

# KATHARINE HOUSE HOSPICE

## CLINICAL RESEARCH POLICY

**Approved by:**

**Date of approval:**

**Originator:**                      **Medical Director**

### POLICY STATEMENT

Good quality clinical research is important for furthering our understanding of the problems encountered in palliative care and for helping us to develop the best management strategies for dealing with these problems. On the other hand, bad quality research can be highly damaging in many ways.

In order to ensure the scientific rigour and ethical appropriateness of all clinical research studies, and also to maintain public confidence, there is a very robust legislative and regulatory framework that must be followed whenever planning or conducting clinical research in any setting. The high importance placed on this is demonstrated by the extensive list of relevant documents listed below, any or all of which might be of direct significance to the would-be clinical researcher. Ethical approval must always have been given by an appropriate body before the project can proceed past the planning stage.

Patient satisfaction surveys, clinical case studies and clinical audits are not considered clinical research and the Katharine House Research Policy does not apply to such activities. It is essential to specifically establish whether any other type of proposed study of clinical activity actually counts as clinical research or not before proceeding with it.

### Compliance with Statutory Requirements

Private and Voluntary Health Care (England) Regulations 2001 Part 1 Regulation 9 (1j) and Part III Regulation 254

National Care Standards Core Standard C32

Human Tissue Act

Mental Capacity Act

Data Protection Act (1998)

Freedom of Information Act (right of access 2005)

Declaration of Helsinki

European Union Directive on Clinical Trials 2001/20/EC

Good Clinical Practice Directive 2005/28/EC

ICH-GCP Good Clinical Practice

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Research Governance Framework for health and Social Care (2<sup>nd</sup> Edition)  
Medicines for Human Use (Clinical Trials) Regulations  
Medical Devices Regulations  
Gene Therapy regulations  
Radioactive Substances Regulations  
Blue Guide on Advertising and Promotion of Medicines in the UK (7 Nov 2005)

## Related Hospice Policies/Procedures

Consent

## Responsibility/Accountability

Director of Nursing	Ultimate Responsibility (as Registered Manager) for ensuring that there is a policy in place and that it is adhered to.
Both Clinical Directors	To ensure that all clinical research conducted at Katharine House Hospice has been planned, approved and executed in line with the hospice's Clinical Research Policy. To seek Trustee approval for appropriate and suitably-developed clinical research projects, and to keep the Board of Trustees updated with regard to any ongoing research activity.
Research co-ordinator	To create a suitable research protocol and body of documentation that satisfies the hospice and the local research ethics committee. To keep the Clinical Directors informed of any significant developments with the project, from the planning stage onwards. To ensure that the agreed research protocol is adhered to. To co-ordinate the required teamwork. To take responsibility for all research-related documentation and for the final write-up of the project.

## PROCEDURE

All clinical staff employed by the hospice are encouraged to maintain an active but critical interest in the clinical research literature pertinent to palliative care. In addition to this, it is possible that staff and volunteers at the hospice may undertake or contribute to clinical research projects from time to time. Any research conducted at the hospice must be of high ethical and scientific quality and be focused on enhancing clinical practice. It must also put patients at minimal risk and be conducted in such a way as not to damage their confidence in the service.

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Katharine House Hospice is not covered by Crown indemnity. The hospice's own insurance policy does not cover risks associated with clinical research. Therefore, before any clinical research is conducted at the hospice, appropriate insurance cover must have been secured.

Conducting clinical research can be demanding of resources, in terms of staff, equipment, space and money. It must be established how these resources will be secured without compromising the delivery of our routine services.

The planning stage of clinical research is typically longer and far more challenging than the data collection stage. The precise research question must be very carefully framed. It must address a relevant clinical issue in a practical manner that is directly explored by the study protocol. All necessary resources for the study (including staffing, equipment and money) must be identified, and the means of securing them must be established. All staff or volunteers involved in the research must have been appropriately trained for the roles they are expected to fulfil. The data analysis method must have been ascertained as part of the planning process. A summary of items to be considered when developing an outline proposal for presentation at a Clinical Practices Committee Meeting is presented in Box 1, although it is acknowledged that not all of these can necessarily be answered ahead of that meeting.

Before any research can be conducted at the hospice, it must have been discussed with and approved by:

- The appropriate Clinical Director.
- The hospice's Clinical Practices Committee.
- The Hospice's Trustees.
- The local Medical Ethics Committee.

The early work of developing a research protocol will be done by the person proposing the piece of clinical research (research co-ordinator) in conjunction with the Clinical Director(s) and the Clinical Practices Committee. The Clinical Directors will decide at what stage Trustees approval should be formally sought. A formal application to the local Medical Ethics Committee should only be made when the hospice has given approval for this step to take place. If the proposed research project is for academic purposes, the University sponsoring the researcher must provide ethical approval in addition to that obtained from the local Medical Ethics Committee. In certain circumstances, the approval of other agencies may also be required, such as the Primary Care Teams of the patients concerned. All of the above agencies have the right to require amendments to be made to a clinical research proposal before approval is granted and no project can proceed past the planning stage without the complete approval of each of these individual bodies.

The local Research Ethics Committee is the Oxford Clinical Research Ethical Committee (OxREC) which is located at the Research and Development Office, Room 13, Manor House, John Radcliffe Hospital, Headley Way, Headington, Oxford, OX3 9DZ. Full details of the requirements of this Committee and copies of the necessary application documents can be found at <http://www.oxfordradcliffe.nhs.uk/research> . Before the research project can proceed, the hospice will need to see written approval for the project from the Medical Ethics Committee itself, or written confirmation from the same committee that its ethical approval is not required for that particular project.

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No subject can be recruited into a piece of clinical research without them or their proxy having provided informed written consent beforehand, except when the Local Ethics Committee has unambiguously overruled this requirement or has indicated that its approval is not required for a specific piece of clinical research.

Whenever full approval from the various agencies has been given for a particular clinical research project to be conducted in the hospice, the agreed research protocol must be strictly adhered to. The hospice and/or the local Medical Ethics Committee maintain the right to require a research project to be discontinued if at any point they have concerns about it.

It is anticipated that the majority of requests to perform clinical research will come from employees of the hospice. Anybody from outside the organisation wishing to conduct clinical research within the hospice must make an appointment to discuss their proposal with one of the Clinical Directors, having provided them with a copy of their CV and a copy of their outline proposal ahead of the meeting.

If somebody from outside the organisation is requesting that the hospice participates in a multi-centre trial, then the person making this request must provide evidence that ethical approval has been granted by the Research Ethics Committee for the co-ordinating centre. Nonetheless, in this situation a Site-Specific Information (SSI) Form and the principal investigator's CV will still have to be submitted to local REC for local ethical approval, and an employee from the hospice will have to be nominated as the in-house study co-ordinator for the research activities that take place at this hospice.

Whenever a piece of clinical research is being proposed, planned or undertaken in the hospice, the in-house named study co-ordinator must present a quarterly progress report to the Clinical Practice Committee.

As with good palliative care, good clinical research requires effective teamwork. Without the interest and commitment of the whole clinical team to assist in the process, the chances of a successful project are reduced. The initiators of any research project should aim to involve the team in the study from the earliest planning stages. Communication with and feedback to the team before, during and after the study should be given a high priority.

The hospice must be provided with a full copy of all completed research projects and these must be stored for a minimum of 15 years. There are legal requirements regarding the secure storage of the clinical records and the raw data collection sheets during a research project and after its completion, in case there is ever a need to re-examine the data. The duration of time for which these items need to be stored depends upon the type of research. The hospice will fulfil this obligation on behalf of its own employees.

In the global interests of palliative care, there will always be an expectation by the hospice that any research work conducted at the hospice will be written up and submitted for possible presentation and/or publication. It is important to remember that even negative results or the description of pitfalls encountered in the attempts to perform research can be of value to palliative care colleagues. When submitting work for presentation or publication, the support of the hospice in the work must always be acknowledged.

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Box One: Ideas that the originator of the research idea will have been expected to have considered by the time of presentation of the idea to the Clinical Practices Committee

1. What is your properly structured research question?  
If it is not well constructed then it will be harder to study.
2. How relevant is this research question?  
Frequency with which the problem is encountered. Importance of the problem being studied.
3. What is the present understanding on this subject?  
What did you find out from reviewing the medical literature?
4. Is this an original idea or is it simply repeating the work of another?
5. What is your proposed study method?  
e.g. prospective or retrospective, observational or interventional, etc.  
Have you kept the method as simple as possible?  
Does the proposed method actually answer your research question?)
6. Have you estimated the necessary sample size for your study?  
What have you based this estimate on?  
Is this study appropriate for a single centre?
7. How will the data be collected?  
By whom? Using what?  
It is preferable to use a validated scoring system that meets the requirements of your project, when one is available. If not, you will need to create a robust documentation system.  
How will you ensure that you collect data on adverse outcomes as well as desired ones?
8. What statistical methods will you apply when processing and analysing the data?  
Is this the right method? Is this the right data?
9. Is the study likely to result in a valuable answer?
10. What resources will you need?  
Time, personnel, location, equipment, money.
11. Will you be eligible for any funding or grants?
12. How will you ensure that you are indemnified for this research?
13. What are the likely risks and benefits of any proposed interventions?  
What is the likely size and importance of each of these risks and benefits?
14. How inconvenient might this be to the patient?  
e.g. Time demands, location requirements, transportation, tests and measurements, multiple reviews.
15. How do you intend to inform the patient of the project and invite them to contribute to it?  
Informed patient consent.  
Voluntary involvement.
16. What issues have arisen for you as you have addressed the legal, ethical and regulatory dimensions to your proposed research project?  
How do you propose to deal with these?
17. Who will be the named study co-ordinator?
18. Who will be members of the research team and what will their roles be?  
What training will be required?
19. What is the proposed time frame for the study?

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## Useful resources

European Union Directive on Clinical Trials 2001/20/EC

[http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/dir\\_2001\\_20/dir\\_2001\\_20\\_en.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf)

Good Clinical Practice Directive 2005/28/EC

<http://gcptraining.org.uk/Files/Doc/EU%20Directive%202005-28-EC%20-%20Summary%20of%20Proposed%20Changes.pdf>

ICH-GCP Good Clinical Practice

<http://www.emea.europa.eu/pdfs/human/ich/013595en.pdf>

[http://www3.imperial.ac.uk/portal/pls/portal\\_live/docs/1/49860.PDF](http://www3.imperial.ac.uk/portal/pls/portal_live/docs/1/49860.PDF)

<http://www3.imperial.ac.uk/clinicalresearchoffice/researchgovernance/goodclinicalpractice/>

Declaration of Helsinki

<http://www.wma.net/e/policy/b3.htm>

Medicines for Human Use (Clinical Trials) Regulations

<http://www.opsi.gov.uk/si/si2004/20041031.htm>

[http://www.mhra.gov.uk/home/idcplg?IdcService=GET\\_FILE&dDocName=CON2022633&RevisionSelectionMethod=Latest](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2022633&RevisionSelectionMethod=Latest)

<http://www.advisorybodies.doh.gov.uk/genetics/gtac/clinicaltrials-mou.pdf>

Research Governance Framework for health and Social Care (2<sup>nd</sup> Edition)

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4108965.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4108965.pdf)

<http://www3.imperial.ac.uk/clinicalresearchoffice/researchgovernance/researchgovernanceframework>

Medical Devices Regulations

<http://www.opsi.gov.uk/SI/si2002/20020618.htm>

Gene Therapy regulations

<http://www.advisorybodies.doh.gov.uk/genetics/gtac/GTAC52.HTM>

Human Tissue Act

<http://www.opsi.gov.uk/acts/acts2004/20040030.htm>

Mental Capacity Act

<http://www.opsi.gov.uk/acts/acts2005/20050009.htm>

Data Protection Act (1998)

<http://www.opsi.gov.uk/acts/acts1998/19980029.htm>

Freedom of Information Act (right of access 2005)

<http://www.opsi.gov.uk/acts/acts2000/20000036.htm>

'Blue Guide on Advertising and Promotion of Medicines in the UK' (7 Nov 2005)

[http://www.mhra.gov.uk/home/idcplg?IdcService=GET\\_FILE&dDocName=con2022589&RevisionSelectionMethod=Latest](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=con2022589&RevisionSelectionMethod=Latest)

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