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| Appendix: Exception request | |
| When to Use this Form Use this form to provide additional information related to the nature of an exception request. Attach this form and any relevant documents in the SUPPORTING DOCUMENTS section of the RNav Reportable New Information electronic form. | |
| Summary of exception and rational. Indicate the date the exception will need to take place. |  |
| Name the Sponsor and or agency that has been notified of the exception (independent DSMB, FDA, NIH). Note, for investigational drug or device studies, the sponsor is responsible for notifying the FDA. | Sponsor  received approval  DSMB or DSMC  received approval  FDA,  received approval  Approval attached in Supporting document section |

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| Additional Information | |
| The exception changes the risks of participation | YES, indicate how       and state if the risks change for this subject(s) or for all subjects enrolled in the study.  NO |
| The exception changes the benefits of participation | YES, indicate how  The benefits change for this subject(s)only  The benefits change for all subjects enrolled  NO |
| Is the change necessary to eliminate an immediate hazard to the participant | YES, explain how  NO |
| Does the exception require a different consent form or an information sheet from what is currently approved for use by the IRB | YES, ensure the document is uploaded in the CONSENT section  NO, explain why |