**Human Research Protocol Application Supplement**

**For Research Funded by the Department of Defense (DoD) or Army, Office of Naval Research, Air Force or Marine Corps Components**

**Form 100 FR 16 (2013-1)**

*For further information regarding requirements for research supported by the Department of Defense, see* [*http://www.yale.edu/hrpp/policies/index.html*](http://www.yale.edu/hrpp/policies/index.html)*, IRB Policy 100, Procedure 100.4*

**Title of Research Project:**

**Principal Investigator:**

**Protocol Number:**

**DoD Component Involved the Research (e.g., DoD, Army, Air Force, Office of Naval Research, etc.):**

**How does this study involve the DoD Component?**

Supported [ ]  Other [ ]  Specify:

**DoD Contact/Liaison Information
Name: Title:**

**Telephone number: Email Address:**

1. **Is this a multi-site research study?** Yes [ ]  No [ ]

*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. The Yale IRB can aid the Yale researcher in developing such an agreement when required. If required, a proposed agreement will be acceptable with the protocol submission. Formal agreements for multi-site research conducted with Army support are generated by the Army as specific duty contracts. The Army contract liaison works with investigators in the execution of duty contracts. For other DoD multi-site studies, the Yale IRB can aid the Yale researcher in developing such an agreement when required.*

 **Roles and responsibilities of each party at each site include:**

1. **Does this research involve surveys or questionnaires with DoD personnel and/or U.S. military personnel?** Yes [ ]  No [ ]

*If yes, the research must be reviewed and approved by the DoD after review and approval by the Yale IRB. When DoD approval is obtained, a copy of the approval must be submitted to the Yale IRB.*

1. **Does this research involve more than minimal risk?** Yes [ ]  No [ ]

*If yes, a Research Monitor is required. The Research Monitor must have expertise consonant with the nature of risk(s) identified with the research protocol, and they shall be independent of the team conducting the research.*

 *management and safety. The research monitor has the authority to stop the research study in progress, remove individuals from the study and take any steps to protect the safety and well being of participants until the IRB makes an assessment.*

*Note: The IRB may require appointment of a Research Monitor for a portion of the study, or for studies involving no more than minimal risk.*

 Research Monitor Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Research Monitor Contact Information \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Monitor’s Responsibilities/Activities \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Attach:** [ ]  **A letter from the Research Monitor accepting this role**

[ ]  **The Research Monitor’s CV**

 By checking the boxes below, I certify the following:

 [ ]  The Research Monitor is independent of the research investigative team

 [ ]  The Research Monitor has been appointed by name as provided above

[ ]  The Research Monitor possesses sufficient educational and professional experience to serve as the participant’s advocate

[ ]  Reports from the Research Monitor will be promptly submitted to the IRB at intervals determined by the IRB.

1. **Will this research be conducted outside the United States and its territories,**

 **and involve human subjects who are not U.S. citizens or DoD personnel?**

Yes [ ]  No [ ]

 *If yes:*

 Name of country where research will be conducted:

 Local IRB that will be reviewing the protocol :

 **Attach Documentation of:**

 [ ]  Permission to conduct the research study in the host county by certification or

 [ ]  Local ethics committee or IRB review

 [ ]  I certify that I have consulted with the host country IRB reviewing this protocol, and the local applicable laws, regulations, customs and practices for the host country will be followed.

1. **Does this research involve U.S. military personnel?** Yes [ ]  No [ ]

 *If yes, the recruitment plan outlined in the IRB application must detail how undue influence will be minimized, including the following additional protections:*

* Supervisors shall not influence the decision of their subordinates to participate in the research
* Supervisors and senior non-commissioned officers shall not be present at the time of recruitment into this research
* Supervisors shall have the opportunity to participate in the research, when applicable

[ ]  **By checking the box, I acknowledge that I have reviewed, and this research is compliant with, requirements on dual compensation for U.S. military personnel and federal employees , as described in DoD Instruction 3216.02, Enclosure 3, Section 11.**

 [ ]  **By checking the box,** **I acknowledge that research with prisoners of war is prohibited.**

1. **Are you requesting a waiver of consent?** Yes [ ]  No [ ]

*If the research participant meets the following definition, a waiver of consent is prohibited unless it is obtained from the Secretary of Defense.*

Experimental subject: Research involving a human being as an experimental subject is an activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32CFR.210.102 (f) reference (c)).

*If research participants do not meet the definition of experimental subject, the IRB may waive consent.*