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| HRPP | Title: HRPO Secondary Research Involving the Use of Data/Specimens  Submission | |
| Form #: FM 409 | Version Date: 18 July 2019 |

# Combat Capabilities Development Command (CCDC)

# Army Research Laboratory (ARL)

# Human Research Protection Official (HRPO)

PURPOSE: All CCDC ARL supported secondary research involving human data, records, human tissue, or human specimens (hereafter referred as data/specimens) must be reviewed for compliance with Federal and Department of Defense (DoD) human subjects protection requirements and approved by the HRPO prior to implementation.

This CCDC ARL HRPO submission form should be completed when the DoD-funded research activities are limited to access, use, and analysis of data/specimens. HRPO review includes assessing the source of the data/specimens and whether the initial manner and consent for the data/specimen collection permits use in the DoD funded research protocol. HRPO must review the use of post-mortem specimens for compliance with the US Army Cadaver Use Policy.

**Instructions**. Enter project information in the spaces provided to complete all applicable sections of the form. 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.

# Checklist of Documents to Be Submitted with this Form:

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| Institutional consent for surgical/care procedure (if applicable) |
| Informed Consent Form (if data/specimens were collected for research purposes) |
| Institutional Review Board(IRB) Determination for the DoD funded activities (if applicable) |
| Protocol(s) for ARL/DoD funded research |
| Other: |

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

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| **Data/Specimens Information** |
| Describe the number and type of data/specimens you will use and or access below, be specific. |
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| Where will you obtain/access the data/specimens? Please be specific (i.e., identify the providing institution, repository, colleague, etc. |

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| Does this DoD-funded research involve secondary use of data/specimens  obtained from a research protocol in which subjects provided informed consent for the collection of their data/specimens? | | | | * Yes ^ | * No \* |
| ^ If yes, i*nclude the collection consent form in your submission for review.* | | | | | |
| \* If no, explain below *(e.g. specimens collected for clinical purposes).* | | | | | |
| If the data/specimens obtained did not come from a research protocol, did they come from any of the following sources *(Check all that apply and include any clinical consent forms in your*  *submission for review)* | | | | | |
| Repository | * Yes | * No | Surgical Discard | * Yes | * No |
| Clinical Registry | * Yes | * No | Deceased Individuals (e.g., autopsy, tissue donation program) | * Yes \* | * No |
| Publically Available Source | * Yes | * No | *\* Contact CCDC ARL HRPO for cadaver research submission review form.* | | |
| Other | * Yes \* | * No |  | | |
| \* If Other, explain: | | | | | |
| Does the consent form (clinical or research) used for the collection of the data/specimens include any limitations or prohibitions on future use of data/specimens? (Include the consent form in the HRPO submission) | | | | | |
|  | * Yes | * No | * Unavailable   (Note: If unavailable, HRPO will require additional institutional certification for permissible use of data/specimens.) | | |
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| Did all of the data/specimens exist when the research was proposed to your institution or Institutional Review Board (IRB)? | | | | | |
| * Yes. If yes, where are they located? *(e.g. central repository, lab, pathology department, collaborating institution, etc.)* | | | | | |
| * No. Explain: | | | | | |

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| **Identifiability of Data/Specimens** | | |
| Will you/your research team obtain information that directly identifies the original data/specimens donor? | * Yes \* | * No |
| \* If yes, explain: | | |
| Will the data/specimens obtained by you/your research team contain codes linking the data/specimens back to the original donor? | * Yes \* | * No |
| \*If yes, will the key to the code ever be made available to you? | * Yes \* | * No |
| \* If yes, explain: | | |
| Are any personnel involved in the proposed use of these data/specimens also involved in the original collection of the data/specimens? | * Yes \* | * No |
| If yes, explain in what capacity. | | |

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| **Institutional Review and Determination Status** | |
| Has the use of data/specimens as proposed in the DoD/CCDC ARL funded project been reviewed by your institution? **Please select one of the following:** | |
|  | Yes, the IRB reviewed the project as an amendment to an ongoing protocol. *(Submit a copy of the current IRB-approved protocol and amendment to incorporate the DoD funded activities.)* |
|  | Yes, the IRB reviewed the project as a new protocol. *(Submit a copy of the IRB submission and applicable specimen collection consent forms for review.)* |
|  | Yes, other Institutional review. Describe: |
|  | No, the use of specimens/data supported by the DoD/CCDC ARL funded project has not been reviewed by my institution because *(Please explain):* |