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| HRPP | Title: FDA Submission | |
| Form #: FM 410 | Version Date: 18 July 2019 |

# Combat Capabilities Development Command (CCDC)

# Army Research Laboratory (ARL)

# Human Research Protection Official (HRPO)

**INSTRUCTIONS:** The following information is required by the HRPO for review of DoD/CCDC ARL sponsored FDA studies.

Provide the following items for IND review: Brochure or Informational sheet, Form FDA 1572 for all investigators, any correspondence from U.S. FDA, and IND number assignment.

Provide the following items for Device (IDE) review: Device manual and summary of experience with device.

Submit this completed form and the project documents to the electronic mailbox [usarmy.apg.ccdc.mbx.arl-irb-office@mail.mil](mailto:usarmy.apg.ccdc.mbx.arl-irb-office@mail.mil). For questions regarding CCDC ARL HRPO review requirements or assistance in completing this form, email [usarmy.apg.ccdc.mbx.arl-](mailto:usarmy.apg.ccdc.mbx.arl-)[irb-office@mail.mil](mailto:usarmy.apg.rdecom.mbx.arl-irb-office@mail.mil) a staff member will contact you.

1.

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| **Study Information** | |
| Principal Investigator (PI) Name |  |
| Title of Study |  |
| PI Phone # |  |
| PI Email |  |
| PI Address |  |

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| --- | --- | --- | --- |
| **Study Type** | | | |
| * Drug | * Medical Device | * Biological Product | * Use of Existing Specimens |
| * Nutritional   Supplement | * IND | * 10 USC 980 Waiver | * ORSG Sponsored   Product |
| * Non-Medical Device | * IDE | * Cadaveric Specimens | * 10 Approval |

2.

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| **Drugs, Biologics or Dietary Supplements** | | | | | | | |
| Name |  | | | | | | |
| Composition |  | | | | | | |
| Product Source |  | | | | | | |
| Dosage form |  | | | | | | |
| Packaging description |  | | | | | | |
| Labeling  description |  | | | | | | |
| Dose Range |  | | | | | | |
| Dose Schedule |  | | | | | | |
| Administration Route |  | | | | | | |
| Is the drug, biological product or dietary supplement U.S. FDA approved? | | | | | | * Yes | * No |
| Will the drug, biological product or dietary supplement be used in accordance with the labeling and indications as reviewed by the U.S. FDA? | | | | | | * Yes | * No |
| Will the study determine the safety or effectiveness of the drug, biological  product or dietary supplement? | | | | | | * Yes | * No |
| Product Name | |  | | | | | |
| IRB/Institution Name | |  | | | | | |
| Was IND required? | | * Yes\* | * No | \*List IND# |  | | |
| Who holds the IND? | |  | | | | | |

3.

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| **Devices** | | | |
| Is there a device being used in the study? | | * Yes | * No |
| Is the focus of the study to assess the use of the device? | | * Yes | * No |
| Device Name |  | | |
| IRB Name |  | | |
| Medical Device Risk Determination |  | | |
| IDE Number |  | | |
| Who holds the IDE? |  | | |

Click here to enter a date.

# (Principal Investigator’s Signature) Date