

Appendix 2: Sample copy of HRA Ethical Review Form²⁰



Health Research Authority

Ethical Review Form (Lead Reviewer/REC Member)

The HRA has an established role to promote transparency, largely through RECs and the publication of research summaries

The lead reviewer(s) should complete this form in preparation for the REC meeting. The form may also be used by other REC members. The REC Chair should use the headings as an *aide memoire* to structure the discussion at the meeting. If paper copies of this form are completed, they should be given to the REC Manager who will arrange for them to be destroyed once the minutes of the meeting have been ratified.

Meeting Date:

IRAS Project ID/ REC Reference Number:

Study Title:

Brief overview of study (optional depending on REC practice)

²⁰ Health Research Authority, 'Guidance and Policy for REC Members' <www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-members-area/guidance-and-policy-for-rec-members/> accessed 23 October 2019. Published with permission from the Health Research Authority.

<p>1. Social or scientific value; scientific design and conduct of the study (IRAS A6, A7-14, A57-62, A75) Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge. RECs should take into account the public interest in reliable evidence affecting health and social care.</p> <p>Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data. Is the research question important and necessary? Is the research design and proposed statistical analysis able to answer the question? Is there equipoise; are all treatment arms viable options for the research participants?</p> <ul style="list-style-type: none"> ● Public Involvement – Is there involvement of patients, service users or the public, in the design, management, and undertaking of the research? (IRAS A14-1)
<p>Comments/issues for discussion:</p>
<p>2. Recruitment arrangements and access to health information, and fair research participant selection (IRAS A16, A17-1, A17-2, A 27-29, A46, A47). Inclusion and exclusion of potential research participants. The benefits and risks of research should be distributed fairly among all social groups and classes, taking particular account of age, disability, gender, race, religion or belief and sexual orientation, as well as economic status and culture. How are research participants recruited? How does participation impact on their clinical care? Are compensation arrangements in place? Insurance (negligent/ non-negligent harm).</p>
<p>Comments/issues for discussion:</p>
<p>3. Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future) (IRAS A18-25 & part B3 if radiation, and part B5 if samples). Minimization of risks. Is there evidence of the consideration of any benefits/risk for individual research participants, past/future research participants, including whether the risk/intervention is sufficiently minimal to require no SSA? Are benefits/risk clearly identified for the research participant? Have steps been taken to minimize or eliminate the risk, hazards, discomfort, and distress and enhancement of potential benefits; risks to the research participant are proportionate to the benefits to the research participant and society? Is the balance between risk and benefit equitable?</p>

Comments/issues for discussion:

4. Care and protection of research participants; respect for potential and enrolled research participants' welfare & dignity (IRAS A25, A50-53, A76, A77).

- * permitting withdrawal from the research
- * protecting privacy through confidentiality
- * informing participants of newly discovered risks or benefits
- * informing participants of results of research
- * maintaining welfare of participants
- * what will happen at the end of the study
- * provision of appropriate indemnity and insurance

Trial Registration (IRAS A50) **Are trial registration arrangements in place?**
(note, this is a condition of the favourable opinion, and is mandatory for the first four categories of study on IRAS)

Data protection & research participant's confidentiality (IRAS A36-43)
Where and how (anonymised/coded) and for how long will data be stored? What purpose will be served by the data? Who will access? Are research participants informed that access to their medical notes may be required? Arrangements made to deal with incidental disclosure?

Comments/issues for discussion:

5. Informed consent process and the adequacy and completeness of research participant information (A30 -34, A46, A49 & PIS). Provision of information to research participants about the purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enrol and continue to participate. Is the language used clear and understandable to the research participant it is aimed at? Does it include all the procedures as described in the protocol? Have uncertainty and randomisation been explained to the research participant? Is consent taken as part of a process with research participants having adequate time to consider the information, and opportunity to ask questions? Is it clear to what the research participant consents or assents? Is there any inducement or coercion? Are vulnerable research participants involved? Is consent obtained to allow GPs to be informed? *(Is the Welsh version an accurate translation of the given English version? Wales only)*

IRAS A35 – What steps would be taken if a participant lost capacity during the study? Subject to ethical approval, tissue samples and data already collected may be retained in identifiable form and used in the research provided that properly informed and expressed consent for this was given prior to the onset of incapacity.

If the applicant states that the participant would remain in the study following the loss of capacity and would undergo further interventions and procedures (including the collection of new samples and/or personal data) this would constitute “intrusive research” for the purposes of the Mental Capacity Act 2005 in England and Wales and would require approval under section 30 of the Act. In Scotland, approval would be required under section 51 of the Adults with Incapacity (Scotland) Act 2000. In Northern Ireland, the common law requirements would apply.

Comments/issues for discussion:

6. Suitability of the applicant and supporting staff (investigator CV & IRAS question A47, A48) Are the applicant and supporting staff suitably qualified and do they have suitable experience relevant to the proposed research? Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. Are the local facilities and arrangements suitable? Have community issues been considered? Have any conflicts of interest been considered?

Comments/issues for discussion:
7. Independent review (IRAS A54-56) Review of the design of the research trial, its proposed research participant population, and risk-benefit ratio by individuals unaffiliated with the research. The REC may be satisfied with credible assurances that the research has an identified sponsor and that it takes account of appropriate scientific peer review.
Comments/issues for discussion:
8. Suitability of supporting information E.g. GP letter, interview schedules, questionnaires, lone working policies etc.
Comments/issues for discussion:
9. Other general comments: E.g. missing information / typographical errors / application errors.

10. Consider and confirm the suitability of the summary of the study (IRAS A6-1). This summary will be published on the HRA website in this format together with the summary of the REC's ethical opinion.

Confirmed satisfactory

Changes requested: