* The Human Research Protection Official (HRPO) completes the following checklist for all Department of the Navy (DON)/USMC-supported research involving human subjects conducted by non-DoD performers. The Contractor/Contracting Officer Representative (COR) will assist in filling out the checklist and submit to the HRPO for final signature. The HRPO must request any missing documentation or missing regulatory requirements until all regulatory requirements are met and supporting documentation provided. The HRPO will return a HRPO determination along with the checklist and required documents to the Program Officer for inclusion in the protocol review package to be sent to the Contracting Officer.
* If the contract award or comparable agreement includes multiple protocols, a HRPO checklist should be completed for each protocol.
* If the research involves special populations/research categories, HRPO must complete the additional checklist, i.e. HRPO Checklist B or C, as applicable.

|  |  |
| --- | --- |
| Program Officer (if applicable): |  |

Agreement for DoD-Supported Research Involving Human Subjects:

|  |  |  |
| --- | --- | --- |
| Contract: | New Contract | Existing Contract # |
| Grant: | New Grant | Existing Grant # |
| Assistance Agreement (AA): | New AA | Existing AA# |
| Cooperative Agreement: | New Cooperative Agreement | Existing Cooperative Agreement # |
| Cooperative Research and Development Agreement (CRADA): | New CRADA | Existing CRADA # |
| Other Agreement Type: | New Agreement | Existing Agreement # |

|  |  |
| --- | --- |
| Expiration Date of Above Agreement (when applicable): |  |

|  |  |
| --- | --- |
| Performer Name: |  |
| Proposal Title: |  |
| Principal Investigator: |  |
| Protocol Title: |  |

New Protocol added under Agreement: Protocol #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Modified Protocol previously HRPO reviewed: Protocol #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Renewal Protocol (every year): Original Protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Not Research Involving Human Subjects Determination Submitted? YES**   **NO**

(If No Skip to #2 and complete rest of checklist – If Yes Complete #1 and #11)

|  |  |  |
| --- | --- | --- |
| **YES** | **N/A** |  |
|  |  | The proposed Statement of Work (SOW) or equivalent has been provided. |
|  |  | Application / Form submitted to HRPP/IRB to make the Determination provided. |
|  |  | The submitted Not Research Involving Human Subjects Determination Letter is accurate. |

**2. Exemption Determination Submitted? YES**   **NO**

(If No Skip to #3 and complete rest of checklist – If Yes Complete #2, #7, #10 and #11)

|  |  |  |
| --- | --- | --- |
| **YES** | **N/A** |  |
|  |  | The proposed Statement of Work (SOW) or equivalent documentation is consistent with the protocol deemed exempt by the IRB or appropriate authority. |
|  |  | The exemption determination letter has been provided, HRPO concurs with accuracy of listed 32 CFR 219.104(d) exemption category number(s) and rationale statement. (A Yes response is required if an exemption is claimed.)  Exemption category number(s):  *The rationale must correspond with the exemption category cited. Determinations may be made by the Performers’ IRB Chairs, Vice Chairs, IRB Administrators or designated HRP persons, but not the PI. Special requirements apply for research involving children or prisoners which requires completing the Additional HRPO Checklist, i.e., HRPO Checklist B.* |
|  |  | Exemption determination is current. (The response to this question cannot be N/A.) |
|  |  | HRPO has ensured that either the Defense Federal Acquisition Regulation Supplement (DFARS) clause (48 CFR 252.235-7004) or similar language for above-listed comparable agreements (not subject to the DFARS clause), is included in the contract/agreement. (DoDI 3216.02 Enc 3 par 4a) |

**3. Assurance and Related Agreements for Non-Exempt Research**

|  |  |  |  |
| --- | --- | --- | --- |
| **YES** | **NO** | **N/A** |  |
|  |  |  | Subcontractors or equivalent institutions are engaged in the human subject research?  If yes, please list: |
|  |  |  | Appropriate Assurance and Agreement documents have been provided by the Performer (including documents for Subcontractors, if applicable).  Complete Assurance and IRB Worksheet in Appendix A of Checklist. (The response to this question cannot be No.)  *Documents must be current (i.e., not expired) and cover the scope of the work proposed. Documents could include an Individual Investigator Agreement and/or an Institutional Agreement for IRB Review.* |
|  |  |  | HRPO has ensured that either the Defense Federal Acquisition Regulation Supplement (DFARS) clause (48 CFR 252.235-7004) or similar language for above-listed comparable agreements (not subject to the DFARS clause), is included in the contract/agreement. (DoDI 3216.02 Enc 3 par 4a) |

**4. IRB-Approved Protocol for Non-Exempt Research**

|  |  |  |
| --- | --- | --- |
| **YES** | **N/A** |  |
|  |  | The proposed Statement of Work (SOW) or equivalent documentation is consistent with the submitted IRB-approved protocol. |
|  |  | An IRB approval letter has been provided by the IRB(s). (A Yes response is required unless an exemption letter is provided.)  IRB approval date:  Expiration Date of IRB approval, as required (see 32 CFR 109 (f)): |
|  |  | The IRB approval period is no longer than 365 days, as required. ( Per 32 CFR 109 (f) continuing review is not required under certain circumstances) |
|  |  | An IRB-approved protocol has been provided. (The response to this question cannot be N/A.) |
|  |  | Documentation provided that IRB review considered the scientific merit of the research. (DoDI 3216.02 Enc. 3, par 4b(2)) |
|  |  | The PI listed on the protocol is correct and the work reviewed by the IRB is the same as the work/effort to be performed under the contract SOW or equivalent funding agreement. (The response to this question cannot be N/A.) |

**5. IRB Risk Level Determination for Non-Exempt Research**

|  |  |  |
| --- | --- | --- |
| **YES** | **N/A** |  |
|  |  | IRB-approved Minimal Risk Level is appropriate.    *Expedited Review is only available for minimal risk research. If research has been subject to Expedited Review it should be at minimal risk level.* |
|  |  | IRB-approved Greater than Minimal Risk (GTMR) Level is appropriate. |
|  |  | **If research presents GTMR, does the protocol adequately address the requirement for a Research Monitor for research involving?**   * The research monitor is independent of the team conducting the research involving human subjects. * The research monitor is identified by name in the IRB-approved protocol. * The duties, authorities, and responsibilities of the research monitor have been approved by the IRB. |

**6. IRB-Approved Informed Consent Form and Recruitment Materials for Non-Exempt Research**

|  |  |  |
| --- | --- | --- |
| **YES** | **N/A** |  |
|  |  | The protocol includes an IRB-approved informed consent form or IRB-approved informed consent script. (32 CFR 219.116 and 32 CFR 219.117) |
|  |  | If no consent form or script is included, the protocol or other IRB provided documentation includes an explanation. (32 CFR 219.116 and 32 CFR 219.117) |
|  |  | IRB-approved recruitment procedures, timing, personnel, and materials are appropriate and consistent with the protocol and consent form/script. (when applicable, see Additional HRPO Checklist, i.e., HRPO Checklist B, for review of research compensation) (32 CFR 219.116, DoDI 3216.02, Enc 3, par 7e) |

**7. Human Subject Protection-Related Training for PI and Key Study Personnel**

|  |  |  |
| --- | --- | --- |
| **YES** | **N/A** |  |
|  |  | Documentation of completed research ethics and human subject protection training by the PI has been provided and is current. (The response to this question cannot be N/A.)  Evaluation of non-DoD institution’s education and training policies to ensure the personnel conducting research involving human subject research are qualified. The rigor of this evaluation should be appropriate for the complexity and risk of the research. (DoDI 3216.02, Enc. 3, par 5d)  *(Complete Appendix A for each individual conducting research involving human subjects)* |

**8. (AFTER INITIAL HRPO APPROVAL ONLY) IRB-approved Continuing Review of DON-Supported Research**

|  |  |  |
| --- | --- | --- |
| **YES** | **N/A** |  |
|  |  | An IRB-approved continuing review submission has been provided, as required (See 32 CFR 109 (f)). Continuing review has been appropriately conducted and at a date that is within a year of the last Continuing Review (or Initial Review if this is the first Continuing Review). (DoDI 3216.02, Enc. 3, par 4b(4) and par 4c(2)(d))  Prior IRB approval expiration date: \_\_\_\_\_\_\_\_\_\_  New IRB approval date: \_\_\_\_\_\_\_\_\_  New IRB approval expiration date: \_\_\_\_\_\_\_\_\_ |

**9. (AFTER INITIAL HRPO APPROVAL ONLY) IRB-approved Amendment of Significant Change(s) to DON-Supported Research**

|  |  |  |
| --- | --- | --- |
| **YES** | **N/A** |  |
|  |  | An IRB-approved amendment of significant changes submission has been provided to the HRPO **PRIOR** to its implementation (unless required for emergency medical care). The HRPO accepts the significant amendment as appropriate.  Note, a “significant change” includes but is not limited to the situation when the IRB used to review and approve the research changes to a different IRB. (DoDI 3216.02, Enc. 3, par 4b(4) and par 4c(2)(c))  IRB approval date: \_\_\_\_\_\_\_\_\_  IRB approval expiration date: \_\_\_\_\_\_\_\_\_  Amendment Description Summary: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**10. Special Subject Populations or Research**

*If yes to any of the following questions, complete and attach the DON HRPO Checklist for Special Populations and Special Research Categories ( HRPO Checklist B).*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Yes** | **No** |  | **Yes** | **No** |  |
|  |  | Compensation for Participation in Research |  |  | Research with test/investigational articles including drugs, devices, biologics/vaccines; clinical trial research |
|  |  | Experimental subjects who do not have the capacity to provide informed consent for themselves due to age, condition or otherwise |  |  | Research likely to bring media attention; potentially or inherently controversial topic |
|  |  | Military or DoD civilian personnel |  |  | Classified research |
|  |  | Pregnant women, human fetuses, neonates, fetal tissue |  |  | Research involving testing the effects of nuclear, biological, or chemical agents |
|  |  | Children |  |  | Research Requiring Additional Federal Approvals per 45 CFR 46 Subparts B through D |
|  |  | Prisoners, Captured or Detained Personnel |  |  | Indigenous Tribes |
|  |  | Subjects in foreign country |  |  |  |

**11. Human Research Protection Official Review Approval Determination and Signature**

Program Officer Review

To the best of my knowledge the information included in this checklist accurately describes the research effort being sponsored.

Program Officer (if applicable) Date

After reviewing the above submitted item, HRPO determines that the institution’s HRPP, including the corresponding IRB of Record has appropriately reviewed and approved (when applicable) the submitted item and that the DON-supported research is in or remains in compliance with DoD and DON policies and regulations (including but not limited to DFARS 48 CFR 252.235-7004, DoDI 3216.02, and SECNAVINST 3900.39E CH-1). HRPO has completed HRPO Checklist A (including Appendix A below), HRPO Checklist B and/or HRPO Checklist C, when applicable.

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

HRPO Name

HRPO Signature Date

HRPO Approval is contingent upon the following:

1. Contracts for DoD-supported research involving human subjects must contain DFARS clause 48 CFR 252.235-7004 which identifies Contractor requirements and responsibilities and role of HRPO. (DoDI 3216.02 Enc. 3, par 4a(1))

2. Comparable agreements (e.g., grants, assistance agreements, CRADAs) not subject to DFARS must contain language affirming responsibilities of non-DoD institution. (DoDI 3216.02 Enc. 3, par 4a(1))

3. HRPO ensures that the institution conducting research involving human subjects is aware of its obligation to comply with DoDI 3216.02 and 32 CFR 219. (DoDI 3216.02 Enc. 3, par 4a)

4. All institutions retain records for at least 3 years after the completion of the research. DoD Components may rely on the non-DoD institutions to keep the required records that were generated by the institution, or the DoD Components may make arrangements to transfer the records. (DoDI 3216.02 Enc. 3, par 15a)

5. Records maintained by non-DoD institutions that document compliance or noncompliance with DoDI 3216.02 shall be made accessible for inspection and copying by authorized representatives of the Department of Defense at reasonable times and in a reasonable manner as determined by the supporting DoD Component. (DoDI 3216.02 Enc. 3, par 15d)

**Appendix A. Assurance and IRB Worksheet for Performer, Subcontractors, etc. engaged in DON-Supported Non-Exempt Research**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Column A | Column B | Column C | Column D | Column E | Column F | Column G | Column H | Column I |
| **Name of Individual conducting DON-Supported Human Subject Research (HSR)** | **Expiration Date of Individual’s Appropriate Human Subject Protection Training** | **Name of Individual’s Institution (Employer)** | **Name of Assured Institution Covering Individual (complete Column H only if Individual’s Institution is not Assured)** | **Assurance Number Covering Individual** | **Assurance Expiration Date** | **Name of Institution with Reviewing IRB Overseeing Individual’s HSR**  **(If not the same as Institution in Column D, complete Column I)** | **IIA Documentation Complete?**  **(List Agreement Effective Date)** | **IAIR Documentation complete?**  **(List Agreement Effective Date)** |
| John Doe, Ph.D. | 2/4/2020 | NovaVax | NHRC | DoD N-40099 | Expiration Date | NMRC | Agreement Effective Date | Agreement Effective Date |
| Jane Doe, M.D. | 3/1/2021 | Johns Hopkins University | Johns Hopkins University | FWA00012345 | Expiration Date | NMRC |  | Agreement Effective Date |