

# NHS RESEARCH Ethics Committee

## APPLICATION FORM

### PART C: LOCALITY ASSESSMENT

This form should be completed by the principal investigator for each locality (see glossary)

Part C should be completed and sent with relevant enclosures to each local research ethics committee which needs to consider locality issues. Consult the application procedure on COREC website.

Name of NHS research ethics committee to which application for ethical review has been made:

Thames Valley MREC

Project Reference number from above REC:

03/12/062

Name of locality LREC (or R&D department) undertaking locality assessment:

Locality LREC (or R&D department) Reference Number:

### Part C: Section 1 DETAILS OF RESEARCH PROJECT

Questions C1, C2, C3, C4, C5 and C6 correspond to questions A2, A3, A1, A25, B21 and B22 on main application form respectively and will populate automatically:

#### C.1 Title of Research

Full title:

A phase II study VEPEMB in patients with Hodgkin's lymphoma aged > 60 years

Short title and version number (max 10 words – to be inserted as header on all forms)

Phase II study Hodgkin's lymphoma in the elderly.

Key words

Hodgkin's lymphoma, elderly, chemotherapy

#### C.2 Applicable reference number (give details and version number as appropriate)

Applicant's/organisation's own reference number (if available):

SJP/MREC/HD Elderly

Sponsor's protocol number:

Funder's reference number:

International Standard Randomized Controlled Trial Number (ISRCTN):

Project website:

#### C.3 Chief Investigator

Title:

Prof

First name/Initials

Stephen J.

Last name:

Proctor

Post:

Professor of Haematological Medicine

Qualifications:

FRCP, FRCPath

Organisation:

University of Newcastle

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**C.4 Give a brief synopsis/summary of methods and overview of the planned research. A flow chart or diagram should be attached where appropriate. It should be clear exactly what will happen to the research participants, how many times and in what order.**

1 Communication will be made with all physicians in the UK who treat Hodgkin's lymphoma through several routes. We will inform them of the data collection programme and the Phase II study.

2 Communication with the patient population will be made through the Lymphoma Association to make them aware of the programme (Website: <http://www.lymphoma.org.uk> : Appendix 8).

3 Documentation (protocol, case report form, patient information sheets etc) relating to the study will be distributed to all investigators.

4 Anonymised data for individual patients will be collected and stored on a database. (Appendices 12 & 13).

5 The study protocol is summarised in Appendix 5(a) and Appendix 5(b).

6 For patients with Hodgkin's lymphoma considered too frail / or with excessive comorbidity, physicians will treat at his/her discretion. Data will be collected on as many patients as possible to gain a full picture of therapeutic effectiveness of the study.

7 Patients will undergo consent procedure and be asked to allow storage of a serum sample for future research. They will be informed that the biopsy sample will undergo central review for diagnosis confirmation.

8 Patient's Treatment Schedule:

The number of courses of chemotherapy (VEPEMB) given, will depend on how advanced the patient's disease is. In "early stage" disease, patients will receive 3 courses of treatment followed by radiotherapy to the areas originally involved.

If the disease is more extensive "advanced stage" the patient will be given 6 courses of treatment and (possibly) radiotherapy to any disease that remains or sites of initial bulky disease.

Each course of treatment lasts 4 weeks and the patient will need to attend the hospital weekly during the treatment phase. The treatment will take approximately 5 months if the patient has early stage disease and 9 months if it is more advanced. These treatments are normally given on an outpatient basis.

9 Data Review Committee will assess progress at six monthly intervals or at the time dictated by patients accrual rates.

10 Clear lines of communication with the study office will be established and a senior clinical investigator will be available at all times for protocol discussion.

11 A team of statisticians, under the supervision of Professor Robin Prescott, Director of the Medical Statistics Unit, Edinburgh University, will analyse the data.

**C.5 Will the research participants receive any clinical intervention(s) or procedure(s) including taking samples Of human biological material over and above that which would normally be considered a part of routine clinical care?** (Populated from B21)

YES  NO

**C.6 Will the research participant be subject to any non-clinical research-related intervention(s) or procedure(s)?** (Populated from B22)

YES  NO

**Part C: Section 2 Locality specific details**

**C.7 Name of NHS or other organisation where the research will take place** (for research in primary care in England, this is normally the primary care trust).

[Dashed box for C.7 answer]

**C.8 Specify the location(s)/department(s) within the NHS or other organisation where the research will take place.**

[Dashed box for C.8 answer]

**C.9 How many research participants/samples is it anticipated will be recruited/obtained from this Organisation.**

[Dashed box for C.9 answer]

**C.10 Is there a principal investigator at local level for this study?** Yes  No

Title: [Dashed box] First Name/Initials: [Dashed box] Last Name: [Dashed box]  
Post: [Dashed box] Qualifications: [Dashed box]  
Organisation: [Dashed box]  
Address: [Dashed box]  
Fax: [Dashed box] Telephone: [Dashed box] Email: [Dashed box]

*A copy of a current CV (maximum 2 pages of A4) for the principal investigator(s) must be submitted with application.*

**Indicate the number of trials/projects within the organisation that the principal investigator has been involved within the previous 12 months.**

[Dashed box for number of trials/projects]

**How many are still current (active or recruiting)?**

[Dashed box for number of current projects]

**Give details of other members of the local research team responsible to the lead local researcher**

**i.** Title [Dashed box] First name/initials [Dashed box] Last name: [Dashed box]  
Position: [Dashed box] Qualifications: [Dashed box]  
Role in Research Team: [Dashed box]

**ii.** Title [Dashed box] First name/initials: [Dashed box] Last name: [Dashed box]  
Position: [Dashed box] Qualifications: [Dashed box]  
Role in Research Team: [Dashed box]

**iii.** Title [Dashed box] First name/initials: [Dashed box] Last name: [Dashed box]  
Position: [Dashed box] Qualifications: [Dashed box]  
Role in Research Team [Dashed box]

**C.11 If there is no principal investigator at local level, is there a local individual who is undertaking a task relating to the research?**

YES  NO  NOT APPLICABLE

**Part C : Section 3 Care and Protection of Research Participants**

**C.12 Give details of who will be responsible for obtaining informed consent locally, their qualifications and relevant expertise and training in obtaining consent for research purposes:**

[Empty dashed box for response to C.12]

**C.13 What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English? (E.g. translation, use of interpreters etc)**

[Empty dashed box for response to C.13]

**C.14 What arrangements have been made to inform those responsible for the care of the research participants of their involvement in the research?**

[Empty dashed box for response to C.14]

**C.15 Are the facilities and staffing available locally adequate to perform any necessary procedures or Interventions required for the study, and to deal with any unforeseen consequences of these?**  
*(This should include consideration of procedures and interventions in both control and intervention arms of a study.)*

YES  NO

*Indicate what arrangements are being made to deal with the situation:*

[Empty dashed box for response to C.15]

**C.16 Give detail of a contact point where participants may obtain further information about the study.**

[Empty dashed box for response to C.16]

**Please specify the headed paper to be used for the Patient Information Sheet.**

[Empty dashed box for response to C.16]

**C.17 Do you need to add additional information about certain questions in Part C?**

YES  NO

**Part C: Section 4 Declaration by the local Principal Investigator**

- The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
- I undertake to abide by the ethical principles underpinning the Declaration of Helsinki, and Good Practice Guidelines on current proper conduct of research.
- If the research is approved, I undertake to adhere to the study protocol without agreed deviation and to comply with any conditions set out in the letter sent by the NHS Research Ethics Committee notifying me of this.
- I undertake to inform the NHS Research Ethics Committee of any changes in the protocol, and to submit annual reports setting out the progress of the research.
- I am aware of my responsibility to be up to date and comply with the requirements of the law and appropriate guidelines relating to security and confidentiality of patient or other personal data, including the need to register when appropriate with the appropriate Data Protection Controller.
- I understand that research records/data may be subject to inspection for audit purposes if required in future.
- I understand that personal data about me as a researcher in this application will be held by the research ethics committee and that this will be managed according to the principles established in the Data Protection Act.

**Signature of local Principal Investigator\***

**Signature .....**

**Date**

**Print Name:**

*\* The chief investigator should sign where there is no local Principal Investigator for the research locality.*

**PART C IS NOW COMPLETE AND SHOULD BE SUBMITTED to the NHS research ethics committees or NHS organisation conducting locality assessment.**