ **Date Signed**
_____ **Print the Name of the Adult Research Participant** (18 years of age or older)	_____ **Signature of the Adult Research Participant**	_____ **Date Signed**
_____ **Print the Name of the Adult Research Participant for whom you are providing permission to be in the study** (18 years of age or older) _____ **Print Your Name as the Surrogate and indicate your relationship to the research participant.**	_____ **Signature of Surrogate**	_____ **Date Signed**
_____ **Print Name of Interpreter** (Applicable when the person authorizing the research has limited English proficiency or uses sign language)	_____ **Signature of Interpreter (if applicable)**	_____ **Date Signed**

NOTE: The interpreter may also serve as a witness, impartial witness, or impartial consent monitor, when applicable.		
_____ **Print Name of Witness** *(Required when obtaining surrogate consent or when obtaining remote consent)* ☐ Check if remote consent (conference call or video conference). ☐ Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered. ☐ Check if participant singled consent to participate (i.e., gave thumbs up). Describe: _____ _____	_____ **Signature of Witness**	_____ **Date Signed**
_____ **Print Name of Investigator Obtaining Informed Consent** ☐ Check if remote consent (conference call or video conference). ☐ Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered. ☐ Check if the informed consent document was not retained, due to contamination of the document by infectious material. ☐ Check to confirm participant was asked to mail, fax, or e-mail a copy of the signed consent to the research team.	_____ **Signature of Investigator Obtaining Informed Consent** In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be, associated with this research, and to answer any further questions.	_____ **Date Signed**