

## MEMORANDUM

To: National Association of Veterans' Research and Education Foundations (NAVREF)  
From: OGC STAR  
Date: May 26, 2022  
Subject: OGC STAR Guidance on NPCs Obtaining Clinical Trial Insurance

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OGC STAR was asked to provide guidance on whether the VA-affiliated Nonprofit Corporations (NPCs) should obtain clinical trial insurance to offset VA's potential expenses resulting from injury to subjects participating in VA-approved research studies. For the reasons set forth below, OGC STAR concludes that NPCs should not obtain such insurance policies.

Generally, clinical trials at VA are conducted by a Sponsor, which provides a study protocol and usually a study drug or device to VA. VA conducts the clinical trial, following the Sponsor's protocol, and the NPC facilitates the transfer of funds from the Sponsor to VA. Generally NPC staff, excluding those with a without compensation ("WOC") appointment, have little, if any, interaction with the clinical trial.

Section 17.85 of the Code of Federal Regulations (C.F.R.) mandates that VA "shall provide necessary medical treatment to a research subject injured as a result of participation in a [VA-approved] research project." 38 C.F.R. § 17.85. Thus, federal law places the burden of responsibility of treatment for research injury on VA. VA generally seeks to recoup this cost through applicable contractual provisions from Sponsors (e.g. Cooperative Research and Development Agreements, subawards).

Further, 38 U.S.C. 7361(d)(2) provides that NPCs are not "an agency or instrumentality of the United States." Similarly, VHA Handbook 1200.17, paragraph 12.d(2) states that "NPCs may not enter into agreements on behalf of VA." VA is the entity that conducts the research – not the NPC. Consequently, when VA asks an NPC to obtain an insurance policy to mitigate VA's risk in conducting VA research, it is inadvertently putting the NPC in a position to act as an "agent or instrumentality" of VA, in violation of the statute and VHA Handbook 1200.17.

Finally, an insurance company policy application that OGC has reviewed asks the applicant, the NPC, to provide information relevant to its prior, clinical trial holds or cancellations, regulatory violations, and research noncompliance — issues that VA is legally obligated to report as a study site. The NPC is not a study site, and as discussed above, it is not an agent nor instrumentality of VA; therefore, the NPC has no legal authority to have, nor report such events.

However, in accordance with VA policy and as a good business practice, NPCs should maintain general liability insurance. See VHA Handbook 1200.17, paragraph 10.b.: "NPCs are advised to purchase insurance to protect Directors, officers and employees against liability for actions of the Board and for employment practices, as well as coverage for NPC property and other activities."

**In conclusion, responsibility for treating research injury, and the costs related to such treatment, lies with VA. NPCs should not obtain clinical trial insurance on behalf of VA.**

OGC is aware of recent concerns regarding financial risk to VA facilities that may arise from assuming responsibility for covering costs of subject injury where neither ORD nor the clinical trial sponsor are providing such coverage. Further guidance will be issued on that broader topic.