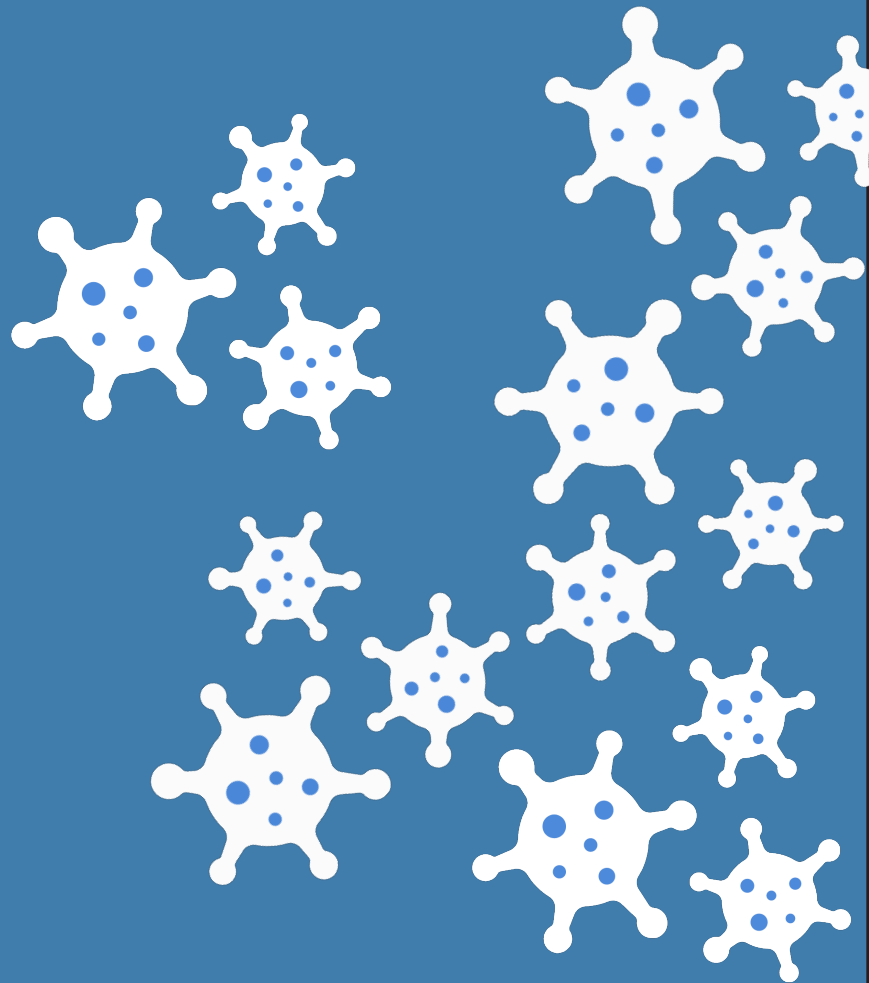**UKRIO**

UK Research Integrity Office

Recommended Checklist for Research Communities During the COVID-19 Pandemic
for both existing and new research

October 2020

Introduction

This checklist, building on UKRIO's Recommended Checklist for Researchers (2008), seeks to help individuals and organisations performing research of any kind during a pandemic. Its focus is to anticipate issues that may affect the integrity of their research and consider in advance how those issues might be addressed, including but not limited to research on COVID-19 and related topics.

These issues can provide challenges for:

Honesty, rigour, transparency and open communication in the design, conduct and reporting of research.

Care and respect for research participants, researchers and all others involved in research

Accountability of researchers, organisations, funders and publishers.

Public trust in research.

Introduction

This Checklist is primarily aimed at researchers, though others may also find it of interest, including: research managers and administrators, technicians, research organisations, funders, reviewers, editors, publishers, research participants and the general public. It is applicable to all research disciplines and all research sectors.

Research carried out during a pandemic or any other challenging situation must comply with all legal and ethical requirements and have the relevant permissions in place before it commences. However, the pandemic has had considerable effects on how research is designed, funded, conducted, managed, monitored and disseminated. These effects will be long-lasting and dependent on the level of infection control measures, and the need to consider how these effects will impact on research will remain for many months.

The aim of this Checklist is not to state the 'right' way to undertake COVID-19 research or research during a pandemic. Instead, the aim is to help researchers be mindful of what issues might affect the integrity of their research and consider in advance how those issues might be mitigated.

This list of considerations builds upon and replaces UKRIO's Recommended Checklist for Researchers (2008), available from www.ukrio.org. Researchers seeking additional information on good practice may find the information contained in the resources section of the UKRIO website helpful.
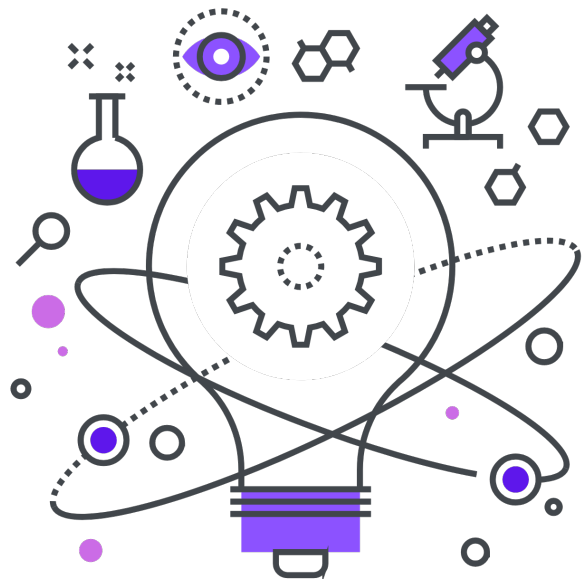
Before conducting the research

Bearing in mind that, subject to legal and ethical requirements, roles and contributions may change during the time span of the research:

Researchers should be aware that the pandemic may have impacted on the ability of funding bodies to thoroughly, objectively and efficiently peer review applications for funding, and within a reasonable timescale. Other types of review may also be affected, such as those for regulatory approvals. Reviewing bodies will be aware of pressure to get research studies underway quickly and will be considering whether they have access to sufficient expertise/ personnel/ resources to correctly review proposals, whether related to the pandemic or not. Reviewing bodies should be taking remedial action where necessary.

1. Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it? ○

    a. For COVID-19 research: does the proposed research add to existing knowledge, and is the inclusion of an emphasis on the pandemic legitimate or peripheral? ○

    b. Has the research been designed in accordance with good practice standards to prevent potential compromise due to resourcing issues and/or pressure to produce results quickly? ○

    c. Does the research design incorporate both existing and new guidance (from funders and others) on research during and/or into pandemics, including guidance on associated ethical considerations? ○

    d. Do applications for funding accurately describe the significance of research question(s), the limitations of potential findings/interpretations, and the calculation of risk against potential benefit, without embellishment or exaggeration? ○

Before conducting the research

2. Is the data management plan appropriate for the proposed research, compliant with relevant legislation, ethical good practice and funder requirements; is it appropriate for pandemic circumstances, including addressing restricted access to facilities and data during a time of infection control measures? ○

   a. Does the data management plan address changes due to the pandemic related to: preregistration and registered reports; preprints; open access; data sharing; open code and software (as appropriate)? ○

   b. How will the pandemic compromise data protection requirements and information security and what remedial action will be taken? ○

   c. Is a member of the research team dedicated to addressing additional data protection requirements? ○

   d. Have potential conflicts between legal/ethical use of personal data and urgent research priorities been declared and mitigated against? ○

3. Does the proposal accommodate for the impact of possible shortfalls in resources, capacity, skills and equality of participation, and offer alternative approaches to addressing real or potential limitations? ○

a. Does the proposal address changing circumstances that may affect the research team (e.g. business closures; supply chain shortages/delays; working off site/homeworking; caring for dependents) and suggest solutions for mitigating limitations that may arise within or outside the immediate research environment? ○

b. Is the proposal mindful of factors which will impact negatively on equality of participation? ○

c. Is there a plan in place for ensuring that all contributors are given sufficient opportunity to participate in spite of limited resources or difficulties with working during emergent circumstances? ○

d. Is there a plan for training collaborators that are new to the research team, or who need retraining after a period of absence, in standards of good practice and other norms, and, similarly, are there mechanisms in place for ensuring their contributions are valued? ○

Before conducting the research

e. Have you considered whether access to training will be impacted by the pandemic? ○

f. Have applications for funding undergone appropriate vetting at the institutional level? ○

4. Have risk assessments been conducted to determine the following:

a. Compliance with health and safety requirements in the context of the pandemic, and measures that adhere to current infection control guidelines (e.g. protective equipment, social distancing)? ○

b. Have the potential risks to the research or the health, safety and well-being of researchers, research participants and others been fully considered? ○

c. Have health and safety requirements been evaluated for specific research environments inherent to the study design (laboratory vs. field, clinical interventions, infection control, access to appropriate equipment, interviews, etc.)? ○

d. Whether (a)-(c) above are affected, or will be affected, by the COVID-19 pandemic both now and as the situation changes. Consider if the study is suitably flexible to adapt accordingly to maintain its integrity whilst ensuring that health ○

and safety requirements are met both locally and nationally.

e. The potential for dual-use, misuse/ malicious use of the research or its processes, data or findings. ○

5. Has the research undergone any necessary ethics review, especially if it involves animals, human participants, human material, or personal data? ○

a. If the research methodology is amended in response to the pandemic, has an individual been designated to make additional notifications to funders and ethics committees, and, if required, seek renewed ethical approval and/or renewed consent from participants? ○

6. Does the research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant? ○

a. Are consent processes being conducted in an appropriate timeframe and are potential participants/ their legal representatives being given sufficient time for reflection ○

b. Is the consent process sufficiently inclusive to promote the participation of all relevant groups? ○

Before conducting the research

For consideration by researchers and research organisations: Monitoring

- Will a pandemic compromise health and safety requirements for the research and how will the organisation monitor these requirements as Government and other health and safety guidance evolves through the phases of the COVID-19 pandemic?

- If the study needs to adapt in relation to the issues outlined in 4 (a) - (e) (see page 6), how will the organisation monitor this?

- If exposure to COVID-19 during the research compromises health and safety, how will researchers and the organisation ensure that local and national health and safety requirements are met? How will the organisation monitor this as Government and other health and safety guidance evolves through the phases of the COVID-19 pandemic?

c. Does the study team have a system for maintaining compliance with legal and ethical requirements in emergent circumstances, including those from other countries, and staying current as they may change, including consideration of an agreed upon standard if national/regional standards differ? ◯

d. Are mechanisms in place to ensure that the informed consent process is ethical, comprehensive, and allowing an appropriate forum for questions and right to withdraw, despite resource limitations and in the context of online or remote communication? ◯

e. In designing the consent process, has an effort been made to reduce the possibility that potential participants or their legal representatives feeling pressured to join a study due to a sense of moral responsibility or financial strain? ◯

7. Have monitoring and audit requirements been reassessed in the context of a pandemic, including consideration for secure record keeping and data exchange? ◯
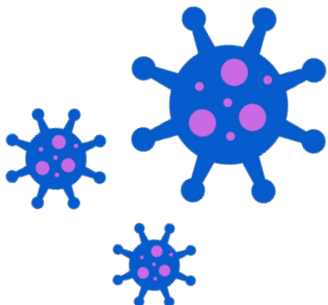
Before conducting the research

Researchers should be aware that the pandemic may have impacted on the ability of research organisations to undertake ethical review in accordance with good practice requirements. This might include access to sufficient personnel/resources to review proposals thoroughly, objectively, efficiently and within an appropriate timescale; pressure to review quickly to get studies underway without delay; sufficient expertise to assess the ethical issues raised by the research. Research organisations will be considering whether these issues are affecting their ethical review processes and should be taking remedial action where necessary.

8. Has consideration been made for possible modifications to contracts and financial agreements relating to the research, include possible delays in meeting deliverables or changes in research design? ○

9. Have agreements related to intellectual property, publication and authorship, or collaboration, including roles and responsibilities of research team members, been agreed and formalised? How have they been affected by the pandemic? If so, do agreements need to be renegotiated? ○

10. Have agreements been reached or formalised relating to collaborative working, especially where the collaborations cross institutional, national, disciplinary or sector boundaries? ○

11. Has consideration been made for supervision and management of research team members in light of remote communication and working from home/ off site? ○

12. Have conflicts of interest relating to the research been identified, declared and addressed in the context of the pandemic, including consideration of pressure to accelerate research projects? ○

13. Has consideration been given to requirements of the institution or funder requirements on research integrity and to The Concordat to Support Research Integrity (2019)? ○

When conducting the research

1. Is the agreed research design for the project being followed? ○

    a. Have all of the following been addressed in relation to the pandemic's effect on the research: ○

        I. health and safety, biosafety and infection control; ○

        II. biosecurity; ○

        III. duty of care to human or animal participants; ○

        IV. compliance with legal, ethical, institutional, or contractual obligations; ○

        V. ability to respond to ethical or safeguarding concerns; ○

        VI. access to necessary skill and resources for the research project; and/or ○

        VII. the completion of data collection. ○

    b. Are protections in place to ensure that the research does not compromise patient/clinical care, including communication, if necessary, with clinical care providers? ○

    c. Have attempts been made to facilitate communication and ensure that study participants understand that they may ask questions, raise concerns, and withdraw from the research at any time? ○

4. Has an effort been made to ensure that the research design is not compromised if staffing levels are reduced, and, if staffing changes have occurred, have necessary notifications to funders/ethics committees/ participants been carried out? ○

    a. Has the research plan been reviewed to address how staffing levels and working conditions will be managed to identify and address the potential risks and impacts? ○

    b. If the design or methodology has changed because the project is being conducted by researchers working remotely, have appropriate notifications and adjustments been made? ○

    c. If pressure to produce results quickly is compromising adherence to the agreed research design for the project, has communication occurred between the relevant parties (e.g. funders, ethics committees)? ○

When conducting the research

d. Have other potential pressures on research design been considered and resolved, such as new or contentious research methods, multi-disciplinary approaches to pandemic research? ○

e. Has attention been placed on accuracy, honesty, transparency and replicability of data/findings, in spite of pressure to produce results quickly and under difficult circumstances? ○

f. If pressure to produce results quickly is leading to additional errors or waste, including waste in relation to use of animal subjects in research (3R's – Replacement, Reduction, Refinement), have adjustments and notifications been made? ○

g. If necessary, have any changes to the agreed research design and methodology been reviewed and approved by the appropriate entity (e.g. institutional, funder or ethics committee approval)? ○

3. If the pandemic is affecting the ability to follow best practice and the agreed data management plan, have adjustments been made to mitigate risk under the circumstances? ○

Researchers should be aware that the pandemic may have impacted on the ability of research organisations, funders and ethics committees to review and approve changes to research designs and methodologies. These bodies will be considering whether any issues are affecting their review/approval processes and should be taking remedial action where necessary.

4. Are agreed roles and responsibilities in place for the management, supervision and support of all staff members, especially new and junior staff members? Is there a structure in place to ensure regular communication and discussion of problems among team members, particularly new and junior staff and those working in remote teams or in isolation? ○

5. If research is being conducted remotely, are there support systems in place to reduce pressures on research team members and ensure that concerns can be raised as far as methodological errors, breaches of protocol, whistleblowing, safeguarding or allegations of possible misconduct? ○

When conducting the research

a. In spite of limitations due to the ○
    pandemic, are all required notifications
    being made as far as protocol changes,
    violations, or possible misconduct?

6. Are systems in place to safely share data ○
    with those conducting monitoring and
    auditing?

a. Does the research comply with any ○
    monitoring and audit requirements,
    or is the pandemic compromising
    the ability to comply with these
    requirements, for example due to
    pressure to produce results quickly?

> **Researchers should be aware** that the pandemic may have impacted on the ability of monitoring/audit bodies to carry out their responsibilities. This might include a lack of access to sufficient personnel/resources to monitor/audit projects in accordance with required standards and/or a lack of sufficient expertise to effectively monitor/audit projects relating to the pandemic. Monitoring/audit bodies will be considering whether these issues are affecting their activities and should be taking remedial action where necessary.

When finishing the research

1. Will the research and its findings be reported accurately, honestly and within a reasonable time frame? Has consideration been given to the best ways to communicate research findings in light of any restrictions on certain methods of dissemination due to infection control measures? ○

2. If publication of results is affected by the pandemic, have adjustments been made in order to nevertheless report research findings accurately, honestly and within a reasonable time frame (in part or in full)? ○

3. Are the necessary protections of academic freedom in place to enable researchers to publish their findings in full without undue influence by funders, Government or other bodies? ○

4. Have any internal pre-publication reviews that the home institution requires or recommends been followed? ○

5. Are there any relevant reporting guidelines or checklists that need to be checked to ensure accurate reporting (for example, the ARRIVE guidelines for reporting animal research), bearing in mind that some organisations may have recently updated their requirements? ○

6. Have all adjustments to the research design and methodology been acknowledged, including changes in personnel, environment, study conditions, research infrastructure support, and other resources?

7. Have all contributions to the research been properly acknowledged, and any adjustments noted? ○

8. Has due consideration been given to the type of publication and the potential effect on interpretation by peers, the media, and lay audiences? Will the type of publication be clear to a lay audience/media representative (this includes for example whether the research has been peer reviewed), thereby giving them a rough idea of what level of reliability should be assigned to the research? ○

9. Have all potential limitations to the study (e.g. sample size, generalisability, resource constraints) been accurately described to prevent misinterpretation and possible misuse of study findings? ○

10. Have journal requirements been checked in case of changes in response to the pandemic? ○

11. Given the constraints of a pandemic, have all data (e.g. samples, code, documentation) been stored in such a way that will ensure proper retention and access for the required duration? ○

When finishing the research

12. If there is significant interest in the research from a non-academic audience (for example Government, media, general public), do those involved in the research have sufficient skills and organisational support to discuss the research accurately and honestly and in a manner that reduces the chances of misinterpretation or embellishment? ○

Researchers should be aware that the pandemic may have impacted on the ability of the journal peer review process to thoroughly, objectively and efficiently review submissions and within an appropriate timescale. Journals will be considering whether they have access to sufficient expertise/personnel/resources to review submissions (whether related to the pandemic or not) in accordance with good practice, given pressure to approve studies for publication quickly, and should be taking remedial action where necessary.
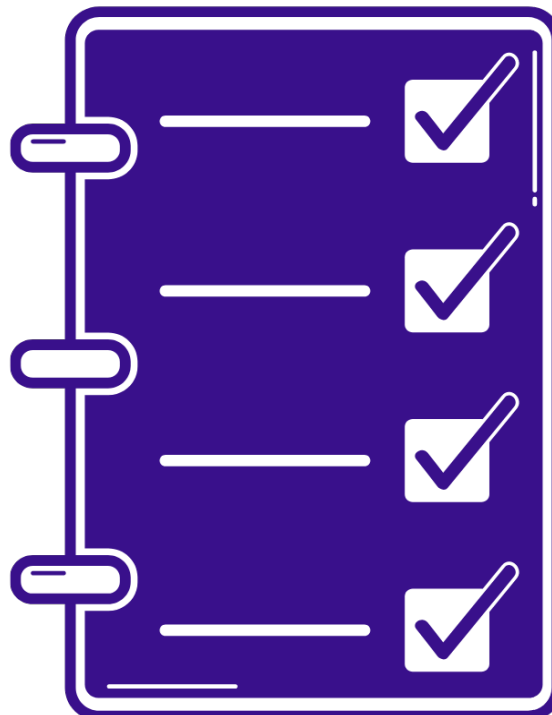
When finishing the research

For consideration by researchers and research organisations: Dissemination of research during a pandemic

When disseminating research, regardless of the type of dissemination, consider:

- The role of the institutional PR team to ensure that the research is promoted accurately and with appropriate caveats about any limitations of methodology, results and conclusions/ interpretations.

- How the research team will take on board legitimate criticism (e.g. via pre-prints of the research) to make amendments/corrections.

- The role of monitoring and engagement on social media to ensure any misrepresentations of the research are corrected.

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Competing Interests

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