

**Ethical Review Form for Mental Capacity Act (MCA) Studies (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.

Note: This form includes the general ethical domains to be considered for all studies, additional considerations for MCA studies are shaded.

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| **Compliance with the Mental Capacity Act (England and Wales), 2005** Under Section 31 of the Act the REC must be satisfied that a number of specific criteria are met in relation to the inclusion of adults lacking capacity to consent for themselves. |

Meeting Date:

IRAS Project ID/ REC Reference Number:

Study Title:

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| **Brief overview of study** (optional depending on REC practice) |

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| **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. 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   * **Public Involvement** - Is there involvement of patients, service users, or the public, in the design, management, and undertaking of the research? (IRAS A14-1)  |  | | --- | | **1.1 Relevance of the research to impairing condition**  The REC must consider whether the research is connected with an impairing condition affecting research participants who are unable to consent, or with the treatment of the condition. An impairing condition means a condition which is attributable to (or causes or contributes to) an impairment or disturbance in the functioning of the mind or brain.  Treatment in this context includes the provision of any clinical treatment or other health and social care in connection with the impairing condition.  **1.2 Justification for including adults lacking capacity to meet the research objectives** The REC must consider whether or not the research could be carried out as effectively if it was confined to research participants able to give consent, i.e. is it necessary to include research participants lacking capacity in order to meet the research objectives? | |
| **Comments/issues for discussion** |

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| **2. Recruitment arrangements and access to health information, and fair participant selection** (IRAS A16, A17-1, A17-2, A27-29, 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)**.**   |  | | --- | | **2.1 Arrangements for appointing consultees**  The REC must be satisfied that reasonable arrangements will be in place to comply with Section 32 of the Act.  This requires the researcher, as part of the recruitment strategy, to identify and consult persons (consultees) to advise on whether a person lacking capacity should take part and, in their opinion, what the person’s wishes and feelings would be likely to be if they had capacity. The research team must take reasonable steps firstly to identify a personal consultee who is engaged in caring for the participant or is interested in their welfare (but not in a professional capacity or for remuneration) and is prepared to be consulted. If no such person is available, the research team should have a strategy for appointing nominated consultees who are independent of the project in conjunction with the host organisations at each site. | | **2.2 The arrangements for recruitment in an emergency setting** (if applicable) The MCA allows for recruitment without prior consultation where treatment is to be provided as a matter of urgency and it is not reasonably practicable to identify and consult with a personal or nominated consultee beforehand. Enrolment may then take place: a) with the agreement of a doctor independent of the project; or, where this is also not reasonably practicable in the time available. (b) in accordance with any procedure approved by the REC.  Where enrolment without prior consultation is proposed, the REC must be satisfied that this is justified in the circumstances. It should also ensure the researcher has procedures in place to seek consent from a capable research participant (if recovered) or to consult a consultee as soon as practicable after urgent treatment has been provided. | |
| **Comments/issues for discussion:** |

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| **3. Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future)** (IRAS A18- 25 & part B3 if radiation, and part B 5 if samples).Minimization of risks. Is there evidence of the consideration of any benefits/risk for individual research participants, present/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 minimise 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?   |  | | --- | | **3.1 Balance between benefit and risk, burden and intrusion**  The REC must be satisfied that one of the following criteria is met by the research:  a) The research is of potential benefit to research participants lacking capacity without imposing a disproportionate burden  or:  b) The research is intended to provide knowledge of the causes or the treatment or care of the condition affecting participants lacking capacity or of a similar condition, and additionally:  • The risk to participants is likely to be negligible  • The research will not significantly interfere with their freedom of action or privacy  • The research will not be unduly invasive or restrictive. | | **3.2 Site specific assessment**  If the study will involve non-NHS sites, the REC Manager should advise the Chair whether the study requires SSA, taking account of the guidance on SSA exemption in SOP 4.27 – 4.29. The Committee has the discretion to waive the requirement for SSA where the study involves no clinical interventions *and*  either all recruitment procedures and all study procedures involving participants are undertaken directly by the CI’s team  or where the Committee is satisfied that the risk to participants is likely to be negligible and will not interfere with their freedom of action or privacy in a significant way or be unduly invasive or restrictive.  The need for SSA should be confirmed by the Committee at its meeting. | |
| Comments/issues for discussion: |

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| **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 arrangements in place? (note, this is a condition of the favourable opinion, mandatory for clinical trials).  **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?   |  | | --- | | **4.1 Additional safeguards**  The REC must be satisfied, from the information in the application and any further assurances given during the review that the additional safeguards set out in Section 33 of the Act will be complied with during the conduct of the research.  These additional safeguards are as follows:  Nothing will be done in the course of the research:  (a) to which research participants lacking capacity appear to object (unless it is to protect them from harm or reduce/prevent pain or discomfort)  (b) which would be contrary to any known advance decision or statement they have made.  If research participants indicate in any way that they wish to be withdrawn from the project, they must be withdrawn without delay, except where this involves stopping treatment and there could be a significant risk to their health.  Research participants lacking capacity must also be withdrawn if any of the criteria set out in Section 32 of the Act no longer apply.  In conducting the research, the interests of research participants must be assumed to outweigh those of science and society. | |
| **Comments/issues for discussion:** |

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| **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 participants 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 GP’s 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.   |  | | --- | | **5.1 Information for consultees**  The REC must be satisfied that appropriate information will be provided to consultees about the research and their role as a consultee. There is no statutory requirement for the consultee to sign a form, but it is strongly recommended that the researcher uses a Consultee Declaration Form to confirm that the consultee has received the information, has had the opportunity to ask questions and has advised they have no objection to the participation of the person lacking capacity. A template for the declaration is set out in the HRA guidance on information sheets. Where carers will also be recruited as research participants in their own right, the information sheet should distinguish clearly between the two roles and the carer should sign a consent form separate from the consultee declaration sheet. |   (Is the Welsh version an accurate translation of the given English version? Wales only). |
| **Comments/issues for discussion:** |
| **6. Suitability of the applicant and supporting staff** (investigator CV & IRAS A47, A48) Are the applicant and supporting staff suitably qualified and do they have 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**: |

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| **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:** |

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| **8. Suitability of supporting information** E.g. GP letter, interview schedules, questionnaires, lone working policies etc. |
| **Comments/issues for discussion:** |

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| **9. Other general comments:** E.g. missing information / typographical errors / application errors. |
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| **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:** |