

**Section I: To be completed by the research team**

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| NAME OF INSTITUTION*(select one)* | [ ]  **University of North Carolina at Chapel Hill (UNC-CH) (including UNC Medical Center and UNC School of Medicine), or** [ ]  **University of North Carolina Health Care Network Entity (UNCHC NE)**  |
| PRINCIPAL INVESTIGATOR |       |
| PROTOCOL NUMBER |       |
| SPONSOR NAME |       |

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| **UNC-CH Required Documents** |
| 1. This Coversheet
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| 1. UNC *IRB Permission to Register* letter
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| 1. Office of Industry Contracting email documenting subject injury language concordance
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| 1. UNC COI Finalization letter (if a COI has been identified) or No COI identified [ ]
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| **UNCHC NE Required Documents** |
| 1. This Coversheet
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| 1. UNC *IRB Permission to Register* letter
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| 1. *Subject Injury Language & COI Validation* form
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 **Section II: Central IRB Processing Instructions**

* This study is being submitted by an investigator at The University of North Carolina at Chapel Hill or affiliated UNC Health Care Network Entity site and should be reviewed under the terms of the UNC Master Service Agreement.
* Do not process if any of the required documents are missing.
* All inquiries should *first* be directed to the UNC or UNCHC NE Study Coordinator or Regulatory Associate.
* If the HIPAA language is embedded into the consent form, the Central IRB should review. Stand-alone HIPAA forms *should not* be submitted for review.

UNC IRB CONTACT for processing questions: central\_irb@unc.edu
UNC IRB CONTACT for compliance issues irb\_compliance@unc.edu

*Version April 3, 2017*