**Section 1: Study Information:**

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| **Date:** |  |
| **Principal Investigator:** |  |
| **Protocol Title:** |  |
| **IRB Number:** |  |
| **Study Sponsor:** |  |
| **Expiration Date:** |  |
| **Date of Initial Approval by the original IRB:** |  |
| **Name of Previous IRB:** |  |

**Section 2: Indicate the documents that are being submitted for review (Check all that apply):**

Most recent version of protocol

Most recent IRB approved version of the consent form

Revised version of consent form(s) with HRP-542c UMN standard language requirements (enrolling studies only)

Recruitment materials currently being used

Investigator’s Brochure, if applicable

Curriculum Vitae for principal investigator

Initial IRB Approval Documentation

FDA documentation of IND/IDE/HDE assignment

New risk or benefit information not previously reported to an IRB

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| **Reason for Transfer to UMN IRB:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

Summary of Study Activity Prior to Transfer Request

**Section 3: Study status information for research conducted at the Principal Investigator’s site:**

I have attached supplemental information that addresses questions 1 through 6 directly (Upload attachment in ETHOS and skip Section 3).

1. Has the study begun? Yes  No
2. Total subjects enrolled (signed consent form):
3. Do you intend to enroll any more subjects? Yes  No
4. Are any subjects currently in active follow-up? Yes  No
5. Are any subjects still on active treatment? Yes  No
6. Is the study completed, but not yet closed out by the sponsor? (Have all subjects at your site completed their final visit?) Yes  No

**Section 4: Summary of any significant study related risk information or concerns:**

1. Has any new risk or benefit information become available that was not reported to the previous IRB? .. Yes\*  No

\*If yes, submit the new risk or benefit information for review with your transfer request.

1. Have there been any unanticipated problems[[1]](#footnote-1) (other than new risk information described in response to question 7 above) related to this research? Yes\*  No

\*If yes, describe the problem and actions taken, if any, as a result of the unanticipated problem (attach a separate page if necessary) and submit **any IRB correspondence related to the unanticipated problem**.

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1. Have there been any subject complaints related to this research? Yes\*  No

\*If yes, describe the complaint and actions taken, if any, as a result of the complaint, and submit any IRB correspondence related to the complaint (attach a separate page if necessary).

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1. Did the previous IRB ever suspend or revoke approval of this research?

Yes\*  No

\*If yes, provide information on the reason for the Board action, the steps taken to resume the research and copies of any IRB correspondence related to the suspension (attach a separate page if necessary).

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**Signature and Attestation Statement of Principal Investigator**

As Principal Investigator, I hereby attest to the accuracy and completeness of the information included in this transfer request. I fully understand my investigator responsibilities as outlined in the [Investigator Manual](https://research.umn.edu/units/irb/toolkit-library/manuals). I understand that I am responsible for notifying key parties (e.g. Sponsor) of this transfer in IRB oversight request and subsequent UMN IRB review determination. I have read and understand my institution’s policy on conflict of interest. I will personally conduct or oversee those who conduct this research. I understand that it is my responsibility to protect the rights, safety and welfare of the subjects involved in this research and ensure research is conducted in an ethical manner and in accordance with all laws, regulations, or policies applicable to the protection for human research subjects and requirements and determinations of the IRB.

Date:

1. Unanticipated problems include any incident, experience, or outcome that meets **all** of the following criteria:

   (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

   (2) related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

   (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. [↑](#footnote-ref-1)