

UoB Research Ethics and Governance position - COVID 19

Exceptional circumstances due to COVID 19

Regular situation reports and updated information is available via:

WHO: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

PHE England: <https://www.gov.uk/government/organisations/public-health-england>

Ensuring the health & safety of participants, research / professional services teams and protecting study integrity

It is challenging to predict the impact of the COVID 19 outbreak on research but the safety of participants, researchers and study integrity must be considered at every stage.

Research and Professional Services Staff

The University has issued guidance for staff and students:

<https://intranet.birmingham.ac.uk/student/coronavirus/Coronavirus-FAQs-for-students-and-staff.aspx#>A risk assessment in relation to the contingency plan for specific functions including research ethics and governance functions has been developed.

Participant recruitment

For projects that recruit participants from a non-UoB site e.g. via Health and Social Care organisations, the guidance provided by that site should be followed.

In the event that a worsening situation leads to there being insufficient resource to conduct research safely and / or research staff are needed to support frontline NHS activity, it is expected that resources will need to be concentrated on research where the immediate safety of patients could be put at risk by suspension and / or studies where patients are currently being treated or the study protocol is the only treatment option.

If possible, research activity will continue as planned and in line with the protocol, taking account of the fast changing developments and necessary study based risk assessed deviations.

Where changes do not effect participant safety and / or data integrity these should be considered non-substantial. For studies that were reviewed by a University Research Ethics Committee, please send a 'for information only' update to the Research Ethics Team.

Research projects that have / will need Approval by the Health Research authority and / or MHRA must work in line with HRA and MHRA guidance:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>

<https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/>

Potential COVID 19 adjustments to the project:

- Research teams will consider additional checks in line with the guidance provided by PHE or WHO, when planning contact with participants e.g. self-isolating, recent travel.

- Study teams will consider developing alternative ways of undertaking study activity and record that the change in activity is related to the COVID risk assessment.
- It might be possible / necessary to re-schedule appointments and this should be guided by requirements for participant / researcher safety and data integrity. Any postponed activity should be initiated as soon as it is feasible to do so.
- Protocol deviations must be recorded on a deviation log and reported to the Sponsor or the Research Ethics Team for studies that were reviewed by a University Research Ethics Committee if there is a possibility that the event constitutes a serious breach i.e. participant safety and / or data integrity were compromised.

Potential need for prioritisation

It might be necessary to prioritise certain UoB research activity and this will be facilitated by the Chair of CTOC for clinical studies, with input from the research team, CTUs, appropriate College Operations Leads and the Sponsor Representative.

For non-clinical research activity, this will be supported by the University Research Ethics Team in collaboration with the Head of Research Governance and Integrity, the Research Ethics Co-Chairs and where necessary the PVC Research and Knowledge Transfer.

Resources:

- University of Birmingham IT Services guidance on acceptable online data storage and data collection software
<https://collaborate.bham.ac.uk/it/itas/Published/Technical%20Standards/IT%20Product%20Guidance.pdf>
- Guidance on the key points to consider when switching from face-face interviews or focus groups to telephone or Skype formats (prepared by Dr Craig McAllister in Sport, Exercise and Rehabilitation Sciences, University of Birmingham)
<https://intranet.birmingham.ac.uk/finance/documents/public/Guidance-on-key-ethical-considerations-when-switching-to-Skype-or-telephone-interviews.pdf>