

MEMORANDUM

DATE: February 14, 2022

TO: CSU Research Community

FROM: CSU Institutional Review Board

SUBJECT: IRB Procedure for COVID-Related Inclusion/Exclusion Criteria

OVERVIEW

This memo defines when it is appropriate for researchers to request COVID vaccination status or a negative COVID test as a requirement to participate in human subjects research under the purview of the CSU IRB, including full-board protocols, projects eligible for expedited review, and exemption determinations. Details of the resulting IRB review are also outlined below. This document considers CSU Policies, state, and national guidance.

It is worth noting that this guidance applies to research participants only and does not extend to applying vaccination status requests for employment purposes. This memo must not be considered approval to address vaccination status as a condition of employment. Please contact CSU Human Resources with questions about vaccination status and employment.

Including COVID vaccination status or test results as an inclusion criterion is approvable with justification in IRB-reviewed research when *all the following* apply:

Standard precautions cannot be accommodated based on the research procedures OR it is required to address the study topic or purpose

- Standard precautions are defined as public health precautions required by Colorado State University for on-campus activity (as informed by state and national guidance) at the time of submission. These precautions may include practices like social distancing, masking, etc. Current requirements can be found on the [CSU COVID Information and Resources](#) webpage.
- Projects requiring vaccine or test results are defined as projects that require that information to answer the research question at hand. For example, research on vaccine status rates may require vaccination inclusion criteria to target the correct study population.

Detail about how and what data will be captured is clearly documented in the protocol

- Methods for identifying and receiving vaccination status or test data must be clearly described in the protocol form. This information may include details on self-reporting, presenting a vaccination card, taking a test on-site, etc.
- If data is requested from a healthcare provider, details of the request process must be provided in the IRB application.

Data management considerations are appropriate

- Any data received from a covered entity subject to HIPAA (Health Insurance Portability and Accountability Act) will be stored in a HIPAA-compliant manner and collected using an appropriate HIPAA waiver or authorization.
- Self-disclosed data is not subject to HIPAA but should be stored securely with details outlined in the IRB application. General privacy and confidentiality practices apply.

A waiver of consent is not utilized

- Individuals must be consented to participate and be fully informed of the COVID vaccination status or test result request and how their data will be used.
- Waivers of *documentation* of consent can be utilized when approved by the IRB.

EXCEPTIONS

Research that is conducted at a third-party facility that requires COVID vaccination or testing for facility use are not included in this guidance. The CSU IRB will not regulate COVID-related facility policies for non-CSU facilities that have existing COVID protocols.

IMPLEMENTATION & PROCEDURES

The standard IRB review process will be used to review any protocols submitted requesting a COVID vaccination status or test result from participants. The review process includes a determination that all criteria required for approval found at 45 CFR 46.111, and any additional applicable regulation, are fulfilled. The Belmont Report, a basis for current human research regulations, explains that the principle of Justice (i.e., the selection of participants is fair and the benefits and costs of research are equally distributed among participants) is paramount to determining the approvability of human research. Reviewers will keep this in mind to decide whether exclusions are reasonable or present an inappropriate exclusion based on the research activity.

The IRB requests that researchers seriously consider these requests and prioritize removing exclusion criteria as soon as appropriate. Due to the fluid nature of the virus and associated guidelines, researchers will need to take ownership of any required protocol amendments and maintain the accuracy of their protocol and any participant-facing documents (consent, recruitment, etc.).

The COVID pandemic is a unique circumstance that has led to the enactment of temporary policies and precautions to protect public health. To avoid extending this allowance past the relevant period, the IRB will re-review this guidance within 1 year of the date of this memo to determine whether it is still applicable.

For questions, please contact the CSU IRB (RICRO_IRB@colostate.edu; 970-491-1553)