This form is to be completed for non-exempt humans subject research. For DoD supported research that is exempt, or that does not involve human subjects, the PI must obtain confirmation from the DoD Human Research Protection Official of their concurrence with the assessment before the activity begins.

**Project Information:**

*1.0 Title*:

*1.1 Principal Investigator*:

1.2 PI Acknowledges that research cannot begin until written approval is received from the funding agency that the required Administrative Review has been completed.

Yes

1.2.a PI acknowledges that DoD component-level administrative review (CLAR) must be obtained prior to starting the research when:

|  |  |
| --- | --- |
| Yes | Human subjects research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens. |
| Yes | The research requires a waiver of informed consent pursuant to 10 USC 980, Subsection (b). |
| Yes | The research is fetal research, as described in 42 USC 289g-2 |
| Yes | Large scale genomic data (LSGD) is collected from DoD-affiliated personnel. LSGD includes data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc. (See definition in DoDI 3216.02 G.2 Definitions) |

1.2.b PI acknowledges that:

|  |  |
| --- | --- |
| Yes | The research is required to be approved by the DOHRP (in addition to the COHRP) in accordance with DoDI 3216.02. |
| Yes | Component review includes review of reliance agreements. |

1.3 PI Acknowledges that records maintained that document compliance or non-compliance with DoD regulations must be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

Yes

**Department of Defense Information**

*2.0 Indicate the specific component of the Department of Defense involved with the research. Appendix A of policy 2013-027.0 provides a listing of DoD components for reference*:

**Response:**

*2.0.1 If the DoD Component noted above is the Air Force or any of its component parts (i.e. Air National Guard, Air Force Reserve), a DoD Addendum to UCHC’s FWA may be required*

No Air Force Involvement → go to 2.1

Yes Air Force is involved → Contact the IRB to determine if a DoD Addendum has been obtained.

*2.1 How is the DoD component involved in your research (select all that apply):*

The research is funded by the component

The research involves cooperation, collaboration, or other type of agreement with a component of DoD. (Example: an Army Medical Laboratory will conduct tests on the blood samples collected)

The research uses property, facilities or assets of a component of DoD

The subject population will intentionally include personnel (military and/or civilian) from a component of DoD, or data or specimens from DoD personnel.

*2.2 Provide Contact Information for the DoD Liaison / Human research protection officer:*

*Name*:

*Title*:

*Phone*:

*E-mail*:

2.3 The PI acknowledges an obligation to keep the liaison/HRPO informed of the following:

Determinations of serious or continuing noncompliance,

Significant changes to the research protocol approved by the IRB

Results of the IRB continuing review,

Change of the reviewing IRB,

When the organization is notified by any Federal department, agency or national organization that any part of the Human Research Protection program is under investigation for cause involving a DoD-supported research protocol

Unanticipated problems involving risk to subjects or others

Suspensions or terminations of IRB approval

**Project Details:**

*3.0 During the research will you administer surveys or questionnaires, or do interviews with DoD personnel or their families?*

No → go to 3.1

Yes → Most DoD components have specific language and administration requirements related to survey, questionnaires and interviews with DoD personnel. Please consult with your DoD component agency contact and respond to one of the following:

I have been advised that additional survey/interview approval by the DoD component is not required **and documentation of such is attached to this appendix**.

I **have attached documentation** of the DoD component’s approval of the survey/interview

I have been advised by the DoD component to obtain IRB approval first, then submit the survey/interview for approval by my DoD component. **No activity will occur until said approval is obtained**.

Other discussion or result as described here:

*3.1 Will the research involve obtaining consent from legally authorized representatives for experimental subjects who cannot provide consent for themselves (e.g. children, impaired adults)*?

No → go to 3.2

Yes → If a subject cannot consent for themselves, the IRB must determine that the research is intended to be directly beneficial to the individual subjects. Please describe the benefits expected for individual subjects (if already described elsewhere you may provide reference (e.g. see page x of document y) :

**Response:**

*3.2 Does the research involve more than minimal risk?*

No, research is minimal risk and/or exempt review → **go to 3.4**

Yes → go to 3.3

*3.3 Does the research involve the recruitment of active duty U.S. military personnel (i.e. not off-duty, not on-leave) or DoD-affiliated personnel into more than minimal risk research?*

No, research is minimal risk and/or active-duty personnel are **not** recruited → **go to 3.4**

Yes → If yes, the recruitment plan must detail how undue influence will be minimized, including the following additional protections. Either refer to a location in the application / protocol that addresses each of the following points, or respond below:

* + 1. *Officers shall not influence the decision of their subordinates to participate in the research*

**Response**:

* + 1. *DoD-affiliated personnel, military and civilian supervisors, officers and others in the chain of command shall not be present at any human subject recruitment sessions or during the consent process for DoD-affiliated personnel*

**Response**:

*3.3.3 Officers and senior non-commissioned officers must have a separate opportunity to participate in the research*

**Response**:

*3.3.4 When recruitment involves a percentage of a unit, an independent ombudsman shall be present during recruitment*

**Response**:

*3.3a Does the greater than minimal risk research involve the* ***recruitment and consent of DoD-personnel in a group setting****?*

No, research is minimal risk and/or active-duty personnel are **not** recruited and/or recruitment and consent occur privately → **go to 3.4**

Yes → If yes, the IRB must appoint an ombudsperson who: must not have a conflict of interest with the research or be a part of the research team; must be present during human subject recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary, and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials; and should be available to address DoD-affiliated personnel’s concerns about participation.

*3.4 Does this research involve a component of the Department of the Navy (Navy, Marine Corp, Navy Reserve, Cost Guard)?*

No → **go to 3.7**

Yes →Secretary of Navy Instruction 3900.39D, Section 8(c)(6) requires the IRB to have documentation of independent review and approval for scientific merit or scholarship prior to IRB review (including a summary of scientific issues raised and addressed during the review). Please indicate below who has completed the independent scientific review. For clinical research, review the Scientific Advisory Council in the Clinical Research Center, the Scientific Review Committee of the HSPO, or peer review (e.g. NIH or funding agency) is acceptable. For non-clinical, minimal risk, or exempt research, review by the PI’s department head is sufficient.

**Who completed the review - Response -**:

A summary of the evaluation and findings **are attached with this form**.

*3.5 The Navy requires that if the research is more than minimal risk (see response in 3.2) there be an arrangement for emergency treatment and necessary follow-up of any research related injury.*

Research is no more than minimal risk, no plan required

Research involves more than minimal risk and the plan for emergency treatment and follow-up of any research related injury is as follows:

*3.6 The Navy requires that research involving human subjects who are not U.S. citizens or DoD personnel, conducted outside the United States, and its territories and possessions, requires permission of the host country. Please describe the ethics review undertaken by an IRB in the host country, or the local Navy IRB in the host country.*

Research is not conducted outside the U.S.

Research is conducted outside the U.S. and approval from host country is attached; and the ethics review process is described as follows:

*3.7 Does this research fall under the purview of the Under Secretary of Defense? (Please refer to* [*DOD Organizational Chart*](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/DoD_Organization_March_2012.pdf)*)*

No → **go to 3.8**

Yes → Health Affairs (HA) Policy 05-003 requires that for research involving a DoD component under the purview of the Under Secretary of Defense that all investigators and research staff directly involved in human subjects research shall have ***Annual*** training on human subjects protections. This requirement is more stringent than UCHC’s policy of retraining every 3 years. Describe how you will ensure you and the other research team members directly involved in the research maintain annual training on HS protections.

**Response**:

*3.8 Does this research involve compensation for participation?*

No → **go to 3.9**

Yes → Select the applicable category(ies) below for the types of personnel who will be compensated, and confirm compliance with DoDI Directive 3216.02 (dated 11/8/2011)

**On-duty Federal Personnel**:

* + Federal personnel (civil servants or Service members) may be compensated up to $50 for each blood draw. No payment shall be made to any person for blood withdrawn for the benefit of the person from whom it is withdrawn.
  + Federal personnel will not receive compensation, other than that allowed for blood draws as noted above.

**Off-duty Federal Personnel**:

* + Federal personnel (civil servants or Service members) may be compensated up to $50 for each blood draw when the blood draw is for research purposes in connection with the care of any person entitled to treatment at Government expense. However, if the research **is not** Federally funded, compensation for blood draws may be in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the blood draw (i.e. the $50 limitation per blood draw does not apply)
  + Federal personnel while off duty may be compensated for research participation other than blood draws in the same way as other non-Federal personnel (i.e. compensated for participation in a reasonable amount as approved by the IRB. However, payment to off-duty Federal personnel for general research participation **must not** be directly from a Federal source (payment from a Federal contractor or other non-Federal source is permissible).

**Non-Federal Personnel**:

* + Non-federal personnel participating in DoD-funded research may be compensated up to $50 for each blood draw when the blood draw is for research purposes.
  + Non-federal personnel participating in DoD-funded research may be compensated for participation in DoD-supported research for other than blood draws in a reasonable amount and payment for such may come directly from a Federal or non-Federal source.

*3.8.1 Does the PI certify that the research complies with the above limitations for each group selected?*

Yes → **go to 3.9**

No → please explain:

*3.9 Check the box to certify that the research does not involving prisoners of war. This includes any person captured, detained, held, or otherwise under the control of Department of Defense (DoD) personnel (military and civilian, or contractor employee) except DoD personnel held for law enforcement purposes.*

By checking the box I certify that detainees, including prisoners of war, **are not** included in this research.

*3.10. Are you requesting a waiver of consent for research meeting the DoD Directive 3216.02 section E2.1.3 definition of “Research Involving a Human Being as an Experimental Subjects” (i.e. research involving an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction (e.g. effectiveness of drug, device))*

No→ **Go to 3.10.a**

Yes→ The Assistant Secretary of Defense for Research and Engineering may grant a waiver with respect to a specific research project to advance the development of a medical product necessary to the armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws. Respond below.

*Has approval for this waiver been granted*

Yes → **Attach documentation of the approval**

No→ Explain (**Note** final IRB approval will not be granted until required documentation from DoD is provided):

**Response**:

*3.10.a Are you requesting a waiver of consent for emergency medicine research research?*

No→ **Go to 3.11**

Yes→ The DOHRP must provide approval on behalf of the Secretary of Defense for a waiver of the advance informed consent provision of 10 USC 980. Respond below.

*Has approval for this waiver been granted*

Yes → **Attach documentation of the approval**

No→ Explain (**Note** final IRB approval will not be granted until required documentation from DoD is provided):

**Response**:

*3.11 Is this a multi-site research study?*

*No*

*Yes* →  *If yes, detail the roles and responsibilities of each party at each site involved in the research. Note a formal agreement between the institutions specifying the roles and responsibilities of each party may be required. Check with your DoD liaison to verify requirements. (e.g. the Army requires execution of specific duty contracts). The IRB can aid the researcher in developing such an agreement*. (*Note:* *tabbing out of the lower most right cell will insert another row*).

|  |  |  |  |
| --- | --- | --- | --- |
| **Site** | **Individual’s Name** | **Role** | **Responsibilities** |
|  |  |  |  |

*3.12 Does this study encompass Fetal Research?*

*No*

*Yes* →  *If yes,* the Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:

* + - * may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
      * will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other mean;

***Response:*** *Explain how the first and/or second bullet point above is addressed*:

* + - * the risk standard for fetuses intended to be aborted and fetuses intended to be carried to term must be same.

***Response:*** Explain how point 1 and/or 2 is addressed:

3.12a *Does this research constitute human subject research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates?*

*No*

*Yes* →  *If yes,* ***written approval from the DOHRP must be obtained through the CHORP prior to research starting****. (US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g)*

By checking the PI confirms written approval from the DOHRP will be obtained and maintained in the study records.

Signature of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(electronic signature is acceptable)