Dear colleagues,

Our VPR has announced that the Expanded Research Designation (ERD) process concluded effective September 1, 2020.

Please see below for more details on what this means for clinical researchers.

- For clinical research that necessitates bringing study participants to UC Foothills Campus facilities, CRD or ERD approvals are no longer required. Clinical research studies can proceed, and study participants can be welcomed back and seen in UC facilities located on the Foothills Campus. To help researchers with safely conducting patient visits on campus, we created the Question & Answer document below.
- For clinical research where participants are recruited and/or seen in AHS facilities, UC policies do not apply. Researchers must ensure that the relevant AHS facilities are ready to resume these research activities. Please check this AHS link for up-to-date information on the readiness of specific AHS facilities.
- Please note that it is the responsibility of the PI to ensure that all relevant UC and AHS policies are followed, including those related to maximum occupancy of research facilities. Researchers planning to return to campus must:
  - follow the guidance available in the Resources for Return to Campus located on the main UCalgary COVID-19 Response page, and
  - complete (or ensure that their labs are included in an existing) Workspace Safety Plan. For details on these items, see the Resources for Return to Campus section located on the main UCalgary COVID response page.

Researchers might consider preparing an information sheet specific to the location and study that can be sent to potential participants in advance, so that they know what to expect and are well prepared for their study visit.

Thank you for your patience with these further measures to keep everyone safe.

Please do not hesitate to reach out to sabine.moritz@ucalgary.ca with any questions you may have.

Kind regards,

Marcello Tonelli

Q & A

This information will be posted on the Guidance for Researchers: Clinical Settings page.

1. My team has already been approved for being on campus and I have submitted a work safety plan, can I resume clinical research studies and bring patients to the Foothills campus: Yes

2. Do I need to meet research participants on arrival at UC facilities, and/or escort them from the building entrance to my research facilities: No, this is not a requirement. However, it might be advisable for research teams to informally do this at least a couple of times during the first few days so that they can identify any issues with the new environment and develop the necessary guidance for research participants.

3. My research requires the use of CSM facilities. Are all CSM facilities open again? All CSM facilities are permitted to reopen and accept research bookings. Please check with the facility you wish to utilize when they can accept your patient booking.

4. CSM facilities have been requesting proof that my studies have CRD or ERD approval, before accepting patient bookings, will this still be required? No, providing this proof will no longer be
5. Is there signage in place on the Foothills Campus instructing visitors about COVID safety measures? Yes, there is signage in place at the entrances to the FMC buildings.

6. Will visitors be provided with masks when entering UC buildings? No, visitors are required to follow City of Calgary By-Laws and UC policies to wear a mask in all indoor spaces and must bring their own masks. Visitors who do not have masks will not be permitted to enter. It is acceptable for research teams to source and provide masks to visitors who do not have them.

7. What parking options exist for visitors? All UC and AHS parkades have reopened on the Foothills Campus. Visitor parking is available for a fee.

8. How can I safely open my research facility to research participants? Protocols should be in place for:
   - pre-arrival visitor COVID screening,
   - on arrival visitor COVID screening,
   - PPE requirements for staff and visitors,
   - hygiene protocols before and after appointments,
   - spacing of appointments,
   - maximum admission of visitors to the facility at any given time,
   - physical distancing in waiting areas,
   - separation of visitors in the research facility,
   - policies for COVID recovered patients.

   Please contact sabine.moritz@ucalgary.ca for more detailed guidance.

9. How do I determine what PPE is required during research visits? AHS guidance on PPE is to be followed at all times.

10. Are food outlets open on the Foothills Campus and available to visitors? Yes

11. Now that the Expanded Research Designation process has ended, what is the role of the Critical Research Designation? The VPR has not discontinued the CRD process in case pandemic-related developments make it necessary to once again restrict access to the UC campus. If this were to occur, the CRD could again be used to identify research programs that have permission to operate.

12. Am I required to keep my Critical Research Designation up to date or to submit a new Critical Research Designation at this time? No, the information in the CRDs is no longer being used at this time and so updates are not required. The VPRO will continue to update this information from researchers who provide it. However, since the only purpose for maintaining this information is as a contingency (see Q11), it may be most practical to NOT update the information unless absolutely required – for instance if an increased rate of infections leads to significant restrictions in access to campus.

13. My research occurs in AHS facilities. How do I ensure that I have approval to proceed? UC policies do not apply for research done in AHS facilities. Researchers must ensure that the relevant AHS facilities are ready to resume these research activities. Please check this AHS link for up-to-date information on the readiness of specific AHS facilities.

14. My research staff work in a non-clinical area of an AHS facility. How do I ensure that I have approval for my staff to work in those areas? Approval to work in AHS facilities (clinical and non-clinical areas) must be provided by AHS.