THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

03 September 2014

MEMORANDUM FOR OFFICE OF THE UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS (OUSD(P&R)) INSTITUTIONS PARTICIPATING IN THE NATIONAL CANCER INSTITUTE (NCI), NATIONAL CLINICAL TRIALS NETWORK (NCTN)

SUBJECT: Reliance on the NCI Central Institutional Review Board (CIRB): a Non-DoD IRB

The Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) issues Assurances for the Protection of Human Subjects (Assurance) through the Research Regulatory Oversight Office (R2O2) in accordance with DoDI 3216.02. DoDI 3216.02, Enclosure 3, Section 3.a(8) provides for a DoD institution to rely upon a non-DoD Institutional Review Board (IRB) when specific conditions are met. Those conditions are:

(a) The DoD Component determines the collaborating non-DoD institution has an appropriate Federal assurance.

(b) The involvement of DoD personnel in the conduct of the research involving human subjects is secondary to that of the non-DoD institution.

(c) The DoD institution, the non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each organization in complying with the terms of the Federal assurance and this Instruction (i.e., have an Institutional Agreement for IRB Review or similar agreement). The DoD Component shall approve the terms of the agreement prior to the DoD institution's engagement in the research involving human subjects.

(d) The DoD Component must conduct an appropriate administrative review of the research involving human subjects to ensure it is in compliance with DoD policies and procedures prior to the DoD institution's engagement in the research.

The National Cancer Institute (NCI) sponsors extramural, multi-site clinical trials through the National Cancer Trials Network (NCTN). The NCTN maintains two Central IRBs (CIRB) that provide reviews of Network studies, one for adult trials, and a second for pediatric trials. Institutions that wish to participate in these Network trials shall rely on the NCI CIRB or obtain a waiver of this requirement from the NCI to conduct a local IRB review.

Component oversight offices, led by the Army Human Research Protection Program Office (AHRPO), worked with the Office of the Assistant Secretary of Defense for Research and

Engineering (OASD(R&E)) to address compliance with DoD policy in the case of reliance on the NCI CIRB, in the context of the CIRB Independent Model. Such reliance has been authorized by OASD(R&E), contingent upon oversight by the Component oversight office (R2O2) to ensure compliance with provisions (c) and (d) of DoDI 3216.02, Enclosure 3, Section 3.a(8).

In accordance with DoDI 3216.02, Enclosure 3, Section 3.a(8)(c), the formal Authorization Agreement and other program documentation intended for submission to the NCI CIRB must be reviewed and approved by R2O2 prior to submission to the NCI, if not already submitted and approved by the NCI CIRB before the date of this memorandum under the oversight of another Component oversight office. This language will be inserted into documents provided to the NCI CIRB as part of the "local context" information.

Through collaboration with OASD(R&E) and other Component oversight offices, standardized criteria for the Component administrative review required by DoDI 3216.02, Enclosure 3, Section 3.a(8)(d) as well as checklists have been developed. These have been shared with institutions and, upon completion of training of institutional personnel, the authority to conduct the Component administrative review of NCTN protocols conducted at OUSD(P&R) institutions may be delegated.

R2O2 is the single point of contact (POC) within the OUSD(P&R) for questions regarding policy and procedures for use of the NCI CIRB. The R2O2 POC is Ms. Kendra Orjada, and she can be reached at Kendra.Orjada.CTR@dha.mil or 703-681-8378.

[redacted]

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