

Community and Off-Campus Research Study Application to Reactivate

The COVID-19 pandemic is unpredictable and expected to remain so for the months if not years ahead. Community-based research teams must now consider how to safely and effectively operate in this new reality. The purpose of this form is to provide university administrators with information on the status and safety measures of studies that include in-person contact with research participants and/or community contacts in community settings (not on the Anschutz Medical Campus). One form per study must be completed.

For guidance on the ramping up of community-based research, refer to the CU Anschutz Medical Campus Principles and Framework Guide to Ramping Community-based Research Activity (Community Based Research).

If your study does not include in-person contact with research participants and/or community contacts in a community setting, please exit this form and complete the appropriate form for your study. Research studies that solely use secondary data are not required to submit a form.

The CU Anschutz Community Research Resumption Committee, comprised of CU Anschutz faculty experts, will review submitted forms in the order that they are received. The committee convenes twice per week and will notify you when the form has been reviewed.

For any questions about this form or approval process, please contact Matt Steinbeiss at matthew.steinbeiss@cuanschutz.edu.

Name of person completing the form:

Role of person completing the form:

Email Address for the person completing the form:

School/Department:

Study Title

PI Name(s)

How many participants and/or community contacts will be seen each day?

Approximately how many participants and/or community contacts will be seen in person in the time between restarting research and study closure?

COMIRB Protocol # for the research study:

Please attach a copy of your COMIRB-approved research protocol here. This will provide the research resumption committee with a better understanding of the project and your research needs.

Provide the justification(s) for why this research must restart utilizing in-person contact rather than remote contact. Check all that apply.

- Funding requirements
 - Academic credit
 - Community healthcare/therapeutic services
 - Other
-

Please specify "Other":

What changes have been made to the study protocol to adapt to the current environment?

- Transition to phone contact
 - Transition to video conferencing
 - Transition to mailed materials
 - Other
-

Please specify "Other":

The following questions pertain to the community and off-campus settings used for your research.

Please indicate the location(s) where in-person contact with research participants and/or community contacts will occur. (Check all that apply).

- Clinical setting
- Campus setting other than Anschutz
- Assisted living facility
- Community center
- Home setting
- Gathering place for communities of faith
- Tribal reservation
- School setting
- Outside of Colorado
- In Colorado, but outside of the Denver metro area
- Other

Please specify "Other":

If the research is occurring in the home setting, how will research staff travel between sites?

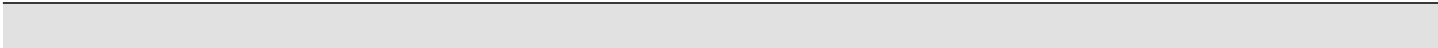
Specify which reservation(s) your research is located on.

Survey 25% Complete

If the research is being conducted outside of Colorado, in what state(s) will it occur? Check all that apply.

- Alabama
- Alaska
- Arizona
- Arkansas
- California
- Colorado
- Connecticut
- Delaware
- Florida
- Georgia
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Kentucky
- Louisiana
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Missouri
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Carolina
- North Dakota
- Ohio
- Oklahoma
- Oregon
- Pennsylvania
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Vermont
- Virginia
- Washington
- West Virginia
- Wisconsin
- Wyoming
- Other territories

Please specify the "Other territories" where your research will occur:



If research is being conducted in Colorado but outside of the Denver metro area, in which county(ies) will it occur? Check all that apply.

- Adams
- Alamosa
- Arapahoe
- Archuleta
- Baca
- Bent
- Boulder
- Broomfield
- Chaffee
- Cheyenne
- Clear Creek
- Conejos
- Costilla
- Crowley
- Custer
- Delta
- Denver
- Dolores
- Douglas
- Eagle
- Elbert
- El Paso
- Fremont
- Garfield
- Gilpin
- Grand
- Gunnison
- Hinsdale
- Huerfano
- Jackson
- Jefferson
- Kiowa
- Kit Carson
- Lake
- La Plata
- Larimer
- Las Animas
- Lincoln
- Logan
- Mesa
- Mineral
- Moffat
- Montezuma
- Montrose
- Morgan
- Otero
- Ouray
- Park
- Phillips
- Pitkin
- Prowers
- Pueblo
- Rio Blanco
- Rio Grande
- Routt
- Saguache
- San Juan
- San Miguel
- Sedgwick
- Summit
- Teller
- Washington
- Weld
- Yuma

A top priority in restarting community-based research is to follow the cognizant Local, State and National Public Health Authority directives to shelter-at-home and implement social distancing. Therefore it is imperative for the PI and research staff to be aware of those directives.

Please provide a link to the governing state or reservation public health ordinances.

Please provide the name and contact information for the relevant public health authority in the location where research is being conducted. This will be necessary if the PI or university needs to coordinate regarding contact tracing.

Any in-person interactions related to this research project should be considered in the research resumption plan. The following questions pertain to the types of interactions that will occur.

Describe what face-to-face visits will occur:

In-person contact will occur for the research project in the following circumstances:
Check all that apply.

- Data collection
 - Research project planning
 - Community meetings
 - Specimen collection
 - Health procedure
 - Other
-

Please specify "Other":

For in-person interactions that are not specifically for data collection, specify the reasons for these interactions and the anticipated frequency of interactions.

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Institutional Guidelines

The use of space outside of the Anschutz Medical Campus may require a strong level of cooperation with the community partner. A high priority in resuming community-based research is that research personnel should follow the site's guidelines and precautions, provided that doing so does not cause them to violate CU Anschutz policies.

If a site does not have published guidelines or precautions, research personnel should follow CU Anschutz policies. Delay research activities until a later date if circumstances at a site may prevent personnel from following either the site's guidelines or CU Anschutz guidelines.

Name and location of the community setting(s) that will be used for this study:

Are institution or setting-specific COVID-19 guidelines in place for the location where research is being conducted?

- Yes
 No

If a document containing the site's guidelines is available to upload, attach the document here.

If a document is not available for uploading, provide a link to the guidelines or outline the guidelines here.

Please describe any potential discrepancies between the research site's guidelines and the CU Anschutz guidelines and how you plan to address them.

Note: If COVID-19 guidelines are not provided by the research site, it is expected that the research study will follow CU Anschutz guidelines.

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Describe social distancing measures that will be in place for break rooms, lunchrooms, or any other communal areas at the study site.

Describe the cleaning protocol to be followed.

Who manages the cleaning protocol and execution?
Check all that apply

- The research site
- The research team
- Third party
- Other

Please specify "Other":

Survey 50% Complete

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Who will provide masks to research staff?
Check all that apply

- PI
- Research site
- Third party
- Staff provides them for themselves
- Other

Please specify "Other":

What types of masks will be used?
Check all that apply.

- Cloth masks
- Surgical masks

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Any in-person contact increases the risk of COVID-19 transmission. The following questions pertain to safety measures that will be put into place for the protection of the research participants and/or community contacts.

What steps will be included in screening research participants and/or community contacts?
Check all that apply.

- Screening questionnaire the day before a study visit
- Screening questionnaire at the time of arrival at the study site
- Temperature scan upon arrival at the study site
- Other

Please specify "Other":

What additional logistical safety measures will be put in place to protect research participants and/or community contacts?
Check all that apply.

- Staggered appointments
- Participants and/or community contacts will be required to wear masks
- Limitations on the number of accompanying parties
- Other

Please specify "Other":

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In addition to the protection of research participants and/or community contacts, considerations must be made for the protection of research staff. The following questions pertain to the protection and education of staff members regarding COVID-19 safety measures.

How many staff members will have in-person contact with research participants and/or community contacts?

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- More than 8

Upload an Excel file with the names, titles, and contact information for staff members who will have in-person interactions with research participants and/or community contacts

Will research staff use the CU Anschutz Return to Campus plan?

- Yes
- No

This includes using the daily COVID Check-In Form and the COVID Self-Reporting Form if an employee becomes ill.

If no, what is your plan for screening the health of research staff?

Transportation

Modes of travel to and from the study site, both for research participants (and/or community contacts) and staff, should be taken into consideration. The following questions pertain to transportation and travel plans for this study.

Will the research study provide transportation to any participants and/or community contacts?

- Yes
- No

If yes, please describe the process and modes of transportation that will be provided.

Survey 75% Complete

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For research studies that are located outside of Colorado or the Denver metro area, do staff members live:

- In the geographic area of the research site
- In the Denver metro area

If staff members live in the Denver metro area, how will they travel out of state to the research site location?

Please describe details about safety considerations around transportation plans for staff that have not been addressed in this form.

A letter of approval from the Dean's Office is required for any out of state travel. Please upload approval here.

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If someone becomes ill

How will participants and/or community contacts be notified if a person that they came into contact with during their time at the study site becomes ill with COVID-19?

How will participants and/or community contacts be informed of what to do if they become ill in the seven days following their visiting to the study site? Please note that local guidance must be followed.

Contact tracing

How will the daily activities of research staff be documented?

This will be helpful to local public health authorities if contact tracing ever becomes necessary.

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Evaluation

Describe the processes that will be put in place for evaluating safety measures on an ongoing basis.

Is this form complete and ready to be reviewed by the
Reactivation Committee?

- Yes
- No