

UNK Policy for In-Person Human Subjects Research during the COVID-19 Pandemic

Summary

In-person human subjects research remains suspended for UNK faculty, staff, and student researchers while the risk of COVID-19 community spread is rated as: **Pandemic (Red)**; **Elevated (Orange)**; or on the line between **Elevated (Orange)** and **Moderate (Yellow)**.

In-person human subjects research may resume for most populations with mandated additional safety precautions when the risk of COVID-19 community spread is rated as **Moderate (Yellow)**.

Research with at-risk and specially-protected populations may resume with mandated additional safety precautions when the risk of COVID-19 community spread is rated as **Low (Green)**; and some safety precautions will be relaxed for research with other, lower-risk populations when the community spread risk is **Low (Green)**.

If the researcher is not based within the Two Rivers Public Health District (comprising Buffalo, Dawson, Franklin, Gosper, Harlan, Kearney, and Phelps Counties) and/or the study participants are outside of the TRPHD, in-person human subjects research will not be permitted when local COVID-19 risks of community spread are rated as Red, Orange, or on the line between Orange/Yellow. Research may resume under the conditions defined below when both the researcher's locality and the study participants' location(s) are rated as Yellow or Green.

Background and Purpose:

On March 13, 2020, the Office of Research Compliance, with support of the Institutional Review Board, temporarily suspended all non-therapeutic, in-person human subjects research due to the health and safety concerns surrounding the COVID-19 pandemic. The purpose of this document is to establish a policy for resuming this research based on the best-available public health data. Two-Rivers Public Health Department Risk Dial and Community Guidance will be used for IRB and Division of Research decisions regarding the requirements for in-person human subjects research during the COVID-19 pandemic.

[Two Rivers Public Health Department Risk Dial for COVID-19 website](#)



Risk Dial for COVID-19
Two Rivers Public Health

In-person human subjects research conducted by UNK faculty, staff, and students will remain suspended while the Two Rivers Public Health COVID-19 Risk Dial is set to **pandemic** (red), **elevated** (orange), or on the line between **elevated** (orange) and **moderate** (yellow). The suspension will be lifted on research involving most populations with additional safety precautions when the dial is set to **moderate** (yellow), and safety requirements will be further tailored to population risk factors when the dial is set to **low**

(green). Finally, all population restrictions and additional safety precautions set forth in this document will be lifted when the COVID-19 risk dial is no longer in use.

Consider Digital Collection:

While the risk dial is needed due to the COVID-19 pandemic's impact on the Two-Rivers Public Health District and/or communities in which researchers are collecting in-person human subjects data, the IRB and the Division of Research strongly encourage researchers to obtain data via digital means whenever possible. To facilitate this precaution, Division of Research staff is available to advise researchers and expedite changes of protocol to reduce or eliminate in-person interactions with human subjects.

Research Outside of Two Rivers Public Health District

The procedures below use the weekly risk-level evaluation provided by the Two Rivers Public Health District. UNK researchers travelling from the district must be mindful of their potential to carry the virus to their study location(s).

If researchers are collecting data in locations beyond the borders of Two Rivers Public Health District (comprising Buffalo, Dawson, Franklin, Gosper, Harlan, Kearney, and Phelps Counties), in addition to the risk level in the Two Rivers District, the risk level of the study participants' location(s) must be taken into account.

If the researcher is based outside of the Two Rivers District, for example, an out-of-state graduate student in an online program, the risk of COVID-19 community spread in the researcher's locality as well as in the location(s) where in-person contact with human subjects will occur must be taken into account.

Since different public health authorities use different reporting schemes, to make it easier to determine risk levels outside of the Two Rivers Public Health District, researchers may consult the following mapping tool from Harvard Global Health Institute, which uses an equivalent color-coding scheme for US counties as the Two Rivers Public Health District:

<https://globalepidemics.org/key-metrics-for-covid-suppression/>

Changes in Risk Dial Level

Researchers are responsible to monitor changing COVID-19 community-spread conditions. In-person human subjects research must be suspended and such suspension reported to the IRB when risk levels for the researcher's locality and/or the study location(s) rise above moderate (yellow). If the local risk conditions change from green to yellow, the appropriate changes to the required procedures must be made immediately with changes of protocol submitted to the IRB to document compliance with this policy. Researchers also may use change of protocol forms to adjust study populations or safety procedures where local risk conditions have changed from yellow to green.

Required Procedures:

For Risk Dial Levels: Pandemic (Red), Elevated (Orange), or between Elevated and Moderate (Orange/Yellow):

In-person human subjects research remains suspended. Risk-level determinations are made by the Two Rivers Public Health District or the Harvard Global Health Institute (for researchers or study locations outside the Two Rivers District) and apply for all UNK researchers (faculty, staff, and students).

For Risk Dial Level: Moderate (Yellow):

In-person human subjects research with additional safety precautions can resume for most populations. Population restrictions are described below:

At-Risk Populations for COVID-19: Populations at high risk for COVID-19 may not participate in in-person human subjects research during risk level moderate (yellow). These populations, as defined by the NIH, are:

“Residents of chronic care and assisted living facilities; community-dwelling older adults; individuals with cognitive impairment or dementia; homeless populations; incarcerated populations and those involved with the criminal justice system (e.g., participants of re-entry programs); adults with medical comorbidities; pregnant women; children and adolescents; individuals with substance use disorders or severe mental illness, those living in congregate housing (e.g., shelters, residential treatment or assisted living); persons who are deaf or with disabilities including visual, hearing, communication, or mobility impairment; detainees in immigration centers; migrant communities; individuals living on tribal lands or reservations; and environmentally vulnerable communities that are exposed to high rates of air pollution or other toxic exposures. Vulnerable groups also include those on the frontlines of healthcare during the COVID-19 pandemic, and those working in essential business operations (e.g., grocery and pharmacy workers, transportation, hospital and community janitorial/sanitation workers, waste collectors, postal and other delivery service and warehouse personnel, etc.).”

Protected Populations under the Common Rule: No human subjects from populations (pregnant women, prisoners, or children) designated for special protections under the Common Rule will be allowed to participate in in-person research procedures during risk level moderate (yellow).

Additional Safety Precautions:

In order to conduct in-person research during risk level moderate (yellow), an addendum must be filed with the IRB in the form of a change of protocol. Said change of protocol must include: updated exclusion criteria to exclude from participation the at-risk and protected populations detailed above; an updated consent/assent form with the required COVID-19 text (below); updated recruitment procedures that explain how safety procedures are being communicated with potential participants; and updated study procedures that address the use of physical distancing, face coverings, hand washing, illness monitoring, and disinfecting of the study site and equipment. Finally, a revised risk and benefits section must be included in the change of protocol and updated protocol application form that includes potential COVID-19 infection in weighing the risks versus benefits for participants.

At a minimum, each protocol approved during risk level moderate (yellow) must include:

- **Consent form text:** “By consenting to participate in this study, you agree to take certain precautions that help protect you and others from exposure, sickness, and possible death as a result of COVID-19. These precautions include being symptom-free; abiding by social distancing

guidelines of federal, state, and local authorities; washing your hands before and after participation; and wearing a mask at all times during research participation.”

- **Physical Distancing:** All study personnel and participants must maintain social distancing of at least 6 feet in all directions as much as possible during the implementation. If necessary to provide sufficient distancing, study personnel must limit the number of participants at a time. When distancing is not possible (e.g. handing out study instruments or taking measurements), study personnel and participants must wear face coverings. Researchers should revise study procedures as needed to minimize interactions that compromise physical distancing.
- **Personal Protective Equipment (PPE)/Face Coverings:** All study personnel and participants must wear at least two-layer masks during the entirety of the protocol implementation, unless these types of PPE are not feasible to implement the study (e.g. fMRI studies). If PPE is not an option, exemption from this requirement must be extensively justified and the risk/benefit calculations must demonstrate the urgent need for the study. Study personnel are responsible for providing PPE to participants should they come to the study without it. However, recruitment procedures must explicitly require PPE as an inclusion criterion for participation.
- **Hand Washing:** Study procedures should direct participants to wash their hands for at least 20 seconds upon arrival at the study site and after sneezing/coughing/touching their face and before eating (if applicable). Hand sanitizer should be provided when hand washing is inaccessible or infeasible.
- **Illness Monitoring:** Study procedures should include plans to screen participants for flu-like or COVID-like symptoms. These plans might include: contacting participants in advance to instruct them to self-monitor and stay home if they are ill; posting signs to remind participants not to enter the study site if they are symptomatic; a symptom screening questionnaire; and/or temperature checks. Additionally, researchers may not establish conditions for receiving compensation for research participation that create incentives for participants to show up when they are ill.
- **Disinfecting:** The application or change of protocol form must explain plans for cleaning and disinfecting any equipment used in data collection and enhanced disinfection for frequently-touched surfaces at the study site. The Centers for Disease Control provide the following guidance (see link below): <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>
In addition, researchers should revise study procedures as needed to minimize bare-hand contact with high contact surfaces by participants and to provide participants with a barrier (such as paper towel or disposable gloves) when contact with such surfaces is unavoidable.

For Risk Dial Level: Low (Green):

In-person human subjects research with additional safety precautions can resume. The types of safety precautions required depend on the characteristics of the study population.

At-Risk Populations for COVID-19 and Protected Populations under the Common Rule: In-person human subjects research involving any populations at high risk for COVID-19 or designated for special protections under the Common Rule can resume under the conditions detailed below. (These safety precautions are the same as those required for research with non-vulnerable populations at risk level moderate (yellow)):

At-Risk Populations for COVID-19, as defined by the NIH, are:

“Residents of chronic care and assisted living facilities; community-dwelling older adults; individuals with cognitive impairment or dementia; homeless populations; incarcerated populations and those involved with the criminal justice system (e.g., participants of re-entry programs); adults with medical comorbidities; pregnant women; children and adolescents; individuals with substance use disorders or severe mental illness, those living in congregate housing (e.g., shelters, residential treatment or assisted living); persons who are deaf or with disabilities including visual, hearing, communication, or mobility impairment; detainees in immigration centers; migrant communities; individuals living on tribal lands or reservations; and environmentally vulnerable communities that are exposed to high rates of air pollution or other toxic exposures. Vulnerable groups also include those on the frontlines of healthcare during the COVID-19 pandemic, and those working in essential business operations (e.g., grocery and pharmacy workers, transportation, hospital and community janitorial/sanitation workers, waste collectors, postal and other delivery service and warehouse personnel, etc.).”

Protected Populations under the Common Rule include: Pregnant women, prisoners, and children.

Additional Safety Precautions for At-Risk and Protected Populations:

In order to conduct in-person research with at-risk or protected populations at risk level low (green), an addendum must be filed with the IRB in the form of a change of protocol. Said change of protocol must include an updated consent/assent form with the required COVID-19 text (below), updated recruitment procedures that explain how safety procedures are being communicated with potential participants, and updated study procedures that address the use of physical distancing, face coverings, hand washing, illness monitoring, and disinfecting of the study site and equipment. Finally, a revised risk and benefits section must be included in the change of protocol and updated protocol application form that includes potential COVID-19 infection in weighing the risks versus benefits for participants.

At a minimum, each protocol for in-person research involving at-risk or protected populations must include:

- **Consent form text:** “By consenting to participate in this study, you agree to take certain precautions that help protect you and others from exposure, sickness, and possible death as a result of COVID-19. These precautions include being symptom-free; abiding by social distancing guidelines of federal, state, and local authorities; washing your hands before and after participation; and wearing a mask at all times during research participation.”
- **Physical Distancing:** All study personnel and participants must maintain social distancing of at least 6 feet in all directions as much as possible during the implementation. If necessary to provide sufficient distancing, study personnel must limit the number of participants at a time. When distancing is not possible (e.g. handing out study instruments or taking measurements), study personnel and participants must wear face

coverings. Researchers should revise study procedures as needed to minimize interactions that compromise physical distancing.

- **Personal Protective Equipment (PPE)/Face Coverings:** All study personnel and participants must wear at least two-layer masks during the entirety of the protocol implementation, unless these types of PPE are not feasible to implement the study (e.g. fMRI studies). If PPE is not an option, exemption from this requirement must be extensively justified and the risk/benefit calculations must demonstrate the urgent need for the study. Study personnel are responsible for providing PPE to participants should they come to the study without it. However, recruitment procedures must explicitly require PPE as an inclusion criterion for participation.
- **Hand Washing:** Study procedures should direct participants to wash their hands for at least 20 seconds upon arrival at the study site and after sneezing/coughing/touching their face and before eating (if applicable). Hand sanitizer should be provided when hand washing is inaccessible or infeasible.
- **Illness Monitoring:** Study procedures should include plans to screen participants for flu-like or COVID-like symptoms. These plans might include: contacting participants in advance to instruct them to self-monitor and stay home if they are ill; posting signs to remind participants not to enter the study site if they are symptomatic; a symptom screening questionnaire; and/or temperature checks. Additionally, researchers may not establish conditions for receiving compensation for research participation that create incentives for participants to show up when they are ill.
- **Disinfecting:** The application or change of protocol form must explain plans for cleaning and disinfecting any equipment used in data collection and enhanced disinfection for frequently-touched surfaces at the study site. The Centers for Disease Control provide the following guidance (see link below): <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>
In addition, researchers should revise study procedures as needed to minimize bare-hand contact with high contact surfaces by participants and to provide participants with a barrier (such as paper towel or disposable gloves) when contact with such surfaces is unavoidable.

All Other Populations: In-person human subjects research involving populations other than those designated as high risk for COVID-19 or for special protections under the Common Rule can resume under the conditions detailed below. (Physical distancing and face coverings/PPE are not required for healthy people from non-vulnerable populations when the risk of community spread is low (green); the other safety measures are still required):

Additional Safety Precautions for All Other Populations:

An addendum must be filed with the IRB in the form of a change of protocol. Said change of protocol must include an updated consent/assent form with the required COVID-19 text (below), updated recruitment procedures that explain how safety procedures are being communicated with potential participants, and updated study procedures that address hand washing, illness monitoring, and disinfecting of the study site and equipment. Finally, a revised risk and benefits section must be included in the change of protocol and updated protocol

application form that includes potential COVID-19 infection in weighing the risks versus benefits for participants.

At a minimum, each protocol for in-person research involving non-vulnerable subjects must include:

- **Consent form text:** “By consenting to participate in this study, you agree to take certain precautions that help protect you and others from exposure, sickness, and possible death as a result of COVID-19. These precautions include being symptom-free; washing your hands before and after participation; and compliance with any health and safety directives from the study personnel.”
- **Hand Washing:** Study procedures should direct participants to wash their hands for at least 20 seconds upon arrival at the study site and after sneezing/coughing/touching their face and before eating (if applicable). Hand sanitizer should be provided when hand washing is inaccessible or infeasible.
- **Illness Monitoring:** Study procedures should include plans to screen participants for flu-like or COVID-like symptoms. These plans might include: contacting participants in advance to instruct them to self-monitor and stay home if they are ill; posting signs to remind participants not to enter the study site if they are symptomatic; a symptom screening questionnaire; and/or temperature checks. Additionally, researchers may not establish conditions for receiving compensation for research participation that create incentives for participants to show up when they are ill.
- **Disinfecting:** The application or change of protocol form must explain plans for cleaning and disinfecting any equipment used in data collection and enhanced disinfection for frequently-touched surfaces at the study site. The Centers for Disease Control provide the following guidance (see link below): <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>
In addition, researchers should revise study procedures as needed to minimize bare-hand contact with high contact surfaces by participants and to provide participants with a barrier (such as paper towel or disposable gloves) when contact with such surfaces is unavoidable.

Mixed Populations: In-person human subjects research involving populations designated as high risk for COVID-19 or for special protections under the Common Rule as well as other populations must follow the requirements for the at-risk and protected populations.