**Office of Research Oversight (ORO) Guidance Regarding Reporting of Coronavirus Disease 2019 (COVID-19)-Related Modifications to or Holds/Stops of VA Research Activities**

**Question**: A VA research investigator halted study recruitment or modified/held study procedures to limit interactions with human research subjects with the intent of preventing community spread of “coronavirus disease 2019” (COVID-19).  These actions were not taken due to a research intervention-specific risk but due to the risk of acquiring coronavirus through interactions with others regardless of whether such interactions are for research or non-research purposes.  The VA research investigator’s actions are consistent with Federal or local public health authority recommendations, or the intent of such recommendations, for limiting community spread of coronavirus. Does ORO need to be notified about such measures per VHA Handbook 1058.01 and the Office of Research and Development (ORD) “COVID-19 Frequently Asked Questions” (March 17, 2020), FAQ #16?

**Answer:** In most cases, such modifications/holds/stops of research activities due to COVID-19-related concerns will **NOT** need to be reported to ORO.

The actions being taken by the VA research investigator are not related to a research-specific risk, but rather to a larger societal risk that exists regardless of the research.  Therefore, such a risk would *not* constitute a “serious problem that is … related to the research” which might otherwise be reportable under VHA Handbook 1058.01 §§6.c and 6.d(4). Social distancing measures, including restricting visitors to hospitals, nursing homes, and other healthcare facilities are broadly being implemented in response to COVID-19.  If a study team implements measures that are reasonably regarded as social distancing measures (e.g., halting enrollment so as to eliminate the need for an individual to travel to a hospital for a non-medically related appointment, reducing or eliminating interactions with human research subjects) in response to concerns about potential spread of coronavirus, then the study team is implementing the measures in response to a broader societal risk rather than a research study-specific risk.  As such, ORO does not consider the taking of such actions by a study team to be indicative of a problem related to research that must be reported to ORO.

Moreover, a temporary stop of research or research activities for the same reasons, such as outlined in ORD’s “**ADMINISTRATIVE HOLD** on Non-Critical, In-Person Interactions with Human Research Subjects in ORD-Funded Studies,” would *not* be reportable to ORO under VHA Handbook 1058.01 §6.h. That reporting provision relates to “Suspensions and Terminations of Research by the VA Facility.” The Administrative Hold referenced above has been imposed by ORD, so ORO is already fully aware of the temporary stop until ORD lifts the administrative hold, its scope, and its applicability to all VA facilities and does not require any additional reporting by individual facilities.

In addition, a temporary hold or permanent stop of research or research activities by an individual VA facility (e.g., a Sponsor’s temporary hold or permanent stop of a non-VA funded study at that particular VA facility) for the same reasons above also would not be reportable to ORO *under the limited circumstances described in this Guidance*. All other suspensions and terminations of a VA human research study by a VA facility must be reported according to the requirements of VHA Handbook 1058.01 §6.h.

As a reminder, any changes in Institutional Review Board (IRB)-approved research procedures must be reported to the IRB and may not be implemented prior to review and approval by the IRB except when necessary to eliminate apparent immediate hazards to the subject. For guidance on implementing changes to research in response to COVID 19 concerns, see **ORD Guidance on Human Subjects Protections Issues Related to COVID-19 Concerns: Implementation of Clinical Screening Procedures for VA Research Protocols and Modifying Study Procedures** at: <https://www.research.va.gov/resources/policies/guidance/ImplementingScreening-COVID19.pdf> and the ORD COVID-19 SharePoint site at <https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19/SitePages/ORD-Communications.aspx>.

**See also the ORO COVID-19 SharePoint site at**

<https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/COVID19%20Guidance/Forms/AllItems.aspx>