Q: What is clinical research?
A: Clinical research is defined by the ACRC as:

- "Clinical research has the goal of improving the diagnosis, prevention and treatment of disease and injury, and improving and evaluating the health and quality of life of individuals….Clinical research includes living human participants, human tissues, human remains, cadavers, biological fluids, embryos, fetuses and patient information. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual." (see acrc.albertainnovates.ca)
- CIHR pillars 3, 4 and much of 2

However this session is focused on a subset of the above, which is **research involving human participants.**

Q: When can we return to work if we work on AHS property – in the office, not necessarily even restarting trials.
A: Per site guidance and subject to capacity restrictions. For sites outside of ACH, please check HSA COVID relaunch readiness updates or contact your HSA advisor; for ACH office space – please check with Nicole Romanow (Pediatrics) ntruest@ucalgary.ca.

Q: At what stage are researchers allowed to do non-critical work (while physical distancing) in the research lab spaces in ACH?
A: The staging will depend on site readiness, and whether patient-oriented work is taken care of first. Watch the AHS website and/or check in with the site to learn about its status.

Q: If my research is being done exclusively in AHS or APL facilities, do I need to secure a Critical Research Designation from the VPR office?
A: No. Please refer to the AHS/APL websites, and/or check in with the site to learn about its status.

Q: At what stage would non-critical research scanning be permitted? Could the transition to this stage be bridged by doing scans off-hours (evenings, weekends) when the clinical DI areas are empty?
A: At this time, non-critical research scanning won't resume. The focus right now is on re-booking clinical patients.

Q: When will in-clinic (specifically outpatient cancer clinics) recruitment restart for clinical trials?
A: Visit the AHS website for guidance: https://extranet.ahsnet.ca/teams/AHSRA/SitePages/Home.aspx

Q: Where should clinical trial participants park on the FMC campus?
A: If you have a participant in a study with an approved Critical Research Designation in the TRW building, and they need access to parking, arrangements have been made to park directly out front or in an adjacent service lot. If you don't know about these arrangements, email Sabine.Moritz@ucalgary.ca for details.

Q: Will service or delivery providers be allowed to enter the building for maintenance of equipment in labs. If so, will they need authorization, and how will the access work?
A: For biomedical labs in general, people who need to have access for maintenance (e.g. to top up liquid nitrogen) have been granted it via the Critical Research Designation. If it's clinical research equipment, email Marcello Tonelli cello@ucalgary.ca to discuss it. In general, we will support maintenance of equipment to meet requirements.

Q: Ethical considerations around consent
A: When considering if there are additional risks that may require re-consenting, it will be important to consider if there are risks associated with bringing participants into a health care setting. For instance, the risk level of an observational study may have changed if participation involves coming to a health care setting where there is an increased risk of exposure to COVID-19.

Q: If we can conduct our research with study patients electronically/virtually/over the phone, are we ok to proceed with that process?
A: If the study already has Ethics approval (or any other necessary approval), then the answer is Yes. The considerations are: a) is your consent still true to what you are doing with the study, and if not, consider whether you need to consult with the REB; and b) whether that study results in having to order anything for the patient (in-person visits). Otherwise you are OK to proceed and you don't need any special approval from the university or AHS. Please document any adjustments you are making to the conduct of the study.

Q: In university facilities: are we now allowed to randomize new patients to projects that have already been deemed critical?
A: The consideration here is operational: if the AHS site can't accommodate those new patients, you would not be able to proceed. If you want to pursue this, speak to the AHS clinic to determine if they can accommodate those visits. There will likely be some adjustments that may need to be made – so get in touch with the clinic as early as possible.

Q: Should there be a COVID-specific consent form/re-consent form?
A: Refer to the CHREB resources to determine whether re-consenting is needed. Visit https://research.ucalgary.ca/covid-19#ethics or the CHREB web page.

Q: How do we approach things like home sample collection, or sample pick up by courier?
A: It's good for us to know about these situations, please email sabine.moritz@ucalgary.ca to discuss your specific situation.

Q: Are there plans to implement a contactless solution for consent?
A: This is being discussed – there are no details at this time.

Q: Are there specific factors or benchmarks that AHS is considering before re-starting human participant research in AHS spaces?
A: All restart activities are guided by what the government has already indicated, but likely will continue dynamically, zone by zone.

Q: Are there specific factors or benchmarks that the university is considering before re-starting human participant research in university spaces?
A: The university is following government guidance, but we also need to carefully consider the unique requirements of our campuses. The university will continue to issue updates as they are available.

Q: Is it permissible to enrol patients in a trial in which no additional in-person visits to AHS are required? Example: Enrol during a clinically indicated outpatient visit at an AHS clinic or a UC facility, and perform follow-up at regularly scheduled visits once these are approved.

A: You would need to go through the AHS unit/clinic, and it would depend upon whether the clinic can accommodate additional personnel in their space, and if there is sufficient supply of appropriate PPE etc. available.

Q: What is the process to resume implementation projects? There are no REB requirements because considered Quality Improvement, but take place across AHS sites with funding from Alberta Health/AHS and require capacity from AHS. Should EDs be engaged to consider these projects?
A: Some implementation projects have been suspended. Resumption will depend on readiness of the AHS unit/team. Connect with the AHS unit/team to determine their status.

Q: Is it permissible to randomize new patients in ongoing approved studies at AHS facilities (e.g. RRDTC)?
A: If the study is ongoing, and is approved to be ongoing, then probably. We recommend you engage with the AHS clinic to determine their ability to support.

Q: How will COVID-19 cases be defined going forward?
A: The university is not creating our own definitions. We're using government definitions.

Q: Will AHS provide masks and gloves at the Alberta Children's Hospital when research resumes?
A: This will depend on the operational area. We are working to determine cases in which AHS will provide vs cases where a researcher is expected to come in with their own. This will be clinic-dependent so please check per clinic.

Q: If patients are recruited during a clinical visit to the Emergency Department, and then followed remotely, could this type of research resume, if unit approval is provided?
A: Yes, that could resume if it has already received appropriate approvals from the REB and AHS.