|  |  |
| --- | --- |
| **PD:** | **Protocol ID:** |
| **Checklist completed by** (IRB Staff name)**:** | **Date:** |

**Instructions**: These DoD and DoD Component requirements *differ from* or are *additional to* our current HRPP policies. **These requirements apply when the research is considered “DoD-supported” i.e. research that uses DoD resources including funding, research personnel, and/or military personnel/service members as human subjects, regardless of funding source**. These requirements must be met prior to initiating human research activities, when applicable.

***IRB Manager:***

* *Attach this checklist in eProtocol when completed.*
* *Send comment code 42-DoD and others as appropriate*
* *Add Admin note about DoD-supported research*
* *Refer to Guidance* [*GUI-42*](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf) *and* [*GUI-46*](https://stanfordmedicine.box.com/shared/static/v0bt30nqo2o5jdb60od0f8sq64qly5aa.pdf) *for more information as needed.*

**1.) Appropriate Review Category (by risk)**

**Yes  No  Is this study greater than minimal risk (i.e. Regular)?**

**If “Yes” (i.e. it is Regular), SKIP to #3. If “No”:** Confirm whether the study meets the DoD definition of Minimal Risk, per [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf).

**2.) Exempt Research**

**Yes  No  Does this study qualify as Exempt?**

**If “No”: SKIP** to next question. **If “Yes”,** have PDconfirm they will submit institutional documentation of the determination that the research is either exempt HSR or limited IRB review to the HRPO, and will include all protocol documents. Research is exempt from other requirements. See [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf).

**3.) Expedited Category 5 Research**

**Yes  No  Does this study qualify for Expedited Review Category 5?**

**If “No”: SKIP** to next question. **If “Yes”,** confirm the study meets DoD’s interpretation of Category 5 as outlined in [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf).

**4) Waivers or Alteration – Limitations on Use**

**a) Yes  No  Is there a request for a Waiver or Alteration of Informed Consent?**

**If “No”, SKIP** to next question**. If “Yes”, one of the following in** [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf) **must be met for a Waiver or Alteration to be granted.   
b) Yes  No** Study does not involve DoD supported emergency medicine research (prohibited at Stanford).

**5) Consent/HIPAA – Required Language**

**Yes  No  Is there a Consent Form and/or HIPAA Authorization?**

**If “No”: SKIP** to next question. **If “Yes”, Does the ICF include additional requirements from** [[GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf)](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf)? **Yes  No  See also 42-DoD Consent** **comment code   
Does the HIPAA Authorization include additional requirements from** [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf)? **Yes  No**

**6) Consent by Legally Authorized Representatives (LARs)**

Yes  No  **Will consent be obtained from the (LAR)?**

**If “No”, SKIP** to next question**. If “Yes”,** does the research involve humans as **experimental subjects**? (i.e. **research that involves an intervention** or interaction for the primary purpose of obtaining data about the effect of the intervention or interaction?) Yes  No

If “**No**”, **SKIP** to next question**.** If “**Yes**”, follow **additional requirements from** [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf).

**7) International Research**

**Yes  No  Will this study be conducted at International site(s)?**

**If “No”, SKIP** to next question**.**

**If “Yes”:**

**The RegulationS:** [DoDI 3216.02 4.c(2)]:All applicable laws and requirements of the foreign country must be met, and the IRB must consider the cultural sensitivities of the research setting.

**8) Research Involving DoD Personnel/Service Members**

**Yes  No  DoD personnel may be enrolled in the study.**

**If “No”, SKIP** to next question**. If Yes, see** [**GUI-42 Other Federal Agencies - Additional Requirements**](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf) **for additional requirements as applicable.**

**Yes  No  DoD personnel/Service Members are compensated?**

**If “Yes”,** note [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf).

**Yes** **No** N/A  If study is **greater than minimal risk**, the IRB appointed an ombudsperson **when recruitment occurs in a group setting**. See [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf) for ombudsperson requirements.

**9) Is the study Supported by the Army?**

**a) Yes  No  If “No”, SKIP** to next question**. If “Yes”,**

**b) Does this research involve:**

Yes  No   [cadavers](https://mrdc.health.mil/assets/docs/orp/irbo/21_Army_Policy_for_Use_of_Human_Cadavers_20_April_2012.pdf)?

Yes  No   [secondary research of data and/or specimens?](https://mrdc.health.mil/assets/docs/orp/Investigator_Guidance_on_OHRO_Review_of_Use_of_Data_Specimens.pdf)

**If Yes to any of the above**, *see* [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf) for additional requirements.

**10) Children, Pregnant Women, Fetuses, and Neonates (Subparts B and C)**

**a) Yes  No** Is this human subjects **research using *fetal tissue?* If Yes,** it must comply with[**U.S.C. title 42 (289g–289g-2)**](http://www.gpo.gov/fdsys/pkg/USCODE-2009-title42/html/USCODE-2009-title42-chap6A-subchapIII-partH-sec289g-2.htm)**.**

**b) Yes  No  Does the study target children, pregnant women, fetuses, or neonates?**

**If “No”, skip** to next question**. If “Yes”, confirm the regulation has been met as applicable, see** [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf).

**c) *The Regulation:*** *DoDI 3216.02 7a.(1) Non-exempt research involving pregnant women, fetuses, or neonates as human subjects must meet the additional relevant protections of subpart B of Reference (i), unless modified by DoDI 3216.02.* ***(This requirement is consistent with HRPP Chapters 7.7; 9.3; and 12.2).***

**11) Prisoners**

**Yes  No  N/A  If Yes, additional requirements in** [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf) **have been met.**

**Note: All** DoD supported research involving Prisoners must be reviewed at a **convened meeting. Note: Detainees and POWs*:*** Research involving prisoners of war (POW) and detainees is prohibited except for circumstances in [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf).  **The Regulation:** [DoDI 3216.02 para. 7b]

**12) Other Vulnerable Populations as Defined by DoD**

**Yes  No  N/A  these requirements have been met.**

***The RegulationS:*** *DoDI 3216.02; AFI 40-402; SECNAVINST 3900.39E. IRBs shall consider the need for additional safeguards (beyond those provided in Subparts B, C, and D) to other potentially vulnerable populations who may be subject to undue influence or coercion because of their age, health, employment, financial status, or other circumstances.* ***Other groups warranting additional protection include severely ill patients, those in employer-employee, student-teacher, or supervisor-subordinate relationships, or deployed active duty personnel. (This requirement is consistent with HRPP Chapters 6.5; 6.8; 7.6; 9.3; and 12.2).***

**13) DoD Component-Level Administrative Review (CLAR)**

**Yes  No  N/A** Investigator has confirmed in application or in response to comment that CLAR will be conducted before approval of research when:

1. Human participants research is conducted in a **foreign country**, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens.
2. The research requires a **waiver of informed consent pursuant to 10 USC 980, Subsection (b)**.
3. The research is **fetal research, as described in 42 USC 289g- 289g-**2.
4. **Large scale genomic data (LSGD) is collected from DoD-affiliated personnel**. LSDG 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)
5. The research is **required to be approved by the DOHRP** (in addition to the COHRP) in accordance with DoDI 3216.02.

**14) Study involves Data Acquired by DoD Component**

**Yes  No  N/A  If “No”, skip** to next question**. If “Yes”, these requirements have been met:**

If data is acquired by the DoD component under the pledge of confidentiality for exclusively statistical purposes, this data must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent. Please confirm the data will be used as above.

**15) Relying on Another IRB**

**Yes  No  N/A** If Stanford is relying on another IRB review for DoD supported research, a formal agreement between organizations is obtained. See more at [GUI-42](https://stanfordmedicine.box.com/shared/static/tuw133jlboffsox877ot2li43gzfectr.pdf).