What do I need to do to get approval for off-campus human participant (private individuals) research under the MQ COVIDSafe Plan for Research?

What is considered off-campus human participant research?

- Research in off campus, university or non-university facilities or sites involving face to face interactions with human participants who are private individuals and not members of organisations with COVIDSafe Plans (e.g., individuals, families, other volunteers in the community who participate in research in their own homes or other locations but not under the auspices of an organisation). This research may be conducted by individuals or teams, MQ staff or HDR students.
- Any off campus human participant research with organisations with COVIDSafe Plans, or with at risk participants or clinical participants, or by MQ staff and students based interstate or overseas is captured and governed by other COVIDSafe Plans. Contact your Department Manager for further information.

What do I need to know before planning?

- Contact your Department Manager to discuss your plans well in advance.
- All applications are to be submitted at least 2 weeks before within-NSW work, and up to 4 weeks before interstate work is to take place. Applications without due notice will be delayed.
- Submission of documents does not mean approval.
- You must await notification of approval before making any arrangements to travel or conduct research.
- If approvals are not in place, you cannot undertake the research.
- Absence on Duty (AoD) applications still need to be approved alongside COVIDSafe applications.

What is the process I need to follow?

1) Consider the status of ethics approvals for your research (see below) and take action where necessary
2) Access the word version of the Off-Campus Travel Sample Form from the Intranet (https://staff.mq.edu.au/intranet/science-and-engineering/teaching-and-research-covid-safe-guidance).
   This application includes a Detailed COVIDSafe travel plan, COVIDSafe emergency response plan and trip-leader signoff.
3) There is an upload documents section at the end of the online form for attachments related to human participant research such as additional risk assessments and a statement confirming the vaccination status of participants, or any ethics related adjustments to projects associated with COVID-19 (see below).
4) Fill this out and then pass it on to the Department Manager. They will review this document and discuss with you ways to improve it if needed.
5) Make sure your vaccination status is up to date with your Department/School.
6) Once the Department Manager gives you the go ahead, submit the official online Faculty form on the intranet (https://staff.mq.edu.au/intranet/science-and-engineering/teaching-and-research-covid-safe-guidance) by copying and pasting information from your approved word file.
7) This goes to the Deputy Dean Research and Innovation, and once approved you will receive an email from them confirming your approval status. Department Manager and HOD will also be on this email.
8) Attach the form with the answers you are submitting to your AoD application.
9) At this point AoDs can be submitted and approved.
10) Only when the COVIDSafe and AoD approvals are place can work be considered approved.

What Stage are we in and what approvals are needed?

- Please check the FSE intranet front page for Stage dates.
- Stage 1 does not permit human participant research with private individuals.
- **Stage 2** permits human participant research (private individuals) **within or across** LGA/regions (e.g., from Greater Sydney to regional areas). Only fully vaccinated MQ staff and students can request approval under this stage. Approval is also contingent on all adult experimenters and participants being full vaccinated (unless exempt or < 16 years old; < 16 yo with vaccinated parents or in educational settings). Vaccination status is to be confirmed by the researcher.

- **Stage 3** permits human participant research (private individuals) within NSW, and may permit interstate and international travel subject to border and travel restrictions. Approval is also contingent on all adult experimenters and participants being full vaccinated (unless exempt or < 16 years old; < 16 yo with vaccinated parents or in educational settings). Vaccination status is to be confirmed by the researcher.

- Approval required by the **Deputy Dean Research and Innovation/Executive Dean**, or depending on the trip, approval from the **Vice-Chancellor** may be needed.

- The 2020 MQ.COVIDSafe plan for human participant research (private individuals) is provided below for your reference, and to aid in your planning and applications.

### Confirming the vaccination status of research participants

1. For all human participant research conducted by MQ staff or research students in Stages 1 or 2 of our recommencement roadmap (expected to continue until 1 December), a pre-session COVID-19 risk screening by phone or email should be conducted. This is consistent with the 2020 COVIDSafe Research Plan (copied below), which requires that potential participants receive COVIDSafe guidance and a pre-session COVID-19 risk screening before their involvement. In addition to the four already agreed questions in that plan, two additional questions should be added:
   
   a) Have you or anyone you have been in close contact with travelled overseas in the last 14 days?
   
   b) Have you been diagnosed with, or are you currently awaiting tests relating to suspected coronavirus (COVID-19) diagnosis?
   
   c) Have you been in close contact with someone with a confirmed or suspected case of coronavirus (COVID-19) within the last 14 days?
   
   d) Do you have, or have you had in the last 14 days a fever, cough, shortness of breath, sore throat, runny or stuffy nose, aches and pains, fatigue, change in sense of smell or taste, chills, body aches, diarrhoea, or headache?
   
   e) Have you been fully vaccinated?
   
   f) Would you be willing to show me a copy of your vaccination certificate (or valid exemption) before the session?

2. It is preferable that this pre-session COVID-19 risk screening be conducted the day or evening before to save a wasted journey by participant or researcher. However, in some instances, risk screening might be conducted just prior to the session.

3. In the event of a yes response to any of the four questions and/or a no response to either of the last two questions, the research session must be cancelled and rescheduled.

4. The researcher should also be prepared to show the participant their vaccination certificate to confirm that they too are following COVIDSafe research practices.

5. The researcher need only sight the vaccination certificate and does not need and should not retain records of certificates or any further details. The answers to the pre-session COVID-19 risk screening will offer a record of compliance with COVIDSafe practices given that only participants who have no symptoms, meet the vaccination requirement and are willing and able to show their certificate should progress to a session.

6. If a researcher is of the view that asking about or sighting vaccination certificates are not appropriate for a particular project or community, then recommencement can start in Stage 3.

### Ethics approval for confirming vaccination status

The Director of Research Ethics and Integrity gave blanket approval on 12/10/2021 for all previously approved projects to include this protocol for confirming vaccination status of adult or child participants in
on or off campus research. **There is no need to seek an amendment to ethics applications to follow this protocol.**

Please also note that the Director of Research Ethics and Integrity gave blanket approval on 12/10/2021 for all previously approved human participant projects to revert back to face to face testing. This **only** applies to projects originally approved by Human Research Ethics as face to face and amended online/virtual due to COVID restrictions. These projects can revert to the original approved mode without seeking an amendment. Projects originally approved online/virtual and seeking to test face to face for the first time, require approval from Ethics.

**New projects** must build in COVID-19 vaccinations status, confirmations and restrictions into their Ethics applications and undertake any required risk assessments.

### 2020 MQ COVIDSafe Plan for human participant research (private individuals)

**-Ethics approvals**

- Off campus human participant research is governed under Macquarie’s Human Research Ethics. COVIDSafe approvals under this plan are separate and in addition to appropriate ethics approval for projects. Ethics approval will continue to be managed by Human Research Ethics at University and Faculty levels. COVIDSafe recommencement of research will be managed within Faculties.
- If a project previously approved by Human Research Ethics was paused and the researcher now wishes to recommence as originally proposed, nothing more needs to be done via Ethics. The researcher needs to apply for COVIDSafe recommencement consistent with this plan following Faculty-based processes.
- If a project previously approved by Ethics was amended in some way with Ethics approval (e.g., to collect data remotely rather than face to face) and the researcher now wishes to revert to the original methods either whole or in part, he or she needs to submit a brief amendment notifying Ethics of this intention via the process described here: [https://www.mq.edu.au/research/ethics-integrity-and-policies](https://www.mq.edu.au/research/ethics-integrity-and-policies). The researcher also needs to apply for COVIDSafe recommencement following Faculty-based processes.
- If a project previously approved by Ethics was amended in some way with Ethics approval (e.g., to collect data remotely rather than face to face) and the researcher wishes to continue with this amended method (and not revert), then nothing more needs to be done via Ethics or for COVIDSafe planning.
- If a researcher wishes to commence a new project under COVIDSafe principles, he or she needs to apply for Ethics approval as usual and submit a COVIDSafe plan following Faculty-based processes.
- People aged over 70, residents or staff in aged care facilities, people with certain medical and chronic health conditions, Aboriginal and Torres Strait Islander people aged over 50 and Aboriginal and Torres Strait Islander communities in rural and remote areas are considered vulnerable populations. Thus, off campus human participant research that involves these people or groups, as researchers or participants, requires additional approval. See **Research with At Risk Populations.**

**-Capacity**

- This plan covers all off campus human participant research with private individuals who are not members of organisations with COVIDSafe Plans (e.g., individuals, families, other volunteers in the community who participate in research in their own homes or other locations but not under the auspices of an organisation). Instead, they fall under Macquarie’s COVIDSafe Plan and responsibility.
- **The current version of this plan covers off campus human participant research with individuals conducted within NSW and in other States of Australia.** The location of off campus human participant research is subject to Government and Macquarie University policies and restrictions on within state and interstate travel ([https://www.nsw.gov.au/covid-19/what-you-can-and-cant-do-under-rules/border-restrictions](https://www.nsw.gov.au/covid-19/what-you-can-and-cant-do-under-rules/border-restrictions)). This plan will be updated when international travel is approved.
• This plan DOES NOT supersede the need for any normal approvals for such research (e.g., Absence on Duty (AOD) Forms, adherence to travel and finance policies where appropriate). Rather, it is in addition to these approvals.

• The following should be submitted with any request to recommence or commence research:

1. A research plan designating the number of participants (with identifying details anonymised), details of type and length of contact (e.g., 2 hour face to face interview), and the locations in which they will participate in the research (e.g., interviewed or tested in their homes, interviewed in a public space);

2. A statement from the researcher and any accompanying team members of how they will adhere to this Macquarie University COVIDSafe plan and mitigate any risks;

3. A COVIDSafe travel plan for travelling to the site/s of off campus research; and

4. An emergency plan in the event of illness.

• Travel is limited to participants you will visit. The number of researchers should be minimised to essential researchers only with consideration as to how interactions (especially with groups > 1) may be completed with physical distancing or staggered over different periods of time.

• If off campus human participant research with private individuals is conducted in collaboration with non-Macquarie personnel or volunteers (as researchers rather than as participants), then they should be covered by their organisation’s COVIDSafe Plan or detailed in this plan.

• Travel by car is recommended if safe and practical to do so. If travelling by public transport or air travel provide plans to assist with health and hygiene (e.g., wearing masks on public transport or planes).

• In the case of all travel other than short trips to local organisations, a detailed COVIDSafe travel plan must be provided that outlines stopping locations and how social distancing will be maintained. This includes passengers and journey stops (e.g., fuel stops, meal breaks, toilet breaks). For trips longer than 2 hours one-way, all drivers are to take a break after 2 hours as per 'normal' practice. This plan should be submitted with the request to recommence or commence research, as noted above.

• Research with private individuals should be abandoned if any researcher experiences symptoms of COVID-19. Researcher and any team to be tested for COVID-19.

• As part of emergency planning, researchers must document the following: The distance to the nearest medical facility that could support them or a team member with COVID symptoms. The mode of transportation of the person to the nearest medical facility. How will they respond if Government guidelines and restrictions change or an area is placed in lockdown? If there are no nearby medical facilities, what other emergency evacuation plans will be activated? For research involving multiple sites, one plan is sufficient that covers COVIDSafe contingencies across the sites.

-Access

• COVIDSafe research with private individuals to be approved by Executive Deans. This is in addition to AOD and MQ travel approvals as per normal procedure.


• Prior to or on the day/s of face to face data collection, confirm access to the research location (e.g., local government areas on high alert) and health of participants.

• If an overnight trip is approved, limit the use of large turnover accommodation such as motels. Separate rooms for all team members (e.g., avoid communal hostels, bunkhouses, bathrooms, kitchens).

• All COVID-19 restrictions guidelines and approvals carried on person at all times.

• All researchers should be recommended (but not required) to download and use the Australian Government’s COVIDSafe App to assist with contact tracing if required.

-Participants

• Off campus human participant research may involve a range of methods including but not limited to individual sessions (single researcher-single participant), very small group sessions (e.g., 1 or 2 researchers-1-3 participants) or larger groups. These methods should be managed consistent with current Federal and State guidelines for size of indoor gatherings ((https://www.health.nsw.gov.au/Infectious/covid-19/Pages/latest-updates.aspx).
• Researchers also should consider the minimum number of people involved, the minimum length of physical contact required, and aspects of the research that can be completed remotely before or after the session (e.g., on-line surveys).

• Researchers should maintain a formal record of all face to face contact with details of who, where and when participants were involved during the course of the research project and this record should be kept with other project needs in the event that contact tracing is required.

- Health and Hygiene

• Activities should comply with physical distancing wherever possible and with physical distancing regulations. During face to face research sessions, appropriate precautions should be considered such as wearing of masks.

• Sufficient PPE, disinfectant and cleaning products should be made available before and after the off campus research, and carried and used regularly.

• Rigorous personal hygiene practices must be implemented multiple times a day and before and after sessions with participants.

• Do not share work equipment (e.g., recorders, computers, stationery). If equipment is used during the research with participants, implement and follow appropriate cleaning between sessions.

• Participants in all studies should receive COVIDSafe guidance and a COVID-19 risk-screening (e.g., by phone call or email) before participating. If practical to do so, this should be done the day before but may need to be done just before the session commences. Potential participants should be asked to answer the following questions truthfully and to the best of their knowledge:
  1. Have you or anyone you have been in close contact with travelled overseas in the last 14 days?
  2. Have you been diagnosed with, or are you currently awaiting tests relating to suspected coronavirus (COVID-19) diagnosis?
  3. Have you been in close contact with someone with a confirmed or suspected case of coronavirus (COVID-19) within the last 14 days?
  4. Do you have, or have you had in the last 14 days a fever, cough, shortness of breath, sore throat, runny or stuffy nose, aches and pains, fatigue, change in sense of smell or taste, chills, body aches, diarrhoea, or headache?

• In the event of a yes response to any one of these questions, the research session should be cancelled and rescheduled.

- Training

• To ensure that researcher and participant safety remains the highest priority during off campus research sessions, Departments and Faculties should ensure via modified or new induction or training that all researchers understand: screening, testing, isolation and quarantine requirements and associated processes relevant to off campus human participant research; understand coughing/sneezing etiquette and other respiratory precautions; understand correct hand washing technique and when hand hygiene must be practised; agree not to conduct research sessions if they are displaying any flu like symptoms; notify if they or participants are in a vulnerable risk group; and understand how to implement health and hygiene protocols as above. This training may include, for instance, Australian Government provided, free COVID-19 Infection Control Training ([https://www.health.gov.au/resources/apps-and-tools/covid-19-infection-control-training#who-this-training-is-for](https://www.health.gov.au/resources/apps-and-tools/covid-19-infection-control-training#who-this-training-is-for)).

- Supervision

• Departments and Faculties should ensure adequate, expert supervision of research students in the field either via direct on site supervision or regular Zoom, phone and/or email contact to ensure that COVIDSafe protocols are followed (e.g., a supervisor, another experienced postgraduate, an experienced collaborator).

- Responsibility

• Approval of all off campus human participant research sits with relevant Executive Deans (and Associate Deans Research) with any advice/queries to the DVCR’s Office, Risk & Assurance and/or the COVID-19 Taskforce.

• Researchers requesting to recommence or commence off campus human participant research should:
  1. Prepare a research plan with details of participants and COVIDSafe planning (as above);
  2. Apply for recommencement or commencement to the relevant Associate Dean Research;
Once approved, on the day/s of research participation (e.g., interviews or testing), confirm access to the location and health of participants.