McLaren HEALTH CARE

Human Research Protections Program

Consenting Process & Documentation Checklist

Subject Name	DOB	Subject ID
Study Title		

- Instructions: Review each consent form and answer the following questions to ensure your consent process was performed and documented*. Only research staff that have completed required training, received MHC IRB approval and delegated by the primary investigator can perform the consenting process.

Consent Process Actions MHC_RP0115	
Subject has a LAR: ☐ No ☐ Yes, legality verified: ☐ No ☐ Yes LAR name: ☐ Subject is a child and the parent is consenting for child AND child is assenting if age appropriate with IRB approved assent form. Parent(s) name:	
☐Yes ☐ No ☐ NA	Subject/LAR was given a copy of the most recent IRB approved ICF and HIPAA authorization to read?
☐Yes ☐ No ☐ NA	Subject/LAR offered to take ICF/HIPAA authorization home to read and return for a later discussion?
☐Yes ☐ No ☐ NA	Subject/LAR was given adequate time to read the ICF/HIPAA authorization in a quiet location:
☐Yes ☐ No ☐ NA	Subject/LAR was given time to discuss the study with others who were present during the consent process. Persons allowed by subject/LAR to be present:
☐Yes ☐ No ☐ NA	The consent was reviewed with the subject/LAR page by page, in *a language the* subject could understand? The following items were reviewed with the subject, but were not limited to: • Purpose of the study, including the investigational nature and follow-up requirements • Risks and benefits • Alternative options of treatment • Right to withdraw without penalty • Participation voluntary • Confidentiality and HIPAA privacy authorization
☐Yes ☐ No ☐ NA	Subject/LAR was directed to section on ICF about contacting the IRB and Principal Investigator should he/she later have questions and/or complaints?
☐Yes ☐ No ☐ NA	Subject/LAR was questioned for understanding using open-ended questions and was consented in a private area in order to maintain confidentiality?
☐Yes ☐ No ☐ NA	All of the subject/LAR questions were answered?
☐Yes ☐ No ☐ NA	Subject/LAR voluntarily agreed to participate in research study without undue influence?
☐Yes ☐ No ☐ NA	ICF/HIPAA authorization was signed and dated (and initialed and timed if indicated on consent) by the subject and/or legally authorized representative and approved study personnel?
☐Yes ☐ No ☐ NA	If ICF has a signature line for witness, the witness signed and dated ICF? [*the witness must be impartial (someone not connected with the research or the study team*]
☐Yes ☐ No ☐ NA	ICF/HIPAA authorization has no modifications or strike-through. The research staff did not hand-write or adds to ICF/HIPAA to reflect change in content of IRB approved forms.
☐Yes ☐ No ☐ NA	A copy of the signed completed ICF/HIPAA authorization was *given* to the subject/LAR?
☐Yes ☐ No ☐ NA	Consent process was completed *before* any study procedures performed?
☐Yes ☐ No ☐ NA	The date the subject, witness, and person authorized to obtain informed consent signed the ICF was the same date? If not, please explain*

Attach additional notes if necessary.

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_____ _____ _____

Signature and Title of Person Obtaining Consent **Date** **Time**