**UNC IRB Protocol Exception Request Form:**

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| IRB Study #: |  |
| PI Name: |  |
| 1. The protocol exception represents a:
 | [ ]  Single Subject Protocol Exception [ ]  Request to continue intervention/ interaction with currently enrolled subjects during lapse of IRB approval |
| 1. State the protocol exception being requested
 |       |
| 1. Provide a rationale for this request
 |       |
| 1. Does the protocol exception affect the safety of subject?
 | [ ]  No[ ]  Yes |
| *For both yes and no responses,* provide justification regarding your response. |  |
| 1. Does the protocol exception affect the integrity of the study data?
 | [ ]  No[ ]  Yes |
| *For both yes and no responses,* provide justification regarding your response. |  |
| 1. Does the protocol exception require a different informed consent **form or process** than the one currently approved by the IRB?
 | [ ]  No[ ]  Yes |
| *If yes*, explain the consenting process you will use in relation to this protocol exception and if applicable, attach any proposed addendum to the informed consent that will be used. |      [ ]  Proposed addendum to the informed consent attached |
| 1. Will data collected as a result of the exception be analyzed in a different manner from other collected data?
 | [ ]  No[ ]  Yes |
| *If yes*, explain how it will be analyzed differently. |       |
| 1. Have you previously requested this exception for this same reason?
 | [ ]  No[ ]  Yes |
| *If yes*, explain if a previous exception was requested for the same reason. Explain why the IRB should approve another one-time protocol exception, rather than require a permanent change to the protocol (i.e., protocol amendment/ modification). |       |
| ***NOTE: Documentation of approval by the sponsor is a requirement if this is an externally sponsored protocol. Upload documentation as Attachment.***1. Identify any external organizations (i.e., sponsor or agencies) that have already approved of this request and provide documentation, if applicable.
 | [ ]  FDA[ ]  NIH[ ]  Industry Sponsor[ ]  other      [ ]  Approval documentation attached |
| 1. For subjects not meeting inclusion/exclusion criteria, a physician uninvolved in the care of the subject must provide a written endorsement for the inclusion of the ineligible person because alternatives are limited to less favorable options.

***NOTE: This is a requirement for all investigator-initiated protocols***  | [ ]  N/A[ ]  No[ ]  Yes[ ]  Written endorsement attached (e-mail correspondence is acceptable) |
| *If yes*, provide the name and department of the individual who provided an independent endorsement:  |       |
| PI Signature:  | Date:  |
| *To be completed by the IRB when this form is submitted to the IRB outside of IRBIS*IRB Determination:[ ]  Request represents *no greater than* minimal risk and/or no more than a minor change[ ]  Approved by expedited review OR[ ]  Request represents *greater than* minimal risk and/or more than minor changes [ ]  Required full board review. To be reviewed by the full board on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Date)Reviewed and approved by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Chair (or designee) (Date) |

UNC IRB Version April 20, 2017