

Original Article

# Conducting Translational Gastrointestinal Research in the Era of COVID-19

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## Abstract

Spread of the novel coronavirus SARS-CoV-2 has resulted in a global pandemic that is affecting the health and economy of all World Health Organization [WHO] regions. Clinical and translational research activities have been affected drastically by this global catastrophe. In this document we provide a suggested roadmap for resuming gastrointestinal translational research activities, emphasising physical distancing and use of personal protective equipment. We discuss modes of virus transmission in enclosed environments [including clinical workplaces and laboratories] and potential risks of exposure in the endoscopy environment for research staff. The proposed guidelines should be considered in conjunction with local institutional and government guidelines so that translational research can be resumed as safely as possible.

**Key Words:** SARS-CoV-2; guidelines; translational gastrointestinal research

## 1. Introduction

The novel coronavirus SARS-CoV-2 [which causes COVID-19] remains a major public health threat. This virulent organism has caused the deadliest pandemic since the 'Spanish' influenza pandemic of 1918.<sup>1</sup> The virus is transmitted mainly through respiratory droplets.<sup>2</sup> However, the virus is also detectable in the gastrointestinal [GI] tract.<sup>3</sup> A recent study reported the isolation of viral nucleocapsid protein and expression of angiotensin-converting enzyme 2 [ACE2] protein [a receptor which facilitates entry of SARS-CoV-2 to cells] in the gastric, duodenal, and rectal epithelial cells of patients infected by SARS-CoV-2.<sup>4,6</sup> Additionally, stool samples from approximately 50% of COVID-19 patients remain positive for viral RNA up to 5 weeks after their respiratory samples test negative.<sup>3,5</sup> Currently, the viability and infectivity of the virus in faeces is poorly understood.<sup>6,7</sup>

Droplet [ $>5$ – $10$   $\mu\text{m}$ ] transmission occurs primarily during close contact [usually within 1–2 m] with an infected person who has respiratory symptoms [eg, coughing, sneezing].<sup>8</sup> However, asymptomatic infected individuals also play a major role in transmission of SARS-CoV-2.<sup>9</sup> Exposure to high concentrations of bio-aerosols in relatively closed environments has also been suggested as a route of virus transmission.<sup>3</sup> SARS-CoV-2 can also be transmitted through fomites in the immediate environment of an infected person.<sup>3</sup> One study reported detection of the virus from sink and toilet bowl samples taken from the isolation room of a COVID-19 patient.<sup>3</sup> In addition, viable virus particles can be detected on surfaces [such as plastic and stainless steel] for up to 72 h.<sup>10,11</sup>

Globally, government and public health bodies have implemented policies in an attempt to mitigate the spread of SARS-CoV-2. Efforts focus primarily on physical distancing, use of

personal protective equipment [PPE], and addressing capacity needs of health care systems to deal with the outbreak. This has led to significant curtailment of translational research activities for multiple reasons. First, physical distancing measures have restricted the ability of researchers to work ‘on site’ and handle samples at the same capacity as before the pandemic. Second, the pandemic has resulted in limitation of resources such as access to shared laboratory equipment, PPE, and endoscopy. Third, availability and willingness of patients to engage in research has been negatively affected, in part due to drastic reduction in non-urgent clinical activity.

We suggest that a phased approach be taken to re-expand non-essential research activities. In this guidance document, we address the roadmap to re-engaging in GI translational research in the era of the COVID-19 pandemic, while keeping researchers and research participants safe. These guidelines were formulated with collaboration across our translational research group, with incorporation of international as well as local institutional recommendations. Given the rapidly evolving landscape of the pandemic worldwide, these guidelines should be considered in conjunction with local institutional and government regulations.

## 2. Workplace and Laboratory Precautions

Considering the risk of viral transmission associated with conducting office/laboratory-based research, re-opening of research environments should be performed in stages. Potential risks relate to sharing of work space and handling of biospecimens. The following suggestions should be considered in the context of local factors including capacity, PPE availability, and feasibility of monitoring procedures

to ensure new safety measures are being followed. All workplaces should be prepared to re-introduce restrictions on research activities in the event of SARS-CoV-2 resurgence.

We propose that re-expansion of research activities take place across four phases [as outlined in Figure 1]: Phase 1, preparation; Phase 2, re-start research activities with total staff numbers not to exceed 20% of on-site capacity; Phase 3, continue to increase staff numbers to maximum 40–60% of on-site capacity; and Phase 4, continue to increase staff numbers to approximately 60–100% of on-site capacity, while maintaining significant SARS-CoV-2 restrictions for the foreseeable future. This phased approach will enable researchers to ramp up projects in order of priority. We propose suggested time frames for implementation of each phase, but the decision to progress through phases must factor in local risk assessment based on prevalence of infection in the community. The time frames described should allow for monitoring of adherence to safety measures and detection of outbreaks resulting from increased traffic in the workplace, both of which must be prospectively and actively monitored within each phase. Decision makers for advancing through the phases should be designated based on institutional policies.

### 2.1. Phase 1, preparation

Phase 1 should be completed within an estimated 2-week time frame. The main scope of this stage consists of: 1] increasing the number of staff on site while introducing new safety routines to maintain physical distancing; 2] provision for increased levels of hygiene [hand, surfaces, and equipment]; 3] increasing access to critical supplies when supply lines may already be stretched. We suggest the following phase 1 measures.

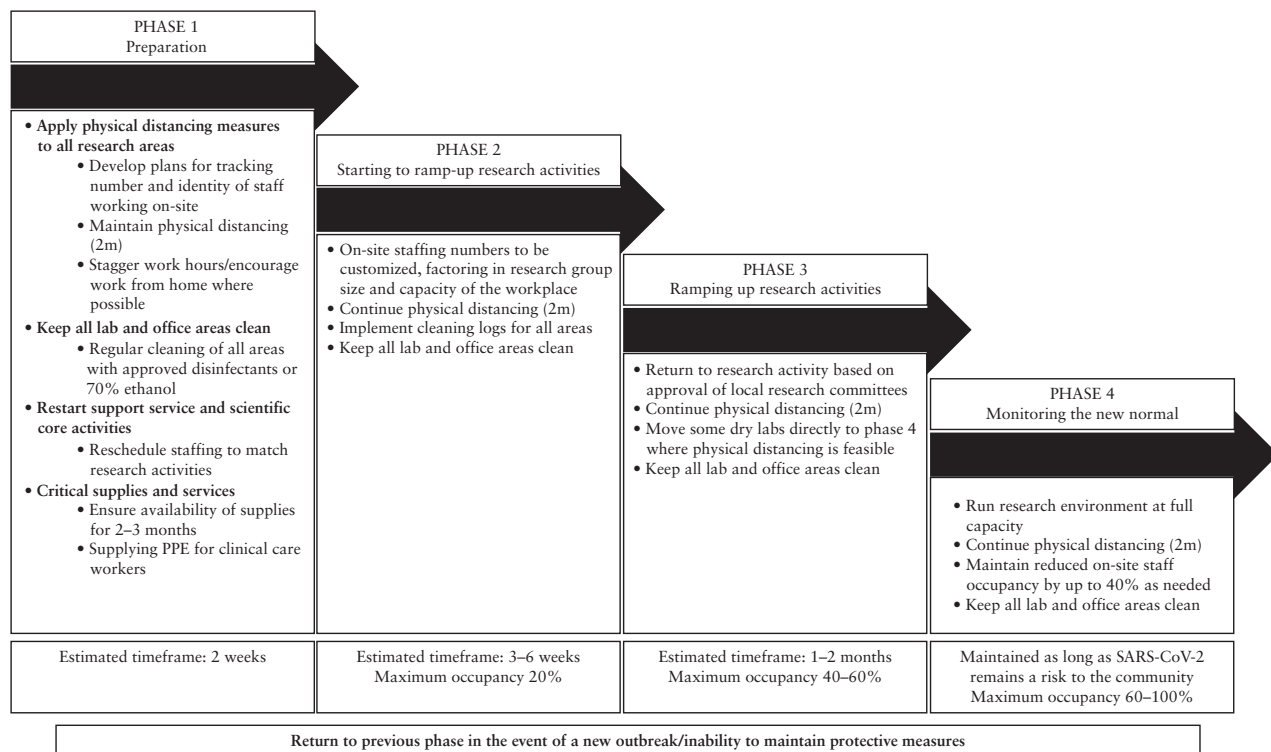


Figure 1. Roadmap for resuming gastrointestinal [GI] research activities.

### 2.1.1. Applying physical distancing measures to all research areas [offices and laboratories]

- Access to all research areas should be restricted to research personnel only. All visitors from outside research institutes, including other researchers, service personnel, delivery personnel, and vendor representatives must follow local SARS-CoV-2 restrictions for booking appointments. Additionally, they must follow screening procedures and wear appropriate PPE.
- Programme leaders should develop specific plans for resuming work in their laboratories, allowing identification of staff who will work on site. This should take laboratory space, layout, and ventilation into account to allow for physical distancing in all shared areas such as laboratory bays, equipment rooms, tissue culture rooms, offices, and break areas. For common areas we suggest an online calendar for booking equipment and rooms.
- Re-organisation of workplace layout may be considered to facilitate shared use of space and equipment while maintaining physical distancing.
- Presence of staff in the workplace should be prospectively recorded to ensure that future contact tracing [if required] is feasible, and to monitor occupancy on site. We suggest web-based sign-in to facilitate this process.
- In-person meetings should be limited to maintain the 2 m rule for physical distancing. In addition, face masks should be required for face-to-face meetings in enclosed spaces.
- Meetings [including in-laboratory meetings and meetings with external groups and collaborators] should take place online wherever possible.
- All staff who can work from home should continue to do so; this includes staff coming into the workplace to carry out specific activities but who do not need to remain for the entire day. Re-assignment of 'on-site' tasks should also be implemented where feasible, in order to minimise staff numbers in the workplace.
- Staggered work hours to avoid crowding of work spaces should be considered.
- In order to maximise opportunity for staff to work from home, access to relevant resources should be addressed. This may include laptops, analysis software, and remote access to datasets. Subsidies for work-related costs incurred to staff as a result of working from home [eg, internet access costs] may be considered.

### 2.1.2. Keeping laboratory and office areas clean

- An updated cleaning schedule for common areas should be executed by housekeeping. Cleaning schedules should include wiping down door handles and other highly used surfaces with approved disinfectants.<sup>12</sup>
- On-site laboratory staff should regularly wipe down common surfaces/equipment using approved disinfectants or 70% ethanol. These areas include but are not limited to:
  - Equipment: incubators, fridge and freezer doors, bench tops, biological safety cabinets [BSC], fume hoods, keyboards, microscopes, centrifuges, etc.
  - Office and break areas: tables, chairs, desks, microwaves, coffee pots, etc.

### 2.1.3. Re-starting support services and scientific core activities

- As research programmes restart, staff in different supply centres, research receiving, stabilisation, and glass washing should re-schedule staffing to match research activity.

### 2.1.4. Critical supplies and services necessary for re-starting work in the laboratories and offices

- Laboratory managers should ensure availability of supplies for at least 2–3 months following re-initiation of research activities. This includes availability of PPE, molecular kits, plasticware, chemicals, and reagents.
- Research units must take responsibility for acquiring PPE, and remain cognisant of any impact on the availability of PPE for clinical care workers. Co-ordination of PPE procurement with allied hospital services may help to mitigate costs through 'bulk buying'.

## 2.2. Phase 2, starting to ramp up research activities

The estimated time frame considered for this phase is 3–6 weeks. During phase 2, we suggest that areas be restricted to a maximum of 20% occupancy at any one time, though this can be customised based on the overall size of the research group.

- As staffing numbers increase at this stage, cleaning logs should be implemented for all laboratory areas.
- Staff will be responsible for self-monitoring for symptoms of COVID-19 [eg, cough, sore throat, dyspnoea, rhinorrhoea, fever, anosmia]. Symptoms and/or close contact with infected individuals should be reported immediately to occupational health and laboratory management. Self-isolation should be adopted while awaiting further direction from occupational health.
- As research projects are prioritised, study designs should be reviewed with regard to feasibility, as affected by the pandemic. This should include consideration of changes in realistic recruitment targets, availability of laboratory resources, funding, etc. Where appropriate, amendments to study designs should be submitted for research ethics board [REB] approval.
- For studies sponsored by outside agencies, clear communication from sponsors with regard to continuation of such studies should be sought. Of note, recruitment of new patients and activation of new research sites has been suspended for many clinical trials.<sup>13</sup>

## 2.3. Phase 3, ramping up research activities

The suggested time frame for this phase is 1–2 months. Phase 3 is subject to a maximum 40–60% staff occupancy at any given time.

- The plan for this stage is to return to research activity based on approvals of local research group work committees.
- Some dry laboratories can move directly to phase 4, where physical distancing [2 m] can be practised or working remotely is possible.
- Physical distancing of 2 m should continue to be practised.

## 2.4. Phase 4, monitoring the new normal

During this time, the occupancy of areas is suggested to be maintained at 60–100% at any one time depending on how space constraints limit capacity for physical distancing. This phase will persist as long as SARS-CoV-2 remains a community health risk.

- The research environment will essentially run at full capacity but on-site occupancy may need to remain reduced by up to 40%.
- Staff should be encouraged to continue to work from home where possible.

## 3. Patient Interaction

Translational research relies on in-person involvement of research staff and patients in most circumstances. Researchers must remain

cognisant at all times of any potential risk posed to research participants and research staff. Whereas all persons should consider themselves at risk of COVID-19, research patients may represent a particularly vulnerable population due to underlying disease processes and/or medical intervention.<sup>14</sup> As always, the option to withdraw from research studies must remain open to participants, whose willingness may be significantly affected by the pandemic. Local and institutional guidance is required to resume translational research activities, including patient interactions. These guidelines are intended to assist safe resumption of such activities.

### 3.1. Minimising in-person contact [non-COVID-19 research]

- Wherever possible, research study participants should be engaged remotely.
- Study protocols should be adapted in order to minimise in-person patient visits. Suitability of phone/video or electronic interaction should be considered. All such adaptations must be subjected to REB approval before implementation with stringent protection of patient privacy and confidentiality.

### 3.2. Precautions for mandatory in-person contact [non-COVID-19 research]

- Visits to hospitals and research facilities should be minimised and confined to clinical research areas.
- Screening for SARS-CoV-2 infection should take place within 48 h before in-person contact. Research participants should be questioned regarding: i) symptoms of COVID-19 [cough, sore throat, dyspnoea, rhinorrhoea, fever, anosmia]; ii) known contact with persons who have tested positive for SARS-CoV-2 within the past 14 days; iii) whether they have been tested for SARS-CoV-2. Screening should be performed using a standardised approach, and should be clearly documented.
  - Patients who have symptoms of COVID-19, have had contact with persons testing positive for SARS-CoV-2 within the past 14 days, have tested positive for SARS-CoV-2 within the past 14–21 days, or are awaiting results of SARS-CoV-2 testing should not be seen in person and should be re-scheduled. To deem a subject no longer a risk, we recommend: i) a minimum of 14 days from onset of symptoms/SARS-CoV-2 contact; and/or ii) a negative upper airway [RT-PCR] swab result.
- In addition to the above screening, testing for SARS-CoV-2 by upper airway [RT-PCR] viral swab should be considered when patients are attending for procedures that may be considered high risk for viral transmission [eg, upper GI endoscopy] based on local testing capacity.
- When in-person contact does occur, a distance of at least 2 m should be maintained where possible.
- Where interpersonal distance is <2 m, eg, for drawing blood, masks, gloves, and gowns should be worn by staff. We recommend the use of standard medical masks for research staff where index of suspicion for SARS-CoV-2 infection is low. Patients can be encouraged to supply their own mask [cloth or medical], though masks should be provided by staff where necessary.
- Research staff should receive training for donning and doffing of PPE.

- Research staff should familiarise themselves with local policies regarding which PPE is warranted in different settings in order to: i) adequately protect themselves and others; and ii) avoid inappropriate use of PPE, which may be of limited supply.
- Hand hygiene should be performed by staff and patients before and after interaction. This should be facilitated by signage and the availability of alcohol hand gel [minimum 70%].

### 3.3. Precautions for mandatory in-person contact [COVID-19 research]

- For research relating specifically to SARS-CoV-2 infection, in-person contact with patients known to be infected may be necessary. For all such contact, full PPE including N95 masks or equivalent, long-sleeve gowns, gloves, and goggles or face shields must be worn. Fit testing of N95 masks must be performed before use.
- Invitation of persons currently infected with SARS-CoV-2 from the community into the research environment would cause unnecessary and inappropriate risk of viral transmission. As such, research involving patients with current SARS-CoV-2 infection should be limited to inpatients.

## 4. Biospecimen-related Precautions

As outlined above, SARS-CoV-2 has been isolated from GI biopsies and stool samples.<sup>5,15</sup> It is unclear at this time whether transmission of SARS-CoV-2 can occur via handling of biospecimens.<sup>6</sup> No cases have been reported to date, but precautions are required. In keeping with standard laboratory protocols, all specimens should be regarded as potentially infected. Additionally, particular consideration is necessary when obtaining biospecimens in the endoscopy environment. The nature of endoscopic procedures poses potential for viral transmission via aerosolisation of viral particles.<sup>11,16</sup> The risk of viral transmission to staff from patients during GI endoscopy has not been quantified, but many consider GI endoscopy ‘high-risk’.<sup>17,18</sup> Here, we provide guidance on laboratory biosafety in relation to sample collection, handling, processing, transportation, and storage.

### 4.1. Sample collection/transport

#### 4.1.1. Blood samples

- For outpatient blood sample collections, patients should be sent to commercial medical laboratory services or hospital outpatient laboratories if possible.
- If in-person blood sampling by research staff is needed, it should be performed in areas where there are minimal additional exposed individuals [ie, dedicated examination rooms], and with adequate PPE. For research staff, gloves and masks should be mandatory. We recommend also using eye protection and gowns. Patients should also be wearing masks.

#### 4.1.2. Stool and urine samples

- Stool and urine sample kits can be couriered to subjects to obtain samples at home. The samples should be couriered back to research staff, if possible.
- Where patients must return biospecimen samples in person, sample drop-off by the patient and pick-up by the research staff should be sequenced with minimal contact. Designated drop-off locations will facilitate these practices.

#### 4.1.3. Biopsy samples in endoscopy

- Permission for research staff to attend endoscopy [with appropriate PPE] should be verified by senior endoscopy management. Close coordination between research staff and clinical staff is important to minimise risk of unnecessary exposures.
- Resumption of research activities should not hamper the efforts of endoscopy units to address clinical demand for services, which for most centres has increased as a result of postponement of non-emergency cases during the pandemic.
- Researchers should be aware that the ability of endoscopy units to facilitate research may change rapidly should a future wave of SARS-CoV-2 infection occur. Factors influencing this would include: i] staff absence due to symptoms, exposure, or positive test results; ii] staff redeployment; iii] re-escalation of physical distancing measures; iv] availability of PPE.
- All patients attending for GI endoscopy should undergo screening, as described above [see 'Patient Interaction'].
- Presence of research staff at endoscopy procedures should be kept to an absolute minimum.
- Where the constraints of endoscopy units [such as the size of procedure rooms] limit the number of people who can be present during a procedure, clinical staff should take precedence over research staff.
- The presence of research staff in endoscopy units needs to be clearly documented so that contact tracing can be facilitated in the future if required.
- Where research staff are not permitted, clinical staff [such as endoscopy nurses] may obtain required biospecimens, subject to approval by local endoscopy management and REB. In this case, explicit instructions [a written checklist] and training should be provided with regard to:
  - location of biopsies, number of biopsies at each anatomical location, pre-labelled biopsy tubes, biopsy tracking sheet;
  - working safely with liquid nitrogen where applicable;
  - sample handover from nursing staff to research staff.
- Where available, endoscopy should be performed in negative pressure rooms.
- For research staff present during GI endoscopy, at a minimum, surgical masks, long-sleeve gowns, gloves, and eye protection [goggles or face shields] should be worn. If the patient either has proven infection with SARS-CoV-2 or there is a high index of suspicion, N95 masks or equivalent should be worn for all GI endoscopy [upper or lower]. Upper GI endoscopy procedures require protection as mandated for aerosol-generating procedures based on the local recommendations; most guidelines recommend that N95 masks be worn by all staff in the room.<sup>19</sup>
- Any research-related equipment being introduced to the endoscopy suite should be sanitised [eg, with a 70% alcohol wipe] before entering and exiting. Such equipment may include recording equipment, specimen containers, etc.
- Researcher handling of any equipment in the endoscopy room should be kept to a minimum.

#### 4.2. Biospecimen transfer

- Samples need to be wiped down with disinfectant before placing them in the storage container and transfer bag.
- A drop-off bay should be designated.

- All surfaces touched by the research staff or specimen containers during drop-off and pick-up must be sanitised. All transfer bags and container bags should be sanitised between uses.

#### 4.2.1. Sample handling/processing/storage

- Dedicated standard operating procedures should be in place for transfer of samples which may contain live virus to research areas.
- Standard universal precautions should be followed when handling clinical specimens which potentially contain infectious materials: hand hygiene, use of PPE, ie, laboratory coats or gowns, gloves, and eye protection.
- All laboratory processing of samples should be performed based on risk assessment and only by certified technicians following local or institutional guidelines.
- Processing of all specimens should be performed in certified Class 2 BSC [with the exception of virus propagation, for which Class 3 BSC is required]. Viral inactivation through addition of 1% detergent or heat treatment is highly recommended and significantly reduces concerns for laboratory handling.<sup>20-22</sup>
- A sample manifest or tracking log should be maintained.
- Routine laboratory practices including procedures for decontamination of work surfaces and disposal of laboratory waste should be followed using local safety protocols.

#### 4.2.2. Exposure control plan

- There should be a clear framework of communication between management and research staff such that relevant parties are notified in a timely manner should inadvertent potential exposure to SARS-CoV-2 occur.
- A contingency plan with a specific protocol must be developed in case of a biosafety incident, ie, exposure to a potentially infected biospecimen.
- Such incidents should be reported immediately to the appropriate personnel.
- Spill kits and first aid kits including medical supplies should be prepared at all times.
- Research staff exposed to a potentially infected biospecimen or infected patient should be self-isolated and be tested for SARS-CoV-2 as soon as possible. This should be performed in collaboration with occupational health services.

### 5. Conclusion

We have proposed guidelines for gradual re-expansion of GI research activities during the SARS-CoV-2 pandemic. Stage-wise resumption of research activities should be implemented with consideration for ongoing risk assessment, availability of resources such as appropriate PPE, and proper physical distancing measures. Considering the risk of exposure in enclosed environments, we propose re-engagement in research activities in four phases: phase 1, preparation, phase 2, start-up, phase 3, ramp-up of research activities; and phase 4, maintaining and monitoring the safety situation at the new normal. These guidelines address safety precautions in relevant workspaces [including laboratory and endoscopy environments] as well as in specific research activities such as sample collection, handling, and transportation. As the pandemic continues to evolve, vigilance and flexibility must be applied, particularly as risk of future waves of infection fluctuates. Accordingly, the guidelines should be interpreted in conjunction with local institutional and government policies.



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The authors have no financial disclosures or conflicts of interest.

## Authors Contributions

SN [joint first author]: drafting of original manuscript, revisions of original manuscript. MW [joint first author]: drafting of original manuscript, revisions of original manuscript. S-HL: significant contributions to original draft and subsequent revisions. MF: significant contributions to original draft and subsequent revisions. SR: significant contributions to original draft and subsequent revisions. AJ: significant contributions to original draft and subsequent revisions. JS: significant contributions to original draft and subsequent revisions. MIS: significant contributions to original draft and subsequent revisions. MSS: manuscript concept, lead supervisor, manuscript revisions.

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