Revisions to Ethics Applications

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| **Question Specific Comments** | **Applicant’s Response** |
| A7.1 Please provide details of who the research governance sponsor will be:  It is unclear why UoM is not the sponsor.  Can you please provide any regulatory approvals received by the sponsor for the conduct of this research? |  |
| Prop.5 Please list and justify the exclusion criteria for participants.  You use the phrase 'might be excluded' for these groups which implies that there may be instances where individuals in these groups are recruited. Is this the case? If yes, please specify under what circumstances they will be eligible. If no, can you please clarify that they will definitely not be included? |  |
| Prop.7 Please describe how each group of potential participants will be identified, approached and recruited?  'When they arrive at the workshop, participants will be asked to sign a participant consent form with details about how their data will be collected, stored and used.'  - It is best practice for the participants to have access to this prior to attendance on the day to ensure they to not make a wasted trip. |  |
| Prop.7 Please describe how each group of potential participants will be identified, approached and recruited?  Will the advert on the UK Data Service website include detailed information, e.g. PIS, for potential participants? If not, at what point will they receive this information to ensure that their decision to participate or not is based on informed consent? |  |
| Prop.7 Please describe how each group of potential  participants will be identified, approached and recruited?  The final sentence in this section seems to be incomplete - please check and complete. |  |
| Prop.8 Please attach copies of all advertising material/emails/letters that will be used to approach and recruit your potential participants.  The promo material does not make it clear that this is a research process for which they will be required to consent. |  |
| Prop.8 Please attach copies of all advertising material/emails/letters that will be used to approach and recruit your potential participants.  Please add a version number and date to the advert. |  |
| Prop.9 Please describe the specific activities that participants will be asked to undertake (e.g. interviews, focus groups, questionnaires, workshops, experiments in a lab etc) including how many, where they will take place) and the expected duration of each activity.  Those who register for the event through the UKDS registration page will need to provide a large degree of special category and personal identifiable information - this is not described here.  It is unclear why this is being collected prior to participant consent which appears to take place on the day of the workshop. |  |
| Prop.9 Please describe the specific activities that participants will be asked to undertake (e.g. interviews, focus groups, questionnaires, workshops, experiments in a lab etc) including how many, where they will take place) and the expected duration of each activity.  'Comments or questions made during the discussions and chit-chat may be noted down for research purposes if useful.'  - please upload the materials that will be used to capture this data. |  |
| Prop.9 Please describe the specific activities that participants will be asked to undertake (e.g. interviews, focus groups, questionnaires, workshops, experiments in a lab etc) including how many, where they will take place) and the expected duration of each activity.  Can you please confirm how many workshops participants will be expected to attend? If it's one as the recruitment advert suggests, are you certain you'll have up to 25 interested people, given that there's just under 3 weeks to the date of the workshop (19th March)? If another workshop is planned for for people who may indicate interest after this date, please add the date of the second workshop to the advert. |  |
| Prop.10.1 Please attach either a copy of all of the data collection tools you plan to use  Please add a version number and date to the workshop guide.  29/02/2024 at 09:26 AM Latest Submission  Prop.12.1 Please provide specific details of how consent will be obtained and recorded.  Implied consent is used for anonymous online surveys only.  Please describe exactly when the participants will receive the PIS and why consent is not being obtained prior to sign up and collection of special category and personal identifiable information. |  |
| Prop.13 Please attach a copy of your UK GDPR compliant participant information sheet(s)/script/summary of information page.  • A paper copy of participants name, email and consent will be used at registration and this will be retained for 1 year in a locked cabinet on UoM premises for audit purposes.  - it is unclear why contact details are being stored.  - it is also unclear what happens with all of the data provided at registration |  |
| Prop.13 Please attach a copy of your UK GDPR compliant participant information sheet(s)/script/summary of information page.  Data Protection and Confidentiality  There is information missing here - please refer back to the UoM IGO approved template and ensure that all GPDR information is provided. |  |
| Prop.13 Please attach a copy of your UK GDPR compliant participant information sheet(s)/script/summary of information page.  Please add the research team contact details at the end of the PIS. Currently, they are only included in the context of receiving complaints. |  |
| Prop.14 Please attach a copy of your UK GDPR compliant consent form(s)/script(s):  The version of the PIS referenced in Statement 1 of the consent form is wrong. The PIS attached to your application is Version 2, 01/02/2024. Please check this and amend. |  |
| Prop.14 Please attach a copy of your UK GDPR compliant consent form(s)/script(s):  The consent form is missing the signature sections for the participant and the consentor, as well as who will receive copies of the consent form. These would usually be found at the bottom of the form - please check the UoM template and add them back in. |  |
| Prop.14 Please attach a copy of your UK GDPR  compliant consent form(s)/script(s):  Consent statement 2 states that it will not be possible to remove an individual participant's data from the project once it has been anonymised. However, the PIS states that it will not be possible to remove data as specific contributions can't be identified. Can you please make sure this statement is consistent in both documents? |  |
| Prop.16 What do you consider to be the main ethical issues and risks associated with the proposed study and what steps will be taken to mitigate them?  Please consider:  informed consent  confidentiality  data protection |  |
| Prop.16 What do you consider to be the main ethical issues and risks associated with the proposed study and what steps will be taken to mitigate them?  In view of your response here, is there any chance of disclosures of professional malpractice? If yes, what will you do in such an instance? Reflect on this and see if this needs to be added to the PIS and consent form. |  |
| Prop.18 How are you planning on sharing the results of your research with individual participants, groups or communities?  If you plan to retain contact details for the purpose of providing study outcome, retention needs to be described in the PIS and an opinion consent statement should be included in the consent form. |  |