POLICY AND GUIDELINES FOR RESUMING IN-PERSON HUMAN SUBJECTS RESEARCH

July 01, 2021

I. Introduction. Due to the initial impact of the COVID-19 global pandemic, the University of New England suspended research activity involving in-person contact with human research participants. While the pandemic is ongoing, the University believes that it can begin to safely resume in-person contact with human research participants. The purpose of this policy is to guide researchers as they resume in-person research. The primary focus of these guidelines is the protection of human research participants. The University of New England has other policies and guidelines for protecting the general population in other contexts such as laboratory/animal research, employee return to campus, and teaching activities.

The University has established four (4) general risk categories for human subjects research:

1. Research that does not require in-person interaction or intervention with a human research participant.
2. Research that requires in-person interaction or intervention but does not involve physical contact or close contact. For the purposes of these guidelines, "close contact" means contact with any individual within 6 feet of that person for at least 15 minutes, which does not have to be continuous.
3. Research that requires in-person interaction or intervention but does involve physical contact or close contact,
4. Any in-person research in which:
    a. researchers or participants are over 65 years of age, or have certain underlying conditions that does or may place them at an increased risk for severe illness from COVID-19, as set forth in contemporary CDC guidance;
    b. the research takes place off-campus; or
    c. situations where the research involves an interaction or intervention in which there is a heightened risk of COVID-19 exposure, for example studies that include aerosolizing procedures (such as sputum induction or exercise tests) and studies that include research participant group activities (more than one (1) participant seen at one time).

Category 1 research was not paused, and all research activities that can be conducted remotely by utilizing online survey, video conferencing, telephone interviews, etc. should continue to be conducted remotely until further notice.

Category 2 and 3 in-person human subjects research may resume upon receiving the approvals set forth in Sections II and III below, and must adhere to the UNE Onward Plan guidelines regarding PPE and proper precautions. If there is any conflict between these guidelines and other applicable Federal, State, or University guidelines, the most protective measures shall take precedence.

Category 4 in-person human subjects research will be considered only on a case-by-case basis and requires an additional level of review by appropriate UNE personnel and the UNE Leadership team.

II. Guidelines for IRB Protocols

All new Applications for IRB review must address how the in-person human subjects research will conform to the COVID-19 specific guidelines. Prior to resumption of previously approved in-person human subjects research, the Principal Investigator must submit an IRB Amendment application that includes a plan addressing how COVID-19 related safety measures will be implemented, any revisions to IRB-approved procedures, and any updated protocol documents (consent forms, recruitment materials, etc.). At a minimum, the IRB Application or Amendment must include:

- A screening process, including but not limited to the completion and execution of the Screening Questionnaire and Research Attestation referenced below, consistent with these guidelines to determine if participants and staff are at a higher risk.
- Procedures for complying with all applicable UNE Onward Plan guidelines, including:
    - verification that each participant is fully vaccinated against COVID-19, consistent with Section III below. If a participant cannot provide a valid card showing they are fully vaccinated, then they must wear an appropriate mask for the duration of the study visit.
    - proper cleaning of materials, equipment and commonly touched areas where the activities will take place.
    - scheduling visits to avoid overlap in appointments, consistent with the current UNE Onward Plan restriction on visitors to UNE campuses..
- The process for providing the University's "Important Information about Research Visits During COVID-19 & Screening Questionnaire" document (as described more fully in Section III below) to participants and answering any questions or concerns they may have.

III. General Guidelines for all In-Person Human Subjects Research

- After receiving IRB approval consistent with Section II above, all Investigators must submit a Resuming Research Activity Plan to the Associate Provost for Research and Scholarship. This plan will undergo a 3-step review and approval process that includes approval by the Associate Provost for Research and Scholarship, the Human Resources Department, and Environmental Health and Safety, which must be completed prior to resumption of in-person human subjects research.
- Research Participants must complete and document a symptom screen by a remote (phone/teleconference) screening within 24 hours before each study visit **and** when the participant arrives for their study visit (assuming they screen negative during the remote screening). The screening questionnaire is included in the "Important Information about Research Visits During COVID-19 & Screening Questionnaire" document. **Please refer to Flow Chart #2 if research participants indicate a "YES" response to any question in the screening questionnaire.**
    - The remote screening must take place within 24 hours of the visit, but can occur anytime within that time period, including the day of the visit, so long as it is conducted prior to the participant entering a UNE campus.

- At least 24 hours prior to a participant's scheduled study visit, research personnel must provide the University's "Important Information about Research Visits During COVID-19 & Screening Questionnaire" document to research participants, answer any questions they may have during the remote screening required above, and ask them to sign it.
- All researchers (faculty, staff and students) must complete the required attestation within 24 hours prior to each in-person human research participant visit. This provides an extra layer of safety for research participants. If the researcher cannot attest to all of the conditions on the Attestation Form, the researcher must not participate in that visit.
- Research participants must show their vaccination card evidencing that they are fully vaccinated against COVID-19 when they arrive for their study visit. Additionally, each research participant must complete and sign the UNE vaccination confirmation form. As long as participants do this, they do not need to wear a mask during the study visit. If any research participant is unable to provide their vaccination card or complete/sign the vaccination confirmation form, then they must wear an appropriate mask for the duration of their study visit.
- Completed screening questionnaires, attestation forms and vaccination confirmation forms must be kept in the same secure location where the researcher keeps other private IRB documents (e.g. participant consent forms) and must be maintained for a minimum of three (3) years.