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Research Ethics Application for University Staff and Postgraduate Researchers (PGRs): Studies Involving Human Participants

Completion Notes

The following notes provide guidance for the completion of the research ethics application for **University Staff and Postgraduate Researchers (PGRs): studies involving human participants**. The guide relates to specific sections of the application form.

[a] A 'member of the research team' in this respect would constitute any individual who will be a named author on formal outputs from the research.

[b] A core function of the REP, as per institutional policy, is to monitor third-party involvement in prospective research, and make provisional assessments regarding the likelihood of a partnership causing reputational damage. Partner individuals or agencies could include public or private bodies (such as charities or businesses) on steering groups or involved in co-production of research tools/strategies, identified 'gatekeepers' in participant recruitment and so forth. It should also include any contracted third-party transcribers or data analysts, with an adapted version of the UoC transcriber confidentiality agreement added as an appendix where necessary.

[c] The end date is the point at which no further direct participant contact (regarding the specific project) is anticipated. This is typically when all direct data have been collected, and analysis is at a stage where summaries of findings can be distributed to involved parties (where this has been promised).

[d] The peer-reviewer(s) who undertake this task (a) must not be part of the named research team and (b) should ideally have recent experience of making an application to the UoC REP. For PGRs, review by supervisors is considered sufficient, though wider review is encouraged. Please be mindful that any named reviewer(s) may be contacted if the REP has reason to require confirmation of this peer-review being undertaken. We appreciate that this may not be possible for some commissioned projects.

[e] This is simply an overview exercise intended to provide ethics reviewers with a general frame of reference when assessing the details of your application.

[f] For example, 'Undergraduate diagnostic radiography students, studying at an English Higher Education Institution (HEI), of 18 years of age or more, in the final year of study at time of interview, with direct experience of at least one simulated clinical placement during their degree'. If the proposed project has more than one component or tranche, please be clear which inclusion criteria apply to which part(s) of the project.

[g] An exclusion criterion is not to be written as the literal opposite of a previously stated inclusion criterion. For example, where the inclusion criteria states 'of 18 years of age or more', there is no need to then add an exclusion of 'Under 18'.

[h] The maximum should be (a) consistent with the project design, (b) manageable within the timeframe given, and (c) should not be exceeded. It is accepted that some designs (such as online surveys distributed via social media) may not have a maximum sample size that can be straightforwardly specified, in which case please state this below. If the proposed project has more than one component or tranche, please be clear which sampling methods/sizes apply to which part(s) of the project.

[i] The text of any invitational emails/posters/posts should be submitted as appendices to these forms, signposted in this section and noted in the Supporting Materials Checklist at the end of the application document.

[j] The text of any participant information and consent questions, using the linked UoC templates, should be submitted appendices to these forms, signposted in this section and noted in the Supporting Materials Checklist at the end of the application document. If you have elected not to use the UoC templates, please outline your rationale for doing so.

[k] 'Making a contribution' in this sense amounts to providing the data that will be used in the project's analysis; i.e. filling a questionnaire, giving an interview, performing a physical task. If your project does not (for any reason) permit this order of withdrawal, which is typically seen as a core right of all participants in research, then strong justification will need to be provided. The only routine exception to this is in projects where Focus Groups are used, and withdrawal of *data* at any time after the group has begun could corrupt the sense of the full transcript. In these cases, it should be specified that participants can withdraw from contributing at any point but, once the focus group has started, they can no longer withdraw any data they have provided.

[l] It is not incumbent upon the researcher(s) to offer *post-hoc* withdrawal opportunities, and it can make some designs difficult to manage (e.g. focus groups), though it also can improve participant uptake and confidence, particularly around sensitive research topics. Do not request email-based withdrawal from an anonymous survey, as this would make breaking anonymity an active condition of withdrawal.

[m] If the proposed project has more than one component or tranche, please be clear which collection/analysis methods apply to which part(s) of the project. Any pertinent research instruments, such as interview schedules and survey designs, should be submitted to the Research Office as appendices to these forms (and should be signposted in this section). Any software to be used in support of data analysis should also be detailed in this section. If you are intending to employ Generative AI at any stage of the research process, please firstly review the relevant section in the UoC Research Ethics Policy.

[n] Note: If any issues of this order arise, they should be described in full here, as must the steps that will be taken if participants disclose past or potential harm to themselves or others. Statements must be aligned with, and linked to, the UoC Safeguarding Policy. All participant-facing documentation must also make any such matters clear to participants. Further direction can be found via UKRI.

[o] This risk analysis should **not** include GDPR and related risks (i.e. those around data security and identity protection), which are addressed in Section 33. Mitigations should refer to key guidelines for good practice where relevant, e.g. 'Maximum dose for the supplement will be adjusted in line with the safe limits determined by the British Medical Association'.

[p] This includes, but is not limited to, conducting surveys, interviews and focus groups online, using only electronic documents and avoiding paper-based printing, and limiting physical journeys (or using public transportation rather than cars).

[q] Regarding risks to personal and institutional reputation, UKRI guidance (and case studies) and the UK Trusted Research Agenda address key issues.

[r] If raw audio/video data are to be transcribed, please note exactly what will be redacted from the transcripts in support of identity protection. This is usually proper names, locations and exact dates at the minimum. Be careful not to misuse the terms 'anonymous/anonymised' and/or 'confidential'. Full conditions of appropriate usage for these terms are stipulated in the UoC Research Ethics Policy.

[s] It is broadly expected that the UoC Debrief Sheet Template will be used and provided to participants at the first available opportunity after their contribution is complete. Provisional findings should be distributed via the channels through which contact was originally made. For full outputs, participants might be directed to conference/journal websites, or UoC's Insight archival system. In the event there is a reason why, for example, funders or commissioners cannot share the data, please explain this in your response.

[t] Participants must be made fully aware of all potential uses of data that you list in your participant information. Data cannot be subsequently used for a broad purpose to which the participants have not explicitly consented (e.g. they cannot be published in a peer-reviewed journal if the participants have not been notified of the possibility).