Mobile Assistance for Groups and Individuals within the Community – Stroke

Requirements for ethical review of MAGIC projects: Information for Suppliers


Horizon 2020

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Contents

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1. Scope

MAGIC focuses upon the development and implementation of technology based solutions for patients who have experienced a stroke. The solutions will be tested in two European countries that are represented in the Buyers Group – Northern Ireland and Italy.

2. Timeframe

MAGIC commenced on 1st January 2016 and will run for 52 months, finishing at the end of April 2020. It will be comprised of 4 Phases 0, 1, 2 and 3

3. Ethics and Security: what suppliers need to know.

3.1 Background

Each consortium member organisation, within the Buyers Group, will ensure the ethics regulations and protocols within their geographical area will be adhered to with regard to the issue of ethics before any task or interventions are carried out on Stroke patients.

It is a policy requirement in the United Kingdom and Italy that any new research study which involves patients directly or their data obtains a favourable ethics opinion from a recognised ethics committee in that country. Where the research involves patients in the UK, this will be a National Health Service or Health and Social Care Research Ethics Committee. In Italy this will be the relevant regional Research Ethics Committee.

Any technology deployment in Phase 3 cannot occur before full ethical review by the relevant ethics committee. If patient data is required in the earlier phases 1 or 2, these proposals will also require ethical approval. The ethics committee has a duty to determine if the supplier's project meets the national legal and ethical requirements of the particular country where the tasks with patients will be carried out.

The suppliers may start testing with patients only when a favourable ethical opinion is in place. They will also be obligated to notify the research ethics committee after the start of the project of any substantial changes to design or patient consent. Therefore, the MAGIC PCP Buyers Group would expect the successful Phase 2 suppliers to be applying for ethical approval to ensure that the necessary permissions to operate field trials in Phase 3 are in place in advance of the start of Phase 3.

The ethics committee will focus on the patient's ability to consent, level of burden, the patient's understanding of risks and burdens of the project, what participating in the field testing means for standard care, what happens at the end of the study, safety and reporting issues, the expertise and experience of the company personnel dealing with the patients in the field testing. The ethics committee will also be concerned that the study design is of high quality and will expect that in the design of any technology that there has been patient public involvement. The IRAS application form will prompt the

ethics applicant to answer a series of ethical questions and prepare the necessary field testing paperwork such as consent forms and information sheets for the patients and/or their carers.

3.2 Guide to the necessary process for the supplier to follow to obtain the approval of the intervention by the relevant Ethics Committee.

The processes considered are those that are relevant in the two countries of the Buyers Group, Northern Ireland and Italy.

Northern Ireland

The ethics committees in Northern Ireland follow a national UK programme, where a standardised suite of documents are completed on-line through Integrated Research Application System (IRAS) will be followed https://www.myresearchproject.org.uk/ .

The IRAS 'my research project' website takes the research applicant through all elements of the proposed activity which is patient/ service user focused. The programme classifies the type of intervention and presents the applicant with the appropriate set of forms to complete. Whilst, this is a meticulous and thought provoking process it will be necessary to repeat for all activities that have an interaction with patients beyond their opinion of 'what type of service they would like to see in future'. Therefore, this process will be undertaken for each of the three phase 3 solutions prior to deployment along with the Work Package 6 impact evaluation.

The IRAS process will help shape the design of the testing in the natural environment to ensure all ethical dimensions are appropriately considered. This would require patient consent and so would need ethical and governance approvals undertaken through one ethics application to ORECNI through the Integrated Research Application System (IRAS) and governance approvals in each Health and Social Care Trust.

It is important that the Research Managers in each of the regional Health and Social Care Provider Organisation are aware of any activity within their Trusts, Hospitals or Community Services. Within Northern Ireland Professors Carmel Hughes and Margaret Cupples are co-leads of the Primary Care Special Interest Group of the Northern Ireland Clinical Research Network; it is intended and valuable to make them aware of the initiative and they will undoubtedly be able to provide advice on conducting research in primary care. In addition, Dr Siobhan McGrath, Head of the Office for Research Ethics Committees for NI, is best placed to provide further advice to the MAGIC project prior to addressing all matters requiring ethical approval at each phase albeit that there will be no requirement placed upon the Suppliers to undertake patient/ service user testing in Phases 1 and 2 (contact details are available on http://www.hscbusiness.hscni.net/orecni.htm).

Italy

The following process will be followed for MAGIC, to gain approval from the relevant Ethics Committee:

- The documentation regarding the MAGIC project will be sent to the Secretariat within 15 working days before the session.

- Administrative referents will send to the scientific group the opinion of the Committee.
- For the studies approved by others Ethics Committees, at the time of preparation of the first dossier should be produced, by the promoter through the Centre, all historical documentation, electronic media (CD or DVD), with all the views already acquired, both for the main study, and for any subsequent amendments.
- No documents should be sent directly to the Secretariat by the Founders, but only by the General and Health Directorates of the Centres, with a special letter of transmittal signed by both directors.
- The practice must be complete, that is including all the documents required by the annexes and perfected with the reports of the experimenters responsible for the feasibility statements (suitability of the experimental centre, the staff involved and cost analysis) and the approval of the General and Health Directorates competent for the centre that requires the evaluation (specific documentation of the centre).

Documentation should include:

- request for an opinion
- authorization request
- research protocol
- synopsis of the protocol
- information sheet for the patient
- informed consent form
- clinic tab for data collection
- list of participating centres
- statement by the proponent on the observational nature of the study
- opinion of the Ethics Committee of the coordinating centre
- curriculum vitae of the experimenter and collaborators
- economic aspects.

3.3 Further guidance on consent documents

Northern Ireland

Informed Consent - Explicit consent will be required from the participants of the pilot in accordance with Health and Social Care Research Ethics Committee procedures and consent forms will be developed in accordance with National Research Ethics Service (NRES) and IRAS guidance.

Consent from guidance is available at

http://www.hra-decisiontools.org.uk/consent/examples.html

Italy

The procedures followed in the Italian regions involved follow a similar set of procedures to Northern Ireland. The subject, before sampling, must be informed about risks and benefits linked to the participation to MAGIC through informed consent that must be submitted to every patient involved. This document must be read/ understood

and signed by the patient. It contains not only all risks/ benefits about their involvement but also all the patient information needed for this study.
Briefly, informed consent contains:

- clear and easy explanation of the scientific project for which patient is recruited,
- duration of the study and role of the patients
- risks and benefits linked to participation
- identity of contact person who answers about question on research, subject's rights; this person will be informed about any injury to the subject
- a statement describing the extent to which confidentiality of records identifying the subject will be maintained
- a statement that participation is voluntary
- personal records request (such as age, sex, birthplace, residence, telephone number, weight, height, occupation, any familiarities, etc)
- specific habits request
- clinical characteristics request

In the informed consent it is specified that the volunteer patient must be able to have their information removed at any time.
Four elements of informed consent (conditions of adequate information, understanding, voluntariness, and decisional capacity) should characterize the subject's authorization at every point of his/her participation in research.
The consent form used is based on that developed by the World Health Organisation Ethics Review Committee. (see attached document uploaded to the portal).

The regulations that may affect the development of supplier technologies in MAGIC

Northern Ireland

In Northern Ireland UK, the research will be undergo ethical review and appraisal in accordance with the governance arrangements set out in the Northern Ireland Research Governance Framework 2007 and in the Governance Arrangements for Research Ethics Committees UK (GAfREC, May 2011). Other laws that apply are Public Health Act (Northern Ireland) 1967, the Data Protection Act 1998 and the Human Tissue Act 2004. This forms part of a national UK programme where a standardised suite of documents are completed on-line through Integrated Research Application System (IRAS):
https://www.myresearchproject.org.uk/

Italy

In Italy, the research will be undergo ethical review and appraisal in accordance with the governance arrangements set out in the provisions concerning the Regional Ethics Committee for the Marche region n.189/2012 and the corresponding Ethics Rules set out for the Piemonte Region.

Issue	***Action***
Research objectives (e.g. study of vulnerable populations, dual use, etc.)	This will be to examine the effectiveness of three, yet to be created, technological interventions where an individual has suffered a stroke and requires on-going

Issue	***Action***
	support to attain their optimal level of functioning 6-months post stroke. There is likelihood that the participants may be vulnerable in that they may be frail, elderly and living alone. Not only will the interventions be tested and compared to existing data on patients who have just received traditional services but also the impact of the PCP MAGIC Project itself will be evaluated.
Research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)	The specific design of the research methodology for the Impact Evaluation has been described in Work Package 6 by Dublin City University. However, there may be three different designs or research methodologies used; one for each of the three stage 3 solutions. The MAGIC Project will steer the research methods used to be as consistent as possible but thought will be given to a research approach fitting the type of intervention designed. As this is a pre-commercial procurement there is no way of pre-empting the research design and ethical ramifications at this stage but the MAGIC Project Team gives assurances that attention to detail with regard to Ethics will ensure the highest standards are maintained.
The potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, malevolent use, etc.).	Early consideration has been given to potential impact even though the PCP Project cannot predict, at this juncture, the type of intervention to be proposed by suppliers beyond the state of the art descriptions already given. However, the MAGIC Project team commit to ensure that the solutions commissioned will aim to minimise harm and maximise benefit. Moreover, as already stated the IRAS process will ensure that every element of the service deployment, research, development and evaluation will be considered to ensure the research activity does not burden practitioners, patients/ service users or their carers.

Health Research Authority

ADDENDUM 1

UK Ethical Review Forms and Guidance Notes for use with research applications

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; this will now be extended to include the publication of the summary of REC opinion.

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. Completed forms 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:

REC Reference Number:

Study Title:

Brief overview of study (optional depending on REC practice)

1. Social or scientific value; scientific design and conduct of the study (IRAS A6, A7-14, A 57-62, 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 participants? Is there involvement of patients, service users, the public, in the design, management, and undertaking the research?
Comments/issues for discussion

2. Recruitment arrangements and access to health information, and fair research participant selection (IRAS A16, A 17-1, A17-2, A 27-29, A46, A47). Inclusion and exclusion of potential research participants. Selection of research participants so that vulnerable individuals are not targeted for risky research and the rich and socially powerful not favoured for potentially beneficial research. 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).
Comments/issues for discussion:

3. Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future) (IRAS A 18- 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, 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 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?

Comments/issues for discussion:

4 Care and protection of research participants; respect for potential and enrolled research participants' welfare & dignity (IRAS A25, A50-53, A 76, A 77).

*permitting withdrawal from the research
*informing participants of newly discovered risks or benefits
*maintaining welfare of participants
*provision of appropriate indemnity and insurance
* protecting privacy through confidentiality
* informing participants of results of research
*what will happen at the end of the study
*trial registration arrangements in place? (note, this is a condition of the favourable opinion, mandatory for clinical trials).

Data protection & research participant's confidentiality (IRAS A 36 - 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 describe 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)

Comments/issues for discussion:

6. Suitability of the applicant and supporting staff (investigator CV & IRAS question A47, A48)
Applicant and supporting staff are suitably qualified and 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:

7. Independent review (IRAS A 54-56)
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**

Ethical Research issues and material available through research portal.

Within the UK and Northern Ireland in particular suppliers are guided to **Integrated Research Application System (IRAS)** https://www.myresearchproject.org.uk.