***Instructions*: Add information included in this document to the NCI IRB approved consent document.**

**Delete instructions highlighted in blue before submission to NCI CIRB.]**

Subject name: Subject date of birth:

|  |  |
| --- | --- |
| **Abbreviated Study Title for Subject Use / Título abreviado del estudio para uso del participante** | **[*Instructions*: *Include abbreviated study tile only if provided by sponsor – delete row in chart if not provided. Do not duplicate below.***] |
| **Official Study Title (which is used for internet search) / Título oficial del estudio (para uso en búsquedas en internet)** | <<Official Study title (must match protocol exactly)>> [***Instructions***: ***Include study title only in this table – do not duplicate full study title below.***] [INCLUDE sponsor protocol number] |
| **AAH Study Investigator /** **Investigador del estudio de AAH** | <<insert AAH principal investigator name>><<AAH PI’s address>><<insert AAH PI’s phone number (daytime)>> <<Insert AAH PI’s 24-hour contact number/after hours number if different from above; otherwise delete>> |
| **Sponsor / Patrocinador** | <<insert name>> |

# Advocate Aurora Health

*If not already included in CIRB consent, insert this title if study includes children as subjects***: PERMISO / CONSENTIMIENTO / ASENTIMIENTO DE LOS PADRES PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN**
 **OR**

*If not already included in CIRB consent, insert this title if study includes Adult subjects only*: **CONSENTIMIENTO PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN**

¿Dónde puedo conseguir más información? <<Add this language to the contact section where the IRB of record contact is provided>>

Comuníquese con el investigador principal de AAH al número de teléfono indicado arriba. Si tuviera una pregunta, problema, preocupación, información, comentario o queja en general, y desea hablar con alguien de Advocate Health Care que no esté afiliado al estudio, puede llamar al Human Protections Administrator en la oficina del RSPP de Advocate Aurora al 414-219-7744 (fuera de Milwaukee: 877-219-7744) o enviar un correo electrónico a IRBoffice@aah.org.

**[***Instructions*: *Add the following to the* ***Signature*** *section if not already included]*

***[****Instructions****:*** *Include the following section if using a Legally Authorized Representative to enroll potential subjects into the research.* ***The use of LAR in the research must be approved by the IRB.]***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Subject / Nombre del participante en letra de imprenta

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of individual legally authorized (LAR) to
consent to the named subject’s general medical care / Nombre en letra de imprenta de la persona legalmente autorizada (LAR) para dar su consentimiento para la atención médica general del participante nombrado

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of individual legally authorized (LAR) to Date / Fecha
consent to the named subject’s general medical care / Firma de la persona legalmente autorizada (LAR) para dar su consentimiento para la atención médica general del participante nombrado

*[Instructions: Include this section if including children in the research study. To be signed by the parent/LAR]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Child/Subject / Nombre en letra de imprenta del niño/participante

Signature of parent(s) or individual legally authorized Date / Fecha

(LAR) to consent to the child’s general medical care / Firma del padre, la madre o la persona legalmente autorizada (LAR) para dar su consentimiento para la atención médica general del niño

*[Instructions: Include this page only if including children in the research study. To be signed by the child/adolescent subject.]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Child (if able to give written assent, otherwise write “NA”) /

Nombre del niño en letra de imprenta (si puede dar su asentimiento escrito; si no puede, escriba “NA”)

Signature of Child / Firma del niño Date / Fecha

*[Include this section only if the situation calls for the use of a witness. For example when the subject is blind, illiterate, does not speak English or for other purposes required by the IRB. The witness must be present for the entire consent discussion, and the witness signature means that the information in this document was presented to the subject, and the subject had all of his/her questions answered.]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Witness (if applicable) / Nombre del testigo en letra de imprenta (si es el caso)

Witness signature (if applicable) / Firma del testigo (si es el caso) Date / Fecha

**Signature of person(s) conducting the informed consent discussion**

Name of person obtaining informed consent (print) Title Phone number

Signature of person obtaining informed consent Date Time (optional)

***RISK/BENEFIT/ALTERNATIVE DISCUSSION***

*[Instructions:* ***THIS SECTION MUST BE PLACED LAST IN THE CONSENT DOCUMENT AFTER ALL OTHER SIGNATURES****. Include this section* ***ONLY*** *if the study is conducted in WI, and includes a clinical intervention -discussion and documentation by a physician investigator is required by WI state law and AAH Legal.]*

Name of person providing this information (print) Title

Signature of person providing this information Date

The above signature section must be completed by a physician investigator if the study is being conducted in WI, and includes a clinical intervention for which state law requires a physician to provide risks/benefits/alternatives for that intervention.

**Risk/Benefit/Alternatives Discussion**

Prior to the subject providing informed consent, I explained and discussed with the potential subject or his/her legally authorized representative as appropriate

* The nature of the research
* Potential risks and benefits
* The available alternate treatments and the benefits and risks of each

THIS PAGE IS FOR DOCUMENTATION ONLY. IF GIVEN TO SUBJECTS, IT MAY BE BLANK.

**FILE A SIGNED COPY OF THIS FORM IN THE PATIENT’S MEDICAL RECORD (if applicable).**

**Keep the original in the investigator’s research records.**

**v.05.06.21**