

 LEHIGH UNIVERSITY	Institutional Review Board (IRB) Guidance: Resuming or Beginning In-Person Human Subjects Research During the Open IV Phase		
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Background

The IRB will determine on a case by case basis, for each individual research project, if it is appropriate for in-person human subjects research to take place. Requests must be submitted via IRBNet, and in-person human subjects research may not be conducted without prior approval by the IRB.

While the University continues to operate in the [Open IV](#) phase, only in-person research that cannot be conducted using remote procedures **and** research that allows for adequate health and safety measures will be considered for resumption. The health and safety of participants, researchers, and those in the community are the first priority of the IRB when reviewing individual requests to conduct in-person human subjects research.

Instructions for submitting a request to conduct in-person research:

If a researcher would like to conduct research involving in-person interactions with participants as part of a study previously approved by the IRB or as part of a new study, the following steps must be completed:

- For new studies not previously reviewed or approved by the IRB: the researcher must submit a Human Subjects Application to IRBNet. The steps for submitting a new protocol are outlined here: <https://research.cc.lehigh.edu/irb-submit-new-protocol>

For studies that have already been approved by the IRB, but where in-person interactions were paused: to request resumption of in-person research, the researcher must submit an Amendment Modification Form. The steps for submitting an amendment are outlined here: <https://research.cc.lehigh.edu/irb-amendments>

When completing either the Human Subjects Application or the Amendment Modification Form, please describe how the study's procedures will be designed to incorporate the Health and Safety Guidelines (described below) to reduce the risk of COVID-19 transmission to participants and researchers.

- All researchers requesting to conduct in-person research must also submit a completed "[Request to Conduct In-Person Research Form](#)" via IRBNet. Please submit this form as part of the New Study package or as part of the Amendment/Modification package, depending on the submission type.
- All research personnel who will conduct in-person research must complete Lehigh's [Return to Campus Safety Training](#) (regardless of whether in-person research will be conducted on or off campus). Please submit a copy of the completion certificate for the Return to Campus Safety Training for each individual who conducts in-person research.
- Before the IRB will approve in-person research that takes place within an organization outside of Lehigh, including within K-12 schools, the organization or school district must give permission for in-person research to take place. If permission to conduct research within an organization or school district was obtained prior to closure of Lehigh's campus on 20-Mar-2020, permission must be re-issued. Documentation of permission from the organization must be signed and dated. All research that takes place within an outside organization and within K-12 schools must follow all rules imposed by the organization or school district, as well as Lehigh's requirements for conducting in-person research.
- The IRB will notify the researcher regarding the decision to approve the request to conduct in-person research or to deny the request to conduct in-person research. The IRB may also require additional information before reaching a conclusion. If additional information is required, Research Integrity staff will communicate the request for additional information.

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Health and Safety Guidelines:

When completing either the Human Subjects Application or the Amendment Modification Form, please describe how the study's procedures will be designed to incorporate the Health and Safety Guidelines to reduce the risk of COVID-19 transmission to participants and researchers. Please also see CDC information on [how the virus spreads](#), and [how to protect yourself and others](#).

Prior to scheduling an in-person study session, participants must also agree to adhere to all health and safety guidelines. All participants must be sent the "[COVID-19 Information Sheet for Research Participants](#)." Participants must review this information before agreeing to take part in in-person research. Participants should also disclose if they have a condition that the CDC has identified as putting individuals at risk of severe illness from COVID-19. If a participant reports having one of these conditions, they should not be scheduled to take part in in-person research.

Participants who will take part in in-person research on Lehigh's campus must also complete and sign a [Mandatory Requirements for Visiting Lehigh University](#) form. This form asks participants to confirm that they will follow all campus safety requirements. It also requires participants to list their contact information for contact tracing purposes. Researchers must store a copy of this document and must send a copy to inreopen@lehigh.edu.

The description of study procedures must include the following elements:

- Social Distancing. Social distancing of at least 6 feet must be maintained between participants and researchers. Please describe the lab's social distancing plan.

Research that requires groups of participants to meet in-person (such as a focus group) is not permitted. However, research that involves the participation of individuals who reside in the same home (such as parents and children), may be permitted.
- Face Coverings. Researchers and participants must wear cloth face coverings that cover their mouths and noses at all times. Please describe the plan to enforce the use of face coverings.
- Hand Washing. Researchers and participants must wash their hands (or use hand sanitizer if unable to access soap and water) immediately before and after each research session. Please see the [CDC guidance on handwashing](#). Please describe the plan to enforce consistent hand washing.
- Cleaning Procedures. Researchers must disinfect all surfaces a participant might come in contact with prior to and following a study session. Please include a plan for enhanced cleaning of all materials/spaces. See the [CDC guidance on disinfecting surfaces](#).
- Screening Procedures. Please include a plan for implementing all screening procedures:
 - Before participants agree to take part in a study, they must be given a copy of the COVID-19 Information Sheet. This document makes participants aware of risk factors the CDC has identified as putting individuals at increased risk of severe illness from COVID-19. The Information Sheet instructs participants to disclose if they belong to a high-risk group. If a participant belongs to a high-risk group, the participant should not be scheduled to take part in in-person research.
 - All research personnel must screen themselves for symptoms of COVID-19 immediately before meeting with a participant to conduct in-person research (e.g., the morning of the scheduled research session). Researchers must screen themselves regardless of

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whether in-person research takes place on-campus or off-campus.

Researchers should use Lehigh’s self-screening tool in the [HawkWatch](#) app. Researchers who are assigned a Red Badge, meaning they are not approved to come to campus, may not engage in in-person human subjects research activities for 14 days (regardless of whether the research takes place on-campus or off-campus). If the researcher receives a Red Badge, the researcher should immediately contact the participant to reschedule the session.

- Participants must also complete a self-screening prior to attending a face-to-face research visit (e.g., the morning of the visit). Participants must screen themselves regardless of whether the in-person research takes place on-campus or off-campus.

Participants should complete the screening within the [HawkWatch](#) app, or at this link: <https://lehigh.apparmor.com/Tools/Assessment/>. Participants also have the option of completing a hard copy of the screening survey. Before the researcher and participant meet for the study session, the researcher must confirm with the participant that the participant has passed the screening. If the participant completes the self-screening using the hard copy, ask participants each of the screening questions over the phone to confirm that the participant has passed the screening.

Participants who are assigned a Red Badge may not take part in in-person human subjects research activities for 14 days (regardless of whether the research takes place on-campus or off-campus). The participant must repeat the screening procedures on the day of the re-scheduled session.

- **Tracking Research Activity:** Please describe the system that will be used to document the individuals who are present during all in-person research activities. This system must be used to identify any person impacted by a report of illness or exposure to COVID-19. All documentation must be stored in such a way that participant confidentiality is maintained.
 - **Research Participants:** In the COVID Information Form, participants also asked to inform the study team if they develop symptoms or have a positive COVID-19 test within 48 hours of participating in the study.
 - **PI Responsibility:** In the event of a reported exposure or symptoms, the PI will pause any planned in-person research and immediately contact the LU IRB at inirb@lehigh.edu. The PI and the IRB will work together to assess the situation and determine next steps.

Lehigh faculty and staff must report a positive COVID-19 diagnosis at the link [here](#), and can contact human resources for additional information at intrace@lehigh.edu. Students who have symptoms of COVID-19 or suspect they have been exposed must contact the Health and Wellness Center at 610-758-3870. If participants report COVID symptoms or a positive COVID test within 48 hours of taking part in in-person research, the PI must contact incovid@lehigh.edu on the participant’s behalf.