

Guidelines for Investigators Conducting Human and Animal Research Under COVID-19 Pandemic Conditions

Overarching Goal:

Our top priority at Radford University is the safety of Radford researchers, staff, students, and the surrounding community. Our goal is to keep all research participants safe while supporting research activity in a phased approach as safety becomes easier to maintain and does not contribute to a resurgence of COVID-19 infection threatening faculty, students, and staff, and local residents or impairs the progress of research at Radford.

- **While Radford University IRB research has not experienced COVID-19 related stoppage, some research protocols have been affected and forced to stop due to external forces beyond Radford researchers' control. This may include facility use changes imposed by Radford University or external facility management (i.e. Carilion Clinic). Any research activities with prior IRB/IACUC approval that has been impacted by COVID-19 may continue as long as the guidelines contained herein are followed.**
 - Research with human subject participants with prior IRB approval, both on and off Radford University grounds can proceed to the extent that it can be conducted safely.
 - Any approved human subjects research that can be conducted 100% virtually is recommended to be continued through all research levels.
 - Radford faculty, research team members, and staff must continue to comply with executive orders and health authority guidance from National, State, Local, and University authorities to protect the safety of research participants, staff, students, and faculty.
 - Consistent with the Governor's Reopening Plan and Guidelines, the approach outlined in this document is based on established physical distancing requirements (stay at least 6 feet apart from other people) for the various research spaces, requiring the use of personal protective equipment (PPE), and sound hygiene practices, such as recommended hand washing/use of hand gel, and routine sanitizing of work areas.
 - **Under NO circumstances should safety be sacrificed due to lack of adequate supplies, such as the type and quantity of PPE.** Researchers are encouraged to plan in advance for PPE supply chain issues when reopening research.
 - Because State public health directives are subject to revision at any time due to many outstanding questions surrounding COVID-19 transmission and infection, researchers should anticipate the possibility of returning to more restricted research levels or cessation of some-to-all research activities should COVID-19 infections increase and conditions require the closing of university facilities.
- **Failure to follow these guidelines may result in suspension of research approval.** Reports of aberrations of these guidelines will be reviewed by the Research Compliance office in consultation with the appropriate oversight committee (IRB or IACUC).

The continuation of research will be highly dependent on ongoing updates from federal, state, local, and University policies related to physical distancing and allowed activities and based on continuous monitoring of the guidelines. ALL safety measures (e.g. social distancing, wearing masks) are required and will continue until further notice.

HUMAN SUBJECTS RESEARCH

The Research Compliance Office's primary focus in these guidelines is to protect human subject researchers and research participants. These guidelines supplement the existing guidelines and policies of Radford University which are aimed at protecting the campus community, faculty, lab workers, students, staff, and other groups.

Federal research regulations require that the IRB review modifications to a study before they are implemented; there is one important exception, "*where necessary to eliminate apparent immediate hazards to the human subjects.*" 45 CFR 46.108(3)(iii) and 21 CFR 56.108(a)(4).

Standard Operating Procedures (SOPs) for personal protective equipment (PPE) or COVID-19 screening do not require prior approval by the IRB, as long as the screening data are not being used for research purposes. However, documentation that the screening took place should be maintained by the principal investigator (PI). If it is not clear whether an activity is considered human subjects research, please contact the Research Compliance Office.

Should the PI determine that such changes in approved procedures are required, the PI may implement them immediately, without prior notice to or approval from the IRB. Implementing protocol changes without prior IRB approval must be limited to changes directly related to eliminating an immediate hazard. While the PI does not have to wait to obtain IRB approval prior to making such a change, the PI must notify the IRB of the changes that were made.

The most protective measures among the CDC, State, Local, facility, and Radford's Environmental Health and Safety Office (EHS) guidelines must take precedence. If the Radford University IRB is the reviewing IRB and the research will be conducted in a partner facility (e.g. Virginia Tech, Carilion Clinic, etc.) that has less restrictive policies, the Radford IRB guidance below will take precedence.

For collaborative efforts where an Inter-Institutional Agreement (IAA) exists, the IRB with oversight must work in conjunction with the facility where the research is performed to set the rules for restart. The reviewing IRB will establish the policies and procedures for restarting the research.

General Considerations:

- The Research Compliance Office encourages researchers to use remote technologies such as video conferencing to conduct research whenever possible.
- All in-person research must incorporate the recommended precautions as defined by:
 - 1) The CDC (<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>),
 - 2) Outlined in the Preventative Measures and Actions for Campus Community <https://www.radford.edu/content/radfordcore/home/coronavirus/preventative-measures.html>,
 - 3) Campus Reopening, <https://www.radford.edu/content/radfordcore/home/reopening.html>, and
 - 4) All existing orders from the governor of Virginia; this may include but is not limited to guidelines on physical distancing, disinfection, PPE (face coverings, masks, face shields), symptom screening, washing hands often, use of hand sanitizer, avoid touching eyes, nose and mouth, cover coughs and sneezes with a tissue or inner elbow).

- To minimize risk to research participants and researchers, **all in-person research requires COVID-19 pre-screening of both researchers and participants**. Sample screening questions and information script/email are in **Appendix 2**.
- Researchers must complete and document a symptom screening each day that in-person contact with study participants is planned with one or more research participants. Both researchers and each research participant must complete the screening. The symptom screen must be completed prior to in-person contact between a researcher and a participant. Radford personnel may utilize the online symptom tracker available on *One Campus*. Research personnel should forward documentation of COVID-19 Symptom Tracker completion received via campus email to their PI.
- The study participant screening questionnaire must include information tailored to the reading/comprehension level of the potential participants, about risk factors for severe illness to allow participants to evaluate their individual risk.
- The study team must encourage the participant to arrive alone for their appointment. If the participant will need a caregiver, the study team must also pre-screen of the caregiver and inform the research staff in advance. It is important to inform caregivers that they will need to bring their own mask or one will be provided by the PI.
- If any individual tests positive for COVID-19 within 14 days of being physically present in a Radford University research facility, the PI should ask that study participants notify the study contact person or PI.
- Research activities involving direct contact with study participants should be conducted by as few persons as necessary, and with minimal contact time.

Modifications to IRB Protocols

Changes that can be implemented without prior notice or approval:

- Replacing in-person visits with telephone calls.
- Replacing in-person visits that do not require HIPAA oversight with Radford University Zoom Conferencing using single-sign-on (SSO). Researchers are advised to turn off the Cloud Recording feature.

Note: Use of programs such as personal Zoom and FaceTime accounts using personal subscriptions are not HIPAA compliant and therefore not allowed for research involving health information.

If revisions to existing IRB-approved procedures are needed other than to mitigate participant risk related to COVID-19 (such as moving to the use of remote technologies), a modification amendment must be submitted to the IRB before proceeding with the modified protocol. **Amendments are not required if the change only involves adding the use of PPEs by participants or a COVID 19 pre-screening questionnaire.**

If a research study cannot adhere to the applicable safety guidelines for scientific reasons, the PI must request an exception to the safety guidelines by submitting a modification amendment to the IRB. The modification amendment must include the information outlined in **Appendix 1**.

For All Studies:

- No notification to the IRB or IRB approval for the above changes is needed at this time.
- For Full Board studies ONLY: If the change in procedures will continue past July 1, 2021, the study team will be required to submit a modification to the IRB. This date may be subject change due to environmental and/or pandemic conditions and recommendations from CDC, OHRP or other state or federal governing bodies. These guidelines will be reviewed at this date for continued relevance and need.

Researchers must submit a modification for approval prior to implementing any additional changes.

Other Notifications:

- It is the responsibility of the PI to make appropriate notifications to sponsors and/or federal agencies, if applicable.

Research Involving Children

Children are a [vulnerable population](#) in research. The researcher would need obtain informed consent of parents, and if required, the appropriate permissions from school officials.

Graduate Students and Research

If graduate student researchers are performing masters or doctoral research that is subject to a pause, and face-to-face research interactions cannot continue (i.e. be performed remotely, OR are not essential to a subject's health and have a direct therapeutic benefit), then the faculty member overseeing their research should work with their students to develop revised/alternative plans to enable continued progress towards their degree.

For new studies and amendments which have not yet been submitted, indicate whether the study procedures include in-person activities.

RESEARCH ACTIVITIES AND REQUIRED SAFETY MEASURES

Research Activity	Location	Guidelines	Notes
	Radford University and Radford University Carilion	<ul style="list-style-type: none"> Vulnerable populations relating to COVID-19 as defined by the CDC: <ul style="list-style-type: none"> Older adults – The greatest risk for severe illness is among those aged 85 and older. People with certain medical conditions such as: <ul style="list-style-type: none"> Cancer Chronic kidney disease COPD (chronic obstructive pulmonary disease) Immunocompromised state (weakened immune system) from solid organ transplant Obesity (body mass index [BMI] of 30 or higher) Serious heart conditions such as heart failure, coronary artery disease, or cardiomyopathies Sickle cell disease Type 2 diabetes mellitus On-campus human subjects research involving children, adults over 65, and other vulnerable populations is discouraged, but not prohibited at this time. However, the use of remote technologies such as Radford University Zoom (SSO) is encouraged. Schedule participants to avoid overlap and waiting time Disinfect research area per Facilities Management guidelines between participants Researchers and participants must wear surgical or cloth masks (or face shields depending on exposure to aerosols during research procedures or high intensity athletic procedures). See the RU Universal Masking and Cloth Mask Guidance. If not all parties can wear masks due to the nature of the research, then clear dividers or face shields must be used within six feet of separation Studies with participants must be held in separate dedicated spaces to avoid exposure to others PI's must adhere to the most protective guidelines regarding personnel density, face covering, and physical distancing If offering snacks, they need to be individually wrapped servings. 	If participants must interact with or on equipment during the study, verbal instructions should be provided for correct operation, with minimal direct physical contact. All equipment must be sanitized after the study session according to Environmental Health and Safety (EHS) guidelines.
	Community/Field site	<ul style="list-style-type: none"> Radford University-research-driven gatherings may take place outdoors if they follow State and Local recommendations: number of people, spacing, and face coverings. No contact is permitted between participants. During site visits or on-site observations, Radford researchers must comply with host organization's COVID-19 guidelines in addition to Radford IRB Guideline Requirements. 	Radford researchers do not control the space, so risk is higher for noncompliance with guidelines. During on-site observations, Radford researchers may observe daily behavior and activity as well as interacting with the host employee(s).

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Physical contact or other procedures that require close proximity	Radford University or within research space in a collaborating institution	<p>In addition to the guidelines above, Radford University guidelines regarding use of PPE must be followed (e.g. gloves, lab coats, surgical masks, cleaning equipment, density measures/physical distancing)</p> <p>Where physical contact is required, the appropriate PPE should be worn and contact time minimized whenever possible.</p>	Research must also adhere to the IRB guidelines of the collaborating institution.

Research Activity	Location	Guidelines	Notes
Home- based study visits with individuals or households	Studies only requiring the installation of technologies in participant homes with minimal interaction in the home.	<ul style="list-style-type: none"> All home studies require IRB review before proceeding. Must follow the same Radford University IRB guidelines for researchers. All materials brought into the home (e.g. technology, cameras, clipboards) must be sanitized directly before entering the home. Set up visit with participant, ask that only one person at most be present in space of installation. A mask and shoe covers must be worn at all times when in the home and hands should be washed/sanitized upon entering and leaving the home. All surfaces that have been touched within the home should be wiped down and disinfected after use. All researchers and home occupants must complete the COVID-19 pre-screening. Researchers should minimize face to face interaction with occupants; preferably limiting interaction to one adult occupant at a safe distance. Participants meet researchers outside and consent to the study. Researchers describe the installation procedures and ask participants for permission to enter homes to install any equipment needed for the study. Participants either remain in a different room or outside during the installation. If shipping research materials to participant homes, guidelines for cleaning should be followed prior to shipping (see notes). 	
	In-Home Studies	<ul style="list-style-type: none"> When meeting with participants in their homes for interviews and observations, researchers use medical-grade masks, gloves, shoe coverings, and protective suits. Participants will be required to use masks and gloves. In-home meetings will be limited to the minimal time period needed for collection of data that cannot be gathered by other means. 	

Research Activity	Location	Guidelines	Notes
All	International	In addition to the Radford IRB guidelines for the above categories of research, researchers must also comply with any more restrictive guidelines in the country where the research is taking place and any additional safety requirements of the setting.	
Research involving children	Carilion Clinic or other medical facility	Researchers shall follow the guidelines and requirements of the hospital facility where the research is taking place.	An exception for inclusion of other hospital/clinical facilities is required to be filed for review.
	Radford University	In-person research with children is permitted at this time with approval of parent or guardian or appropriate official if research is conducted in a school setting.	
Research involving older adults age 65 and up	On-campus Or Off-campus	Off-site facility must not be experiencing active transmission of COVID-19. Researchers shall follow the guidelines and requirements of the hospital facility where the research is taking place.	An exception for inclusion of other facility is required to be filed for review.

RESEARCH INVOLVING USE OF VERTEBRATE ANIMALS

- The Research Compliance Office remains open.
- The processing and review of protocols, amendments, and annual progress reports continue.
- IACUC meetings are currently being held remotely via Zoom.
- Prioritize health and safety when deciding to conduct vertebrate animal research activities.

The conduct of all animal activities should be carefully planned by the PI or lead research team member. These plans should include, for example, making sure an adequate number of research staff members are present to conduct the activity before it is started, taking into consideration that social distancing practices should be followed as noted in the *SOP for ACSAT Vivarium Use for COVID-19 Mitigation* and *SOP for CHBS Vivarium (COVID-19 Mitigation Version)*.

IACUC Protocol Changes Requiring an Amendment

Given the COVID-19 pandemic conditions, Principal Investigators should review their protocols carefully to determine if the work with animals can be conducted as written in the protocol. If not, an amendment must be submitted to update the protocol accordingly.

Potential changes include but are not limited to the following:

- Experiment modifications
- Timing of procedures
- Age of animals at the time of use
- Experimental groups or design
- Details of procedures conducted
- Increase in animal numbers for breeding/experiments
- **Note:** the number of animals used to date on protocols includes any euthanized without assignment to an experiment.

- Animals bred should be counted as used at the time of weaning and all animal usage should be tracked, accurate, and up to date.

FREQUENTLY ASKED QUESTIONS

Q. What if a participant refuses to wear a mask or comply with safety precautions?

A. The study visit should either be rescheduled for a time when the participant agrees to comply, or the session should be terminated if the participant states that they will not comply (in which case the subject should also be withdrawn from the study).

Q. What if I, in the role of a researcher, cannot follow all the guidelines while conducting my in-person research activities?

A. Submit a modification amendment to the IRB or IACUC to determine if an exception can be made prior to resuming those activities.

Q. What if my international research is in a resource-poor setting, and I cannot obtain the required PPE?

A. At this time, the research may not resume.

Q. Can an Investigator make a change in the IRB-approved method of documenting informed consent prior to obtaining IRB approval in order to eliminate immediate hazards to human subjects?

A. Investigators may implement changes to approved research prior to IRB review and approval, if the changes are necessary to eliminate apparent immediate hazards to the subject ([45 CFR 46.108\(a\)\(3\)\(iii\)](#) under the 2018 Requirements and 45 CFR 46.103(b)(4)(iii) under the pre-2018 Requirements). For example, we expect that investigators are cancelling or postponing non-essential study visits or conducting phone visits instead of in-person visits to reduce COVID-19 transmission risks.

In these situations, investigators may make such changes to the research to reduce risks without prior IRB approval, but they should report those changes to the IRB when possible.

Q. What if my research is conducted at museums, schools, hospitals, or other external partners?

A. This is considered more than minimal risk at this time. Please submit a modification amendment and attach external documentation validating that the external partner has provided and is following a compliance procedure with COVID-19.

Q. Is the Radford University Zoom adequate and meet HIPAA regulations?

A. Yes, Use of Radford University Zoom with single-sign-on access meets HIPAA; however, use of Zoom through personal accounts does not meet HIPAA guidelines.

Q. What if a participant appears to be sick before or during a research interaction?

A. Follow the [Radford guideline](#)s as follows:

Step 1: Communicate

1. Notify the Principle Investigator and/or faculty member(s).
2. If the subject is a Radford student, email the Radford Student Health Center at RUSH@CarilionClinic.org 540.831.5111
3. Inform the participant to contact their primary care doctor for guidance regarding medical evaluation.
4. Send the participant immediately home and if possible, have them avoid all public transportation, ridesharing, or taxis.

Q. Can COVID-19 directly infect or impact research animals and/or present an exposure risk to personnel working with them?

A. While dogs and cats living with people diagnosed with COVID-19 in several countries have been reported to have been infected with SARS-CoV-2, infectious disease experts and multiple international and domestic human and animal health organizations continue to agree that there is no evidence at this point to indicate that, under natural conditions, pets spread COVID-19 to people. – Source: [American Veterinary Medical Association \(AVMA\)](#)

It is recommended that those ill with COVID-19 limit contact with animals until more information is known about the virus.

Although several new research articles have been disseminated showing that some domestic animals can be experimentally infected with SARS-CoV-2 and may transmit the virus to other animals in an experimental setting, it is important to note that:

- Studies include a very small number of animals in an experimental setting and, therefore,
- Results from these studies should not be extrapolated to the potential for SARS-CoV-2 to be transmitted by companion animals kept as pets. – Source: [AVMA](#)

A required component of continued institutional planning is reversibility, in case a recurrence of COVID-19 forces another contraction of research activity. If this were to happen, the following guidance and resources may be applicable to your laboratory research operations involving animals.

Q. What are the best methods for us to reduce our animal breeding colonies, if absolutely necessary?

A. If you are suspending breeding of commercially-available animals, try to conserve the fewest number of animals needed to maintain the strain or line. **Specifically:**

- Remove male breeders from breeding cages and identify the male
- Ideally, save the youngest weanlings of a strain (~3-5 weanlings, male and female in separate cages)
- Save one cage of female weanlings (3-5 weanlings, ideally 6-8 weeks old or youngest available) and label the cages with a “Save for Breeding” note
- Save one cage of male weanlings (2-3 weanlings, ideally 6-8 weeks old or youngest available) and label the cages with a “Save for Breeding” note
- If possible, recombine females into socially-housed cages (up to 5 per cage); females from different strains may be combined if socially compatible
- Consider euthanizing males if there are several of the same strain to reduce the number of singly-housed animals

For strains that need to be maintained by breeding:

- It is recommended that you reduce the number of breeding cages to 2-3 cages and allow mice to continue to breed
- Pups should be euthanized prior to weaning except in cases in which breeder cages are being replaced due to age or poor breeding

Plan for a gradual restart to breeding. Setting up a large number of simultaneous matings will result in a large number of simultaneous litters that will need to be weaned over a short period of time.

PIs should be mindful of the restart of breeding to ensure adequate caging and other resources will be available.

APPENDIX 1: MODIFICATION GUIDELINES FOR EXCEPTION REQUEST (MODIFICATION AMENDMENT)

1. Which specific safety precautions are impossible to perform while maintaining the integrity of the research activity?
2. Why is it not possible to comply with those precautions?
3. What proposed steps will be taken to mitigate risk in place of those precautions?
4. Does the research involve any populations that may be at heightened risk (e.g., older adults or immunocompromised individuals) if the safety precautions are not used?

APPENDIX 2: COVID-19 PRE-SCREENING QUESTIONNAIRE/SCRIPT FOR STUDY PARTICIPANTS

Appropriate screening questions should include the following, which could be modified to fit your specific participant population and the location of in-person interactions.

Any YES answer should be considered a sufficient reason to postpone in-person visits for at least 14 days. If applicable, please also refer to your facility's screening requirements.

Note: Using these screening questions does NOT require an IRB modification amendment if the data will not be used for research purposes.

Protocol #: _____ PI Last Name: _____

Subject ID: _____

Research Personnel's Name: _____

Date, Time of Phone Screen: _____

Script for Research Staff:

"For health safety reasons, and to help prevent the spread of the Coronavirus, we are asking a few questions regarding how you are feeling and any cold or flu-like symptoms you may have, before you are scheduled for your research study"

Have you had any of the following within the past two weeks (14 days):

1. A fever (temperature over 100.4⁰ F or 38⁰ C)?
2. A loss of smell or taste?
3. A cough?
4. Muscle aches (those not associated with physical over-exertion)?
5. Sore throat?
6. Shortness of breath?
7. Chills?
8. A new or unusual headache?
9. Any gastrointestinal symptoms such as nausea/vomiting, diarrhea, loss of appetite?

10. Have you, or anyone you have been in close contact with, been diagnosed with COVID-19, or been placed on quarantine because of possible exposure to COVID-19 within the last 14 days?
11. Have you, or anyone you have been in close contact with, been in a workplace or other setting where someone has been diagnosed with COVID-19, or been placed on quarantine because of possible exposure to COVID-19?
12. Have you been asked to self-isolate or quarantine by a medical professional or a local public health official in the past 14 days?
13. Have you traveled domestically to any location experiencing a large number of COVID-19 cases within the last 14 days?

If any of the questions have been answered **YES**, the in-person visits should be postponed for at least 14 days.

“Out of an abundance of caution, we must reschedule your in-person appointment. You will be contacted by a member of the study team in 2-3 weeks.”

[If the subject has fever:] *“We recommend you self-quarantine (stay at home) and contact your healthcare provider. Thank you for your understanding.”*

If all answers have been answered **NO**, proceed to the next item.

14. Decisions about in person visits should be especially cautious for people at higher risk per public health recommendations. If any of the below describe you, you may wish to postpone your in-person visit:
 - Older adults age 65 and over; and
 - People of all ages with underlying medical conditions, including but not limited to:
 - Heart disease/conditions, high blood pressure, chronic lung disease or moderate to severe asthma, severe obesity (body mass index of 40 or higher), diabetes, chronic kidney disease, or liver disease
 - Weakened immune system (immunocompromised)
 - Pregnant