# First Steps to Resuming Face-to-Face Human Participant Research: Capacity Evaluation, Readiness Assessment, and Priority Setting

## Capacity Evaluation

Involves an assessment of whether research spaces can resume human participant research safely. The assessment of research space is to be carried out by the PI with the Department Chair, in consultation with ADR, and with approval from the Dean.

During the evaluation, ask the questions provided below to guide the assessment. Be available for an audit of your research space by faculty safety reviewers.

**Questions to ask:**

Can staff and students return to campus? Are they willing to return?

Can we make our research spaces safe for study participants, faculty, staff, and students to conduct face-to-face research activities (based on public health and safety office guidance)?

Additional considerations include, but are **not limited to**, the following:

- Does the space support the physical distancing requirements?
- Can we ensure the sanitizing/decontamination requirements are in place and completed regularly (based on public health and safety office guidance)?
- Do we have enough supplies of GPE/PPE, sanitizing sprays/wipes, etc. that we need for our staff, students, and study participants?
- Do we need to install plexiglass barriers? Do we need face shields for our staff, students, and study participants?
- Are we able to post signage re: physical distancing, travel patterns, use of common areas?
- Are we able to supervise the studies closely and meet with students regularly?
- Are we able to establish a schedule to support occupancy limits, physical distancing, and contact tracing?
- Are we prepared to handle the privacy and confidentiality requirements to hold personal information for contact tracing purposes?
- Does any equipment need maintenance or testing because it has been underutilized for months?
- Is there adequate ventilation in the space?

- Will there be a need to arrange travel for participants or is it ok for them to use personal or public transportation?
- Is special permission needed from a gatekeeper/off-campus site to resume my face-to-face human participant research and is that gatekeeper ready to resume research activities (e.g., businesses, retirement facilities, not-for-profit organizations, school, day care, etc.)?

## Readiness Assessment

Involves an assessment of readiness to resume specific studies. This is study-specific and primary a responsibility of the PI.

In addition to capacity questions, ask the following:

- Do all aspects of the study need to be conducted in-person?
- Is the participant population particularly vulnerable with respect to COVID-19?
- What modifications/amendments are needed to the study procedures and what can now be done remotely?
- How will we conduct health assessments prior to participants entering the building in a private manner?

Requests to resume Face to face in-person human research will be asked to show evidence of having conducted a thorough readiness assessment.

## Priority Setting

OR-Ethics is expecting a high volume of amendments and new study submission in the coming weeks/months. We are asking for a collegial and consultative priority setting exercise be conducted among the PI, Chair, ADR, and Dean. This exercise is to determine which studies will receive priority to resume.

If the PI manages multiple studies, then the PI should submit requests over several weeks in order of priority. Use the aid of the Risk Analysis Chart and Decision-Making Matrix below for priority setting.

Use the Risk Analysis Chart below to perform a risk analysis to help establish priorities.

Use the Decision Matrix to identify Tier 1 projects. Tier 1 projects should be considered over Tier 2 projects. Consider postponing Tier 3 projects until urgency level or circumstances change.

# Risk Analysis Chart

| Research method | Examples | Direct contact with participants | COVID-19 research risk | Priority |
|---|---|---|---|---|
| **1-to-1 interaction** | Task manipulation, standardized IQ or cognitive tests | Some physical contact but limited; majority of study visit is from a distance | Low - Level 1 | High if contact limited & GPE used |
| **Non-invasive procedures** | Diet, exercise studies with spotters | Intermittent physical contact: most of study visit is from a distance | Med - Level 2 | Medium if distance maintained & GPE used |
| **Invasive procedures** | Biopsy, blood collection, ultrasound, gas inhalation | Sustained and close physical contact | High - Level 3 | Low even if GPE used |

# Decision-Making Matrix

| Decision matrix | Urgency and circumstances | | |
|---|---|---|---|
| **Benefits to study participants/impact of research** | **Low:**<br>Not urgent or vulnerable participants<br>(e.g., could be done later, no one is disadvantaged by delay, start date is not immediate, ethics approval pending or recent) | **Medium:**<br>Some urgency and less-vulnerable participants<br>(e.g., delay may cause issues, deadlines or milestones not met, loss of funding, start date is within next 2 months, ethics approval date > 2 months prior) | **High:**<br>Urgent and less-vulnerable participants<br>(e.g., COVID-19 research, study interrupted mid-stream, delay means student cannot graduate next term, start date is immediate, ethics approval date > 3 months prior) |
| **Low:** Limited or none<br>(e.g., course research, benefit primarily to undergrad student researcher) | Tier 3 | Tier 3 | Tier 2 |
| **Medium:** Some benefit<br>(e.g., individuals with shared characteristics, society at large, policy changes) | Tier 3 | Tier 2 | Tier 1 |
| **High:** Significant or direct benefit to study participants/group they represent<br>(e.g., development of service/program, intervention) | Tier 2 | Tier 1 | Tier 1 |