**Update 21st September 2021**

This statement replaces and supersedes previous notifications circulated to all staff in 2020 and 2021.

1. Given the exceptional nature of the situation arising as a result of the novel Coronavirus (COVID-19) pandemic, the College Ethics Committee requires all ongoing research involving human participants to make changes to how participant interactions are conducted and how ethical approvals are granted. This applies to staff and students’ research.

2. Lockdown restrictions have now been removed but we need to be mindful that the virus is still in circulation and restrictions may be re-imposed at short notice and that different restrictions may be applied in different areas.

3. It should be noted that, at this time, the risks to both our participants and our researchers are still real and tangible. The College position remains that where it is possible and/or practical for human participant data to be collected remotely, ethical approvals should only be given for remote data collection. Please be mindful that not all remote platforms support confidentiality and this should be explicitly considered in any approvals. Many subject associations provide subject-specific advice about this.

4. For the avoidance of doubt, given the ongoing risks and the need for our students to have clarity, for the 21/22 academic year students on taught programmes should continue to use remote data collection methods or should adopt a different methodological approach to their research which does not involve direct interaction with human participants (for example, secondary data analysis) *unless* the participant interaction requires access to specialised lab-based facilities within College buildings and/or is an essential core part of the students training at this level. In these exceptional cases a taught student may collect data in person as long as a suitable College-level risk assessment is in place. Any other projects at this level which require in-person data collection can only be approved with the written permission of the relevant subject AD.

5. However, we recognise that for our academic and research staff and for our PGR students, in some cases it is not possible and/or practical to collect human participant data remotely. In these cases in person data collection resumed from 15 April 2021 and is still subject to the considerations listed in this document.

**These rules apply whether the research is routine or sensitive.**

6. It should be noted that whilst the College the Health and Safety Committee do not sign off individual research projects, they have signed off the framework which allows in person human participant data collection to resume. Any researcher who wishes to have their research approach considered for ethical approval should have read (and make explicit reference to) College Risk Assessment Reference RA998645, shown in Appendix A to this document) in their approval. This risk assessment is built on the premise of face coverings and 1m+ social distancing. If you hold an external grant for this research please charge the costs of these materials to the grant, otherwise please contact your Departmental ASM in the first instance to charge these costs correctly if required.

7) Given the increased risks posed by the COVID-19 pandemic, no data collection can be undertaken on any project involving human participants until the ethics application has been signed off at the appropriate level. Please be mindful that the requirements for enhanced checking of ethics applications described in this document may mean that obtaining ethical approval takes longer than it has previously.

8) The following changes to ethical approvals are also required:

* All applications which include in person human participant data collection activities must include reference the College Health and Safety Assessment Reference RA998645, shown in Appendix A
* All applications which include in person human participant data collection activities must be accompanied by a completed risk assessment (which complies with Birkbecks usual approach to risk assessments as required under health and safety law) which considers the specific health and safety risks of the proposed data collection activity in the context of the research being undertaken. This risk assessment must explicitly include reference to any Covid-19 specific safety measures which are in operation in the location where the data collection will take place. This includes where the data collection will take place within the College.
* There may be some rare occasions where the risk assessment for an individual research activity cannot comply with the College Health and Safety Assessment Reference RA998645, shown in Appendix A.  In this case please contact the Head of Research Strategy Support for advice in the first instance (sarah.lee@bbk.ac.uk)

9. Ethical approval should not be granted for applications which include in person human participant data collection activities unless the applicant has demonstrated a good understanding of the COVID-19 risks and risk mitigation strategies which apply to their specific research.

* Ethical approval forms which include in person human participant data collection activities should all include a separate section which explicitly asks the applicant to consider how the Covid-19 pandemic may have impacted upon the participants that data will be collected from and whether the nature of the research is such that the participants are at a significantly greater risk of finding the research harrowing or distressing as a consequence of this.
* Ethical approval forms which include in person human participant data collection activities should all include a separate section which considers what the researcher will do in the event that the area where they wish to collect data (or the location of many of their participants) is put under a local lockdown or other restrictive measures such as “no socialising” rules, which considers how the re-imposing of those rules which have been used to date would impact on the research activities. If data collection activities are taking place outside the UK then factors such as quarantine, insurance, etc. also need to be addressed.

Where template ethical approval forms are provided by the School or Department they should be amended to include this information as an additional section or sections.

10) Before signing off an application as routine, the Departmental Research Ethics Officer must be confident that:

* The researcher has demonstrated a good understanding of the risks to health associated with undertaking their research
* It is either not possible or not practical to collect this data or equivalent data using remote methods
* The proposed data to be collected reflects good ethical principles, and the researcher has demonstrated:
  + that the potential benefits of collecting this data outweigh the risks associated with doing so and that suitable safeguards have been put in place for any vulnerable participants (as necessary)
  + any exclusion criteria remain inclusive
  + why they need to collect the data, that the size of the dataset is proportionate to the research question or hypothesis under investigation, and that the investigation is focussed on addressing this question or hypothesis without drifting off into other areas,
  + that the participants who have been selected are the most appropriate participants to provide this data
  + transparency with the participants about what data they are collecting, how and why they are collecting this data, how the data will be processed, aggregated with data from other participants and used, and how the dataset generated from this research will then be anonymised and made available to other researchers using FAIR principles (findable, accessible, interoperable, and reusable) - and that this information is effectively conveyed to the participants in both the information sheet and the consent sheet
  + that suitable processes are in place to protect the anonymity of participants, or (if this is not possible) that the likely circumstances where anonymity cannot be maintained are fully described in the information sheet alongside an explanation of what will happen if this situation occurs
  + the researcher understands the origins of their research questions and has demonstrated that they are aware of any pre-existing data that is relevant and could be used to supplement the data collected in this research. Where such supplementary data is available they are familiar with any constraints on its re-use
* For research which includes in person human participant data collection activities the researcher has striven to find a sensible balance between the sometimes conflicting demands of participant/researcher safety and confidentiality – for example, although the most effective way to ensure safety for the participant and the researcher would be for all data collection to take place outside with two metre distancing and the researcher and participant not sitting face to face,  such a public discussion is not conducive to confidentiality and is only suitable for a small subset of research areas. The College Risk Assessment RA998645 (and Appendix A below) allows for data to be collected inside with suitable face coverings and one metre+ social distancing. Ethics approvals should not be granted for applications which do not meet or exceed the minimum requirements set out in the Colleges Risk Assessment Framework Reference RA998645, shown in Appendix A
* For research which includes in person human participant data collection activities, the researcher has demonstrated a reasonable understanding of the constraints which relate to the place where data will be collected and has considered any ways that this needs to be reflected in their research design, including making any necessary changes to the Data Management Plan.

11) If a DREO is not confident that all these criteria have been fulfilled then the application should be either be sent back to the researcher for clarification passed to the School Ethics Committee for further consideration, even if the research would normally be considered to be routine.

12) Please be assured that we will continue to monitor the situation closely and will communicate any further changes at the appropriate time.