Research Involving human participants during the COVID-19 pandemic

1. Introduction:

1.1 Research involving human participants is often undertaken via face-to-face contact. The COVID-19 pandemic has meant that social distancing rules must be complied with in order to minimise the potential spread of the virus. As efforts are made to return researchers to the campus, consideration is necessary for the commencement of research studies involving human participants.

1.2 This framework has been produced to support decision making for this area of research. Paramount to any decision must be the health and safety of both researcher and research participant(s).

1.3 The principles outlined in this framework must be applied equally to new research, or studies re-commencing following a temporary pause because of COVID-19.

2. Requirements for commencement of face-to-face research:

2.1 The restrictions and conditions being placed on daily life change in accordance with latest information regarding infection rates. Subsequently, the first reference point must be the latest guidance from the N.I. Assembly https://www.nidirect.gov.uk/campaigns/coronavirus-covid-19.

2.2 The University has developed a generic risk assessment for dealing with COVID-19 in the workplace. Albeit the risk assessment is for the return to campus this can be modified and completed to capture the risks posed by face-to-face research. https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/CoronavirusCOVID-19Guidance/. As each research project presents its own unique circumstances the risks specific to individual projects must be considered, documented and appropriately mitigated. Risk assessments should be completed and submitted for consideration to the School Operational Recovery Group via the School Manager, or to the Faculty Operational Recovery Group via the Director of Operations.

2.3 When applying to a Faculty or School Research Ethics Committee to undertake face-to-face research, the risk assessment must be completed and agreed to, as outlined in 2.2 above, before an application is made for REC approval or to QUB Research Governance for sponsorship of studies to be conducted in the NHS/HSC.

2.4 For studies that are to be re-started following a temporary suspension, an assessment must be undertaken to determine the appropriate methodology to enable the research to continue. Any amendments to methodology must be submitted to the relevant Research Ethics Committee and/or Sponsor for NHS/HSC research projects.

3. Principles for research involving human participants

3.1 Face-to-face research should be eliminated where possible. Therefore, plans to undertake face-to-face research should only be made where it is not possible to conduct the research remotely, either by telephone or using on-line platforms.

3.2 Before necessary face to face meetings take place, the research participant should first be asked to complete a health analysis of themselves and close family regarding any COVID-19 recent symptoms. This health assessment should take place as close as possible to the face to face meeting. Any symptoms of COVID-19 in the person or family would exclude them from the research at that time.

3.3 The researcher should also undertake the same health assessment at regular intervals throughout the duration of the research in order to minimise the risk of them infecting others.

3.2 Some groups of people are at higher risk from coronavirus: https://www.nhs.uk/conditions/coronavirus-COVID-19/people-at-higher-risk-from-coronavirus/whos-at-higher-risk-from-coronavirus/. Researchers must carefully consider their target group and mitigate exposure to high risk groups.

3.3 Research should only be started when it is safe to do so. All research should be planned to take account of potential future changes to restrictions and conditions imposed by the NI Assembly.

3.4 Non-essential visitors are discouraged from the Queen's site. The location of the research must be in keeping with University guidance and the local NI Assembly's restrictions. These should be checked regularly and the research methodology adapted to ensure compliance.

3.5 Personal Protective Equipment (PPE) must not be used as an alternative to social distancing, except where there is no other practical solution (i.e. taking of a blood sample).

3.6 Researchers should work in close collaboration with key partners in the planning of their research e.g. health and social care trust, local schools, small businesses, etc. It is important to recognise that the research may place extra demands on these organisations, therefore it is vital to ensure that they have the capacity and are willing to facilitate/support the research before an application is made to a Faculty/School REC or to QUB Research Governance for sponsorship of studies to be conducted in the NHS/HSC.

3.7 External key partners may also have additional expectations/requirements that must be adhered to. There must be clear and explicit confirmation from key partners prior to commencement of research.

3.8 Further surges in COVID-19 could affect studies involving face-to-face contact. Researchers must be prepared for such studies to be stopped, paused or suspended.

4. Points for consideration when completing risk assessment

4.1 What is the risk of exposure to COVID-19 for both the research participant and for the researcher? How will these risks be mitigated against? Has the health analysis been completed for both the researcher and the research participant?

4.2 Does the physical access to the planned research location comply with current restrictions on social distancing in the nation where the research is to be conducted?

4.3 If using a host site (e.g. School, hospital, health centre, community centre, local business premises, hotel) has capacity of site been assessed to ensure social distancing can be maintained?
- 4.3.1 Where necessary, has permission been granted from the site to (re-) commence the research?

4.4 How will participant's concerns about COVID-19 be addressed by the researchers? How safe do they feel
- 4.4.1 About travelling to the venue (e.g. use of public transport)?
- 4.4.2 Attending the appointment, in particular, if in a perceived area of higher risk?
- 4.4.3 Engaging with persons outside of their "Coronavirus support bubbles"?
- 4.4.4 Will the person be accompanied? What arrangements have been made to facilitate a safe waiting area for person waiting?

4.5 What additional guidance on safety has been provided to participants and research staff?

4.6 What consideration has been given to people considered to be "clinically extremely vulnerable" who are "shielded"? For clinical studies it is recommended that their GP and/or specialist should be consulted to ensure they continue to receive the appropriate care with only essential visits to the research sites.

4.7 Is it necessary to change the research protocol/study plan to reduce risk to both participant and researcher?

4.8 Is there a need for additional PPE and/or COVID-19 testing, if the study is clinical in nature? Has the research protocol/study plan been amended to incorporate these requirements?

4.9 For studies being re-commenced within the health and social care sector, do any of the mitigations or flexibilities being put in place have an adverse impact on participant safety?