

Guidance – Face-to-Face Research with Human Subjects during the COVID-19 Pandemic

General Description

This guidance provides steps on how to submit and gain approval for human subjects research during the COVID-19 Pandemic.

When it applies / context

This applies to UNLV faculty, staff, residents, fellows, and students conducting research with human subjects. Researchers should review this guidance so that appropriate IRB submissions are submitted and approved prior to engaging with human subjects.

Considerations & Best Practices

Researchers may not re-engage in face-to-face research without completion of the Safe Practices for Human Subjects Form and the associated SOP being submitted and reviewed by the IRB.

1. The PI must develop a standard operating procedure (SOP) that is specific to the research study and must describe all measures to mitigate the risk of transmitting COVID-19. For example, the SOP must describe appropriate Personal Protective Equipment (PPE), screening of subjects, disinfecting common touch points, etc. See resources below for documents.
 - The SOP must be approved by the Department Chair and Dean.
 - The SOP must be submitted to and reviewed by the IRB
2. The PI must modify the Informed Consent document to include the following statement at the beginning of the informed consent:
 - “The level of risk for transmission of COVID-19 is unknown. The research activities will utilize accepted guidance standards for mitigating the risks of COVID-19 transmission.”
 - It may be necessary to update the procedures and/or risk section of the informed consent based upon what subjects will be asked to do.
3. For new proposals, this must be included with the initial submission. For proposals previously approved by the IRB, a modification which includes the SOP and Safe Practices for Human Subjects Form must be submitted and approved prior to re-engaging in face-to-face research procedures.

PLEASE NOTE: Face-to-Face research is not recommended during Step 2. However if time- sensitive, research will be considered on a case-by-case basis. In order a request to be considered, in addition to the points above, the PI must describe the time-sensitive or urgency for needing to conduct a research study during step 2. Please refer to the Restarting Research plan. The IRB must agree that the research is time-sensitive and urgent for approval of face-to-face research while UNLV is in Step 2 of the Restarting Research Plan.

Resources

UNLV Guide to Restarting Research:

<https://www.unlv.edu/news-story/unlv-guide-restarting-research>