Applications to HSE/Hospital research ethics committees
Dr Jean Saunders
Director SCU/CSTAR @ UL
Member EHSREC/SciEngREC/MWRHREC

7th March 2012

ULREG Guidelines

- Apply to all research involving people (or their data) within UL
- Research/audit
- Where the research involves patients in hospital (or a GP surgery) or employees of the HSE, ethical approval should be sought from the HSE REC rather than the University.
- All applications should include an information sheet and a consent form.
RECSAF website

- [http://www.molecularmedicineireland.ie/research_ethics](http://www.molecularmedicineireland.ie/research_ethics)

PILOT WORKING GROUP
In alphabetical order:
Collins, Claire Irish College of General Practitioners
Gaynor, Siobhan Irish Clinical Research Infrastructure Network
Lamb, Caroline HSE South East
McCourt, John Dublin Centre for Clinical Research
McDonnell, Joan St. Vincent’s Healthcare Group
O’Neill, Sarah Mater Misericordiae University Hospital
Ryan, Ursula Adelaide & Meath Hospital, Dublin, incorporating the National Children’s Hospital / St. James’s Hospital
Saunders, Jean Mid Western Regional Hospital Complex
Towns, Jeremy (Facilitator) Dublin Centre for Clinical Research
B8 (a) How many research participants are to be recruited in total?

Answer

B8 (b) Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice.

Answer

B8 (c) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

Answer

B8 (d) Where sample size calculation is impossible (e.g. It is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

Answer
RECSAF Guidance Manual

• Very comprehensive
• Input from many Research Ethics Committees throughout Ireland including the 13 Clinical Trials Committees
• Available also on MMI website

B8 (a) How many research participants are to be recruited in total? (State total number of participants.)

B8 (b) Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice. (It is important to get the advice of a statistician in relation to all research studies. The statistician will advise if a statistical approach is relevant to this particular research study.)

B8 (c) Please give a brief justification of sample size and details of the sample size calculation (including minimum clinically important difference). (It is important to obtain the advice of a statistician in relation to all research studies.)

C1.3 How will the participants in the study be recruited? (Please indicate how and who will identify the participants for the study e.g. letter of invitation, verbal approach when attending the clinic, poster advertisement, web advertisement etc. Please ensure that you provide copies of all letters and advertisements referred to in your response for review)
At present no one hospital/HSE ethics committee can give permission for (non-clinical trial) research in multiple centres except within their own area – not allowed currently legally

A separate application needs to be made to each ethics committee for the areas involved but the same application form can be used for those committees using it.

This is different from Clinical Trials over multiple sites where only one Clinical Trial Committee needs to be applied to for each trial.

However even with clinical trials hospitals need to be contacted for approval to run the trials at each hospital – site approval – this is usually given by hospital management

NB Clinical Trials Ethics committees charge for giving ethical approval for Clinical Trials. This is because clinical trials tend to involve a huge amount of documentation to look through!

NB Some RECS charge for approving ANY research e.g. ICGP REC

NOT MWRHREC!
Therefore only one form required for most hospital/HSE committees BUT there are slight differences between centres as to required information e.g.

- Researchers should be aware that if completing the RECSAF and submitting the same form to multiple committees simultaneously, that they may need to change their response to Question A2 (Name of Principal Investigator), Question A4 (Names of Co-Investigators) and/or Question A5 (Name of Contact Person) depending on each committee’s local requirements.
- A number of other committees would prefer the PI to locally based, with a local contract of employment and some specify further that only a hospital consultant or department head can be PI.
- Where committees do not specify this, some specify that at least one of the co-investigators (A4) should be locally based, or if not, that the contact person be locally based (A5).
- But these differences can be easily discovered by contacting the local Rep for the appropriate REC

Other Hospital Research Ethics Committee Applications Forms

- A number of Hospital Research Ethics Committees use local, committee-specific research ethics committee application forms as follows:

1. Cappagh National Orthopaedic Hospital (Finglas)
2. Children’s University Hospital (Temple Street)
3. Letterkenny General Hospital
4. Mayo General Hospital
<table>
<thead>
<tr>
<th>Committee/Location</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trials Committees in Ireland</td>
<td>at present</td>
</tr>
</tbody>
</table>
| **St. Vincent's Healthcare Group Ethics and Medical Research Committee**, Elm Park, Dublin 4 | **Research Ethics Committee**  
St. Vincents Hospital, Level C, 5, St. Vincents Hospital, Elm Park, Dublin 4 |
| **Tallaght Hospital, Dublin 24** | **Research Ethics Committee**  
SJH/AMHCH SJH/AMNCH Research Ethics Committee, Tallaght Hospital, Dublin 24 |
| **Sligo Research Ethics Committee**, Sligo | **Research Ethics Committee**  
Sligo Research Ethics Committee, Research & Education Foundation, Sligo General Hospital, Level 5, Sligo General Hospital, The Mall, Sligo |
| **Mater Misericordiae University Hospital and Mater Private Hospital**, Eccles Street, Dublin 7 | **Research Ethics Committee**  
Mater Research Ethics Committee, Mater Misericordiae University Hospital and Mater Private Hospital, Eccles Street, Dublin 7 |
| **The Irish College of General Practitioners** | **Research Ethics Committee**  
ICGP The Irish College of General Practitioners Research Ethics Committee, 4/5 Lincoln Place, Dublin 2 |
| **South Eastern Area** | **Research Ethics Committee**  
South Eastern Area Research Ethics Committee Office, Waterford Regional Hospital, Waterford Region, Waterford |
| **Mid-Western Region** | **Research Ethics Committee**  
Mid-Western Region Research Ethics Committee, Mid-Western Regional Hospital, Dooradoyle, Limerick |
| **National Maternity Hospital**, Holles Street, Dublin 2 | **Research Ethics Committee**  
Holles Street Ethics Research Committee, National Maternity Hospital, Holles Street, Dublin 2 |
| **Our Lady's Children's Hospital Crumlin**, Dublin 12 | **Research Ethics Committee**  
Crumlin Our Lady's Children's Hospital Research Ethics Committee, Crumlin, Dublin 12 |
| **Cork Clinical Research Ethics Committee of the Cork Teaching Hospitals**, Cork | **Research Ethics Committee**  
Cork Clinical Research Ethics Committee of the Cork Teaching Hospitals, U HSE South Eastern Area HSE North Eastern Area Research Ethics Committee, Old School of Nursing, Waterford Regional Hospital, Waterford Region, Waterford |
| **Galway Regional Hospitals Research Ethics Committee**, Galway | **Research Ethics Committee**  
Galway Regional Hospitals Research Ethics Committee, Unit 4, Merlin Park Hospital, Galway |
| **Waterford Regional Hospital**, Waterford | **Research Ethics Committee**  
Waterford Regional Hospital Research Ethics Committee, Waterford Regional Hospital, Waterford |

**www.ul.ie**
Contact Details- MWRHCREC

• To obtain the form – RECSAF – and to get details/times of application deadlines meetings contact (at present): joanne.oconnor@hse.ie

Joanne O'Connor, Staff Officer, Risk Management.
Tel: 061 482519 Fax:061 482920

But form can also be downloaded from MMI website – however check number of copies to be sent plus local site forms to be filled in by contacting Joanne or other REC contact

---

Procedure

• Simple research can be given Chair’s approval before the next meeting
• Where questions arise or research more involved then the applicant may be asked to attend the next ethics meeting
• At meeting applicant gives summary of research and answers any questions asked by REC members
• Turnaround usually 2 weeks for committee’s decision (2 weeks after the REC meeting)
• Last meeting was Feb 22nd – next meeting Mar 21st Application deadline (approx) Mar 7th – today!
• Any permission for research granted by HSE ethics committees must be notified to EHSREC (Anne O’Brien)
• Only one ethics committee’s approval necessary i.e. UL/EHSREC approval not required if obtained from MWRHREC (and vice versa) (unless multi-site research being carried out)
Data Protection website & other Guidelines/Sites

- [www.dataprotection.ie](http://www.dataprotection.ie)
- Contact: gdavis@dataprotection.ie
- Data Protection Guidelines on Research in the Health Sector
- DOHC website for Clinical Trials
  [http://www.dohc.ie/other_health_issues/clinical_trials/](http://www.dohc.ie/other_health_issues/clinical_trials/)
Questions???