**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) | | | |

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