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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. For questions regarding CCDC ARL HRPO review requirements or assistance in completing this form, email usarmy.apg.ccdc.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 |  |
| Labelingdescription |  |
| 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, biologicalproduct 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