iStar HS or UP ID#: Date:

Principal Investigator Name

Email address

Amendment Information

AM1.1. * **Identifier for this Amendment:**

AM1.2. Type of Amendment (check all that apply) and complete the corresponding section below:

Type
☐ Drug or Device (AM3)
☐ Informed Consent and/or Addenda (AM5)
☐ Procedures and/or Protocol (AM8)
☐ Risks/Harms (AM11)

AM1.3. Will the changes you are making affect the accuracy of the study abstract?

◯ Yes ◯ No

AM1.6. Has the risk/benefit ratio changed?

◯ Yes ◯ No

AM3

Drug or Device

This section is required if you indicated this amendment involves Consent Form or Consent Form Addendum changes (Question AM1.2.) Attach any/all documents applicable to this section.

AM3. Describe each of the drug or device changes and provide a rationale for the change. Describe any additional risks associated with the changes to the drug or device.

AM5

Informed Consent and/or Addenda

This section is required if you indicated this amendment involves Consent Form or Consent Form Addendum changes (Question AM1.2.) Attach any/all documents applicable to this section.

AM5.1. Please summarize each change to the Informed Consent process, forms, and/or documents and provide a rationale for the change:

AM5.2. Have you ever enrolled anyone in this study?

◯ Yes ◯ No

AM5.3. If you answered yes above, should enrolled or previously enrolled participants be informed of the changes?

◯ Yes ◯ No

AM5.3.1. If you answered no to AM5.3, please explain why participants need not be informed.

AM5.3.2. If you answered yes to AM5.3, how do you plan to inform them?

- ☐ Verbal Disclosure
- ☐ Script / Information Sheet
- ☐ Addendum Informed Consent / new (additional) Informed Consent
- ☐ Revised Informed Consent / Information Sheet

AM5.3.3. Explain who will do this and when it will be done:

AM8

Procedures and/or Protocol

This section is required if you indicated this amendment involves changes to Procedures and/or the Protocol (Question AM1.2.) Attach the revised protocol with this document and submission. If applicable (and available) also include the sponsor's Summary of Changes.

AM8. Please describe the nature and rationale for changes to the protocol, procedures or methods:

AM11

Risks / Harms

This section is required if you indicated this amendment involves changes to the Risks or Harms. Attach any/all documents applicable to this section.

AM11. Please describe each of the changes to the Risks/Harms of the study and provide a rationale for the change.