Department of Veterans Affairs

Memorandum

Date: March 17,2020

From: Chief Research and Development Officer (10X2)

Subj: **ADMINISTRATIVE HOLD** on Non-Critical, In-Person Interactions with Human Research Subjects in ORD-Funded Studies

To: VA Medical Center Directors (00); Associate Chiefs of Staff for Research & Development (151)

1. In context of the novel Coronavirus Disease 2019 (COVID-19) situation, this memorandum provides direction pertaining to Office of Research and Development (ORD)-funded human subjects research interactions requiring in-person contact.

2. To help protect the safety and health of Veterans, VA staff and the community, as well as to reduce the burden on the VA health care system, I am placing an **ADMINISTRATIVE HOLD**, effective the date of this memorandum, **on non-critical, in-person**, ORD-funded human research subject interactions.

3. *Critical interactions are* defined for the purpose of this memorandum as interactions that involve a potentially lifesaving intervention (e.g., IV oncology drug delivery) or an intervention that is required to maintain essential activities of daily living or subject well-being, including mental health and suicide prevention research that cannot occur remotely. This administrative hold means that non-critical, in-person activities involving human subjects **are not to occur until further notice.** This includes all human subjects regardless of whether they are **inpatients or outpatients.**

4. **Except for critical interactions** (for example, recruitment/enrollment into a clinical trial for an oncology therapeutic, suicide prevention), the following study procedures **MAY NOT** be conducted in ORD-funded research:

    a. In-person recruitment/enrollment, including screening visits

    b. In-person interaction or intervention with human subjects

    c. In-person follow-up

5. Examples of ORD-funded studies and study activities that **MAY** continue include:

    a. Animal and laboratory studies

    b. Certain categories of exempt or expedited review studies that do not involve interactions or interventions with human subjects (for example, online survey research, analysis of existing clinical data)

    c. Studies using telephone or internet-enabled recruitment, surveys, and follow-up.

d. Interventions involving telephone, video telehealth, internet, secure messaging or other technology-enabled applications to interact with subjects

6. An ORD-funded study may continue recruitment and/or follow up visits for non-critical research activities if the methods of the study may be modified to eliminate the in-person contact. See the ORD guidance on implementing changes in response to the COVID-19 outbreak at: www.research.va.gov/resources/policies/guidance/ImplementingScreening-COVID19.pdf.

7. Additionally, ORD-funded Principal Investigators who find that they are unable to continue with their research during this time due to increased clinical demands should contact their ORD funding service for guidance at their earliest opportunity in accordance with the COVID-19 Administrative Hold Frequently Asked Questions.

8. We request that all facilities, through their R&D Committees, develop local policies and procedures to implement this guidance to reduce non-critical, in-person contact between study staff and study participants, including for those funded by other federal, private or public funders.

9. Initiation of an administrative hold must be reported to the appropriate committee or subcommittee overseeing your research within 10 business days and a note to file should be placed in the Investigator's study records. If a non-ORD funded study implements the administrative hold, the study sponsor and/or funding agency should be notified.

10. To support social distancing, all VA research committee and subcommittee meetings should be held virtually. If local SOPs require in-person research committee and subcommittee meetings, a temporary local policy waiver or an immediate local policy revision should be pursued.

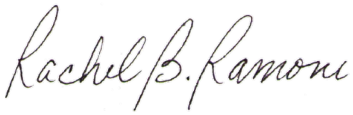
11. ACOS-R&Ds and R&D Committees (R&DC) are encouraged to talk with each other and investigators (remotely/virtually if possible) to help determine how this memorandum applies to studies at each facility. Investigators are encouraged to identify their studies to their R&DC that involve non-critical, in-person recruitment and/or in-person follow-up visits.

12. Studies that focus on COVID-19 may be exempted from this guidance based on local R&DC approval. Prior to submission to the R&DC, we strongly encourage investigators to submit a brief description of their research to ORDCOVID19@va.gov. Local R&DCs should consider restricting the start of any COVID-19 research that has not been coordinated with ORD to ensure that COVID-19 research efforts are coordinated and maximized across VHA.

13. The Office of Research Protections, Policy and Education (ORPP&E) within ORD will be responsible for guidance and direction on this matter. Please direct any questions to ORDCOVID19@va.gov. A set of frequently Asked Questions regarding this administrative hold and questions related to ORD research funding is released with this memorandum they are posted at: https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19.

14. Facilities will be notified by memorandum when this administrative hold is lifted on non-critical, in-person contact for ORD-funded studies.

15. Thank you for your efforts to fulfill our commitment to the health and well-being of Veterans as we meet the challenges brought by COVID-19.



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