

Supplement: Human Participants Form

**(Information in shaded boxes is required. Boxes expand with text.)**

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| **Version No:** |  |

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| **Applicant name** |  |
| **Title of the study** |  |

# human participant information

## Type of participants

Please tick all that apply. Leave blank if none apply to your study.

[ ]  Under 18’s,

[ ]  NHS Patients\*,

[ ]  Expectant or new mothers,

[ ]  Refugees, asylum seekers or recent migrants,

[ ]  Learning disabilities,

[ ]  Communication disabilities,

[ ]  In custody\*,

[ ]  Impaired mental capacity,

[ ]  Any other condition which may affect ability to consent\*,

[ ]  Anyone engaged in illegal activities,

[ ]  Staff, service users, volunteers or data under the responsibility of a social care organisation,

[ ]  Prison or probation staff, clients, premises or records, or datasets,

[ ] Participants in an institutional context (e.g. school, healthcare or custodial settings) or organisational settings (e.g. business, workplace),

[ ]  Participants in an organisation or setting in which the researcher has a past/current role or position of authority.

**\*Please note that studies recruiting participants from these groups are also required to apply for IRAS approval (**[**https://www.myresearchproject.org.uk/SignIn.aspx**](https://www.myresearchproject.org.uk/SignIn.aspx) **) following receipt of an QMU favourable ethical approval opinion.**

## Recruitment process

Describe your recruitment process (maximum 200 words).In other words, who are your participants (eg inclusion/exclusion criteria)? How many are you planning to recruit? How will they be identified? (eg via posters, emails, moderator message, online, from a database, etc.) Do you need approval to access participants for your research (eg from a clinical manager, charity manager, etc.) [add approval letters/emails as additional relevant documentation]? How do participants make contact with the researcher?

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## Informing participants

Describe how participants will be informed about the research prior to taking part (maximum 200 words). In other words, how and when will they be provided with the participant information sheet? How much time do they have to decide? How do they contact the researcher to make initial meeting? (This could be online or face to face, in some cases they may require a link to online survey.)

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## Taking informed consent/assent

Describe the strategy for gaining consent/assent from participants (maximum 200 words). In other words, who will take informed consent/assent? How will informed consent/assent be taken? Where will informed consent/assent be done? Please note: assent is only required in studies involving children (under the age of 16 years).

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## Confidentiality and Anonymity

Describe how anonymity and confidentiality will be managed (maximum 300 words). In other words, what is your approach to maintaining confidentiality of data given by participants? Will participant anonymity be assured for participants and how? For example, what data you are planning to collect? (eg video, audio, printed data, electronic data, etc)? Where you plan to store the data? (eg in your QMU One drive file, etc). For how long? (eg destroyed at the end of the study, kept for five years and then destroyed, kept indefinitely for secondary data analysis, etc). What type of data are you collecting? (eg anonymised[[1]](#footnote-1), pseudo-anonymised[[2]](#footnote-2) or fully identifiable or personal data[[3]](#footnote-3)). Who is the custodian of the data collected? (For students this is their supervisor. The custodian of the data is responsible for storing/ensuring destruction of the data).

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## Potential risks to participants

Summarise any risks to participants and how these will be managed (maximum 200 words). In other words, give details of protocols in place in the event of participant disclosures of, for example, criminality, unprofessional conduct or risks to themselves or others. Does the research involve topics that participants might find distressing? (If so, what protocols are in place to manage participant distress?) Will the research involve any element of deception? (Provide a rationale for, and an explanation of the approach taken to deception.)

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# Criminal record check

## Is a criminal record check required\* for the proposed research? *(Tick one only)*

[ ]  YES [ ]  NO

\*[Check PVG guidance](https://www.qmu.ac.uk/about-the-university/quality/forms-and-guidance/qmu-disclosure-and-pvg-membership-guidance-version/)

## If YES, what is the status? *(Tick one only)*

[ ]  Not applied yet

[ ]  In progress

[ ]  Received by QMU

##  Is it a PVG or Disclosure Check? *(Tick one only)*

 [ ]  PVG check [ ]  Disclosure check

1. No personal data is collected hence participants cannot be identified from the collected data. [↑](#footnote-ref-1)
2. Study data that can be indirectly linked to an individual using a ‘key’. (eg. identifiable personal data like participants names is keep in a separate file with their allocated study number [key]. All study data collected is linked using the study number [key]. Thus, participants cannot be identified from study data when analysing the data but if you need to identify a participant you can use their study number to do this). [↑](#footnote-ref-2)
3. Personal data that can be directly linked to an individual (eg names, address, etc). [↑](#footnote-ref-3)