

**STANDARD APPLICATION FORM –  
FOR THE ETHICAL REVIEW OF HEALTH-RELATED RESEARCH  
STUDIES WHICH ARE NOT CLINICAL TRIALS OF MEDICINAL  
PRODUCTS FOR HUMAN USE AS DEFINED IN STATUTORY  
INSTRUMENT 190/2004**

**PILOT PHASE**

**EVALUATION REPORT**

**PREPARED BY STANDARD APPLICATION FORM CONSULTATION GROUP –  
PILOT FORM SUB-GROUP**

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## INTRODUCTION

This report presents the results of an evaluation of the use by four Research Ethics Committees (RECs) of the Standard Application Form for the ethical review of health related studies which are not clinical trials of medicinal products for human use as defined in SI 190/2004 (Standard Application Form).

In 2009 a group of Irish Research Ethics Committees agreed to collaborate on developing a common form for research ethics applications (See Appendix A - Consultation Group). While trials of medicinal products are subject to a common application form issued by the Department of Health and Children, this has not been the case for other types of health-related research. This includes, for example, investigator led research, radiotherapy trials and trials of medical devices. This placed a burden on those researchers wishing to undertake multi-site studies who had to complete a separate REC application for each hospital site. The main rationale of the Standard Application Form project was that applicants would be able to complete a form once and submit it to multiple committees. One of the anticipated benefits of one standard application form is that the research ethics application process will become more streamlined and the costs of health-related research, which are often funded by charitable bodies and the taxpayer, will be reduced.

Over the course of 2009 the Consultation Group developed a Standard Application Form that was issued as a pilot form in January 2010. The four following RECs agreed to pilot the form for a period of 3 months (subsequently extended to six months):

1. Adelaide and Meath Hospital incorporating the National Children's Hospital/St. James's Hospital
2. HSE South East
3. Irish College of General Practitioners
4. Mater Misericordiae University Hospital and Mater Private Hospital.

In addition, for a small number of REC applications, the St. Vincent's healthcare Group REC agreed for the pilot form to be used in situations where it was being submitted to one or more of the piloting RECs. From the outset it was agreed that the piloting of the new form should be evaluated from both the perspective of applicants and those RECs receiving applications.

The following Pilot Form Sub-Group was established to conduct the evaluation process:

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	AMNCH/ St. James's Hospital
Saunders, Jean	Mid Western Regional Hospital Complex
Towns, Jeremy	Dublin Centre for Clinical Research (Facilitator).

The purpose of the evaluation is to recommend to those considering adopting the Standard Application Form that it is fit for purpose and meets the needs of potential applicants and Research Ethics Committees.

The Consultation Group's mandate comes from its members who have voluntarily agreed to collaborate on the development of the Standard Application Form.

## EVALUATION OBJECTIVES

The evaluation group set itself the goal of being able to recommend at the end of the trial period whether the form should continue to be used by the piloting committees and adopted by other committees across Ireland. The specific objectives of the Pilot Working Group were:

1. To design an evaluation framework for the piloting of the Standard Application Form and to assess whether it is suitable for widespread use;
2. To gather the data required to evaluate the use of the form by both applicants and RECs;
3. To perform the analysis of the information required to make the evaluation;
4. To amend the text of particular questions in the Standard Application Form in response to issues and concerns identified in the course of the pilot;
5. To ensure that the final version of Standard Application Form Guidance Manual, where appropriate, responds to information needs identified during the course of the pilot;
6. Based on the evaluation, recommend whether or not the Standard Application Form should be adopted by other Irish RECs;
7. To keep the Non-Piloting Committees updated as to the progress of the Pilot Working Group at regular intervals.

The achievement of these objectives is documented in this evaluation report.

## EVALUATION METHODOLOGY

This section describes the implementation of the pilot phase and the approach to evaluation adopted by the Pilot Working Group. The Pilot Working Group did not have extensive resources available for its work and the overriding concern was to conduct a good quality evaluation within the resources and time available. The Pilot Working Group is confident that a good evaluation has been undertaken and believes that a more comprehensive evaluation would not alter the overall conclusion of this report.

### INITIATION OF THE PILOT PHASE

The pilot version of the Standard Application Form (Version 0) was finalised in December 2009 and made available through the Molecular Medicine Ireland web site ([www.MolecularMedicineIreland.ie/Research](http://www.MolecularMedicineIreland.ie/Research)). Two versions of the form were made available:

1. A straightforward Word document.
2. A programmed Word document ("Smart" Form) that provided a "help" function and automatically deleted irrelevant sections of the form based on applicant responses to particular questions.

In addition, a Guidance document was made available to help applicants download and complete the form. Four RECs agreed to use the pilot form, initially for a three month period, which was subsequently extended to a six month period.

The Pilot Form Sub-Group held its first meeting on the 19<sup>th</sup> January 2010. The following four committees subsequently volunteered to trial the form and to take part in the formal evaluation process:

1. Adelaide & Meath Hospital, Dublin, incorporating National Children's Hospital / St. James's Hospital
2. HSE South East
3. Irish College of General Practitioners
4. Mater Misericordiae University Hospital and Mater Private Hospital.

All four Committees agreed to exclusively use the Pilot Standard Application Form during the pilot phase for all proposed research studies not covered by the existing DoHC form. In addition the REC at St. Vincent's Hospital Group agreed that their Committee would allow the use of the form in situations where REC applications were being made to one or more of the other RECs.

## DATA PLAN

The Pilot Form Sub-Group decided to evaluate the use of the form from three main perspectives:

1. The perspective of the researcher applicant completing and submitting the form
2. The perspective of RECs evaluating applications and administrating the REC approval process
3. A systemic perspective that examines the common form from the perspective of improving the overall clinical research system in Ireland.

To meet these needs the Pilot Working Group agreed to the following Data Plan. The results from these data sources are presented in the next section.

USER PERSPECTIVE	DATA SOURCE
Researcher Applicant	On-line questionnaire survey
Research Ethics Committee/Administrator	Correspondence with Research Ethics Committee
Clinical Research System	Irish Clinical Research Infrastructure Network On-line survey

## WORK PLAN

The Pilot Working Group met on four occasions between January and July 2010 on the following dates:

Meeting Date	Main Meeting Outcomes
19 January 2010	Confirmation of RECs participating in Pilot Agreement on evaluation methodology Agreement on on-line questionnaire for applicants
27 <sup>th</sup> April 2010	Decision to extend pilot to end of July Acknowledgement that "Smart" version of form not suited to all IT environments
24 <sup>th</sup> June 2010	Confirmation that Pilot Phase to end at the end of July Agreement on format of Common Form Guidance Document Agreement on outline of Evaluation Report
26 <sup>th</sup> July 2010	Finalisation of Evaluation Report

## FINDINGS

During the course of the pilot 150 applications were made to the piloting RECs using the Common Form. The breakdown of applications between RECS is presented in the following table.

<b>Breakdown of REC Applications Made Using the Pilot Standard Application Form Between January and July 2010</b>	
<b>Research Ethics Committee</b>	<b>Number of Applications Received Using The Common Form</b>
AMNCH/St. James's Hospital	104
HSE Southeast	12
Irish College of General Practitioners	24
Mater Misericordiae University Hospital	8
St. Vincent's Healthcare Group	2
<b>TOTAL</b>	<b>150</b>

## APPLICANTS

Each applicant was requested to complete an online survey questionnaire and the questions are presented in Appendix B. It can also be found on-line at <http://www.surveymonkey.com/s/RKZHTWE>. A detailed analysis of the applicants responses can be found in Appendix C.

The main findings are:

- 87% (13/15) of the respondents agreed, or strongly agreed, that the questions were clear
- 87% (13/15) of the respondents agreed, or strongly agreed, that the directions/explanations given were helpful
- 60% (9/15) of the respondents agreed, or strongly agreed, that the form was easy to complete from a technical perspective
- 45% (6/13) of the respondents agreed, or strongly agreed, that they found the form easier to use than that previously used

- All (14/15) of the respondents agreed, or strongly agreed, that they would prefer to have only one form to complete if applying to multiple centres
- All (14/14) of the respondents agreed, or strongly agreed, that they would be in favour of a fully on-line submission.

Importantly, a cross-tabular analysis of the data confirmed that the majority of respondents were in favour of a common form, even those that had a less favourable experience of using the Standard Application Form.

In the early part of the pilot, some of the applicants using the “smart” version of the Standard Application Form had difficulty using it. This was judged to be because the file was large and required a lot of computer memory. In addition, because of its size, applicants were sometimes prevented from downloading the smart form by institutional firewalls. These problems mostly, but not entirely, affected applicants with older IT infrastructures, particularly those applying from HSE sites. Later in the pilot these applicants were encouraged to use the normal Word form. This is judged to be the reason why some respondents were less favourable in their responses about the form being easier to use from a technical perspective and better than previous forms.

## COMMITTEES

Each of the piloting RECs were asked to consider their experience with the Common Form and all Committees formally responded by letter. These are contained in Appendix D.

All of the piloting committees were satisfied with the Pilot Standard Application Form and are prepared to continue using the form following some minor amendments.

Committees appreciated the value of a common form for researchers making applications to multiple RECs.

## RESEARCH SYSTEM PERSPECTIVE

The Pilot Form Sub-Group is responsible for evaluating pilot phase. RECs are not responsible for the clinical research system, but agree that the common form has the potential to improve the operational performance of clinical research in Ireland. These benefits include:

1. More and more clinical research involves multiple sites and a Standard Application Form streamlines the research ethics process for researchers involved in multi-site studies.

2. By adopting a Standard Form, RECs and Hospital Boards/HSE Regions can be reasonably confident that the form follows a national standard and is fit for purpose.
3. A Standard Application Form makes it more viable to train researchers on how to complete a Research Ethics form. Ireland is investing heavily in clinical research training in terms of training research nurses and clinician scientists and training on the Standard Application Form can be introduced to these and other training courses.
4. A Standard Application Form may also enhance the training already being provided to REC members.
5. A Standard Application Form makes it easier to promote a consistent national approach to the submission and evaluation of REC applications.

## CONCLUSIONS

The overall conclusion is that the Pilot Application Form worked well for both applicants and committees.

The “smart” version of the form was not always as successful and the lesson learned is that in healthcare settings there is a wide national variation in IT infrastructure, standards and policies (e.g. firewall settings). The conclusion drawn is that technical solutions need to be carefully planned and implemented.

The logic of a Standard Application Form seems to have gained wide acceptance across most RECs. There is recognition that a Standard Application Form will be more comprehensive than most current forms because it needs to address the widest range of possible research activities (e.g. Paediatrics, Radiotherapy, Medical Device Trials). There is a trade-off between the efficiencies of a standard form against the added scope of a form that must satisfy a variety of research needs. Within the standard form this is managed by identifying specific sections that only need to be completed for specific types of research.

# RECOMMENDATIONS

Based on the foregoing evaluation the Pilot Form Working Group makes the following recommendations:

1. That the Standard Application Form (Version 5.4, August 2010) be made available to other Research Ethics Committees.
2. That RECS accept the offer made by Molecular Medicine Ireland to make available its website for hosting the Standard Application Form (Version 5.4) and accompanying Guidance Manual permitting these documents to be freely downloaded by applicants.
3. That the Standard Application Form (Version 5.4) be 'locked' or 'frozen' for an initial period of 6 months (until 1 March 2011) and after this date a meeting should be held among representatives of committees using the form, and those considering using the form, with a view to amending the form, and its accompanying Guidance Manual if required. This review would take into account any changes to legislation and international guidelines and facilitate requests from individual committees with regard to changes to the text of individual questions.
4. Those Committees wishing to proceed towards an on-line REC application process be encouraged to do so, as long as the on-line version of the form is consistent with the agreed Standard Application Form.
5. Where technically feasible, applicants should be encouraged to use the "smart" version of the form as they will find the form easier to use. Where technical and other issues make this difficult, then the normal Word Version of the form should be used.

APPENDIX A – STANDARD APPLICATION FORM CONSULTATION GROUP  
MEMBERSHIP

CONSULTATION GROUP

Bradley, Colin	Irish College of General Practitioners
Collins, Claire	Irish College of General Practitioners
Fitzgerald, Barbara	Naas General Hospital
Gargan, Angela	National Maternity Hospital
Jensen Kavanagh, Mette	Sligo General Hospital
Kirkham, Colin	Rotunda Hospital
Lamb, Caroline	HSE South East
Leonard, Marie	Our Lady's Children's Hospital
Lynch, Dan	Adelaide & Meath Hospital incorporating the National Children's Hospital / St. James's Hospital
Marsden, Paul	HSE Midland Area
Mayne, Philip	Children's University Hospital
McCourt, John	Dublin Centre for Clinical Research
McDonnell, Joan	St. Vincent's Healthcare Group
McLoughlin, Declan	St. Patrick's University Hospital
O'Neill, Sarah	Mater Misericordiae University Hospital
Owens, Valerie	St. Luke's Hospital (Rathgar)
Quinn, Rosie	HSE North East
Rice, Claire	Our Lady's Children's Hospital
Ryan, Ursula	Adelaide & Meath Hospital incorporating the National Children's Hospital / St. James's Hospital
Saunders, Jean	Mid Western Regional Hospital Complex
Stanton, Alice	Beaumont Hospital
Toomey, Dave	Dublin Centre for Clinical Research
Towns, Jeremy (Facilitator)	Dublin Centre for Clinical Research
Vale, Gillian	Beaumont Hospital

PILOT FORM SUB-GROUP

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 (Project Lead)	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

# APPENDIX B – ON-LINE SURVEY QUESTIONNAIRE

## Applicant Evaluation of Common Ethics Application Form

Edit Survey [Preview Survey](#)

To change the look of your survey, select a theme below.

[Show More](#) [Create Custom Theme](#)

[Add Page Before](#)

Page #1 [Edit Page](#) [Copy](#)

### 1. Evaluation of Common Ethics Application Process

A number of research ethics committee from around the country have come together and designed an application form, which they all may use in the future. The motivation behind this is to simplify the process for researchers who need to apply to more than one committee. Six of these committees (listed below) are currently running a trial of the form. We would be grateful if you would complete this short questionnaire regarding your experience of using this application process.

[Add Question Here](#)

[Edit Question](#) [Move](#) [Copy](#) [Delete](#)

1. Applicant Name:

[Add Question Here](#) [Split Page Here](#)

[Edit Question](#) [Move](#) [Copy](#) [Delete](#) [Add Question Logic](#)

2. Please tick the Research Ethics Committee(s) you applied to on this occasion using the common form. [Tick all that apply]

- Mater Misericordiae University Hospital and Mater Private Hospital Research Ethics Committee
- SJRHANNUCH
- ICGP
- HSE South East
- HSE North East
- St. Patrick's Donegal
- St. Vincent's University Hospital
- St. Luke's Hospital

[Add Question Here](#) [Split Page Here](#)

[Edit Question](#) [Move](#) [Copy](#) [Delete](#)

3. Please insert the date of the committee meeting. (If you applied to more than one of the committees listed, insert

the date of the first committee meeting]

DD MM YYYY

Committee Date:  /  /

[Add Question Here](#) [Split Page Here](#)

[Edit Question](#) [Move](#) [Copy](#) [Delete](#) [Add Question Logic](#)

4. Was the application in respect of a single or multi-site study?

Single site study

Multi-site study

[Add Question Here](#) [Split Page Here](#)

[Edit Question](#) [Move](#) [Copy](#) [Delete](#)

5. Was the form user friendly with respect to:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
The questions were clear	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The directions/instructions given were helpful	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The form was easy to complete from a technical perspective	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The form is better than that previously used	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is preferable to have only one form to complete if applying to multiple committees	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would be in favour of a fully online submission	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

[Add Question Here](#) [Split Page Here](#)

[Edit Question](#) [Move](#) [Copy](#) [Delete](#)

6. If you found any questions to be ambiguous or confusing, please list them here:

Section A:

Section B:

Section C:

Section D:

Section E:

Section F:

Section G:

Section H:

Section I:

Section J:

Section K:

Section L:

[Add Question Here](#) [Split Page Here](#)

[Edit Question](#) [Move](#) [Copy](#) [Delete](#)

7. For questions listed above, which you found to be ambiguous/confusing; please add comments here to explain the problems:

[Add Question Here](#) [Split Page Here](#)

[Edit Question](#) [Move](#) [Copy](#) [Delete](#)

8. If you wish to make any further comments, please include them here:

[Add Question Here](#)

## APPENDIX C – ONLINE SURVEY RESPONSES

### The questions were clear

		Frequency	Percentage
Valid	Strongly agree	3	20.0
	Agree	10	66.7
	Neither agree nor disagree	1	6.7
	Disagree	1	6.7
	Total	15	100.0

### The directions/explanations given were helpful

		Frequency	Percentage
Valid	Strongly agree	6	40.0
	Agree	7	46.7
	Neither agree nor disagree	1	6.7
	Disagree	1	6.7
	Total	15	100.0

**The form was easy to complete from a technical perspective**

		Frequency	Percentage
Valid	Strongly agree	2	13.3
	Agree	7	46.7
	Neither agree nor disagree	2	13.3
	Disagree	4	26.7
	Total	15	100.0

**The form is better than that previously used**

		Frequency	Percentage
Valid	Strongly agree	2	15.4
	Agree	4	30.8
	Neither agree nor disagree	4	30.8
	Disagree	2	15.4
	Strongly Disagree	1	7.7
	Total	13	100.0
Missing	System	2	
Total		15	

**It is preferable to have only one form to complete if  
applying to multiple committees**

		Frequency	Percentage
Valid	Strongly agree	14	93.3
	Agree	1	6.7
	Total	15	100.0

**I would be in favour of a fully online submission**

		Frequency	Percent	Valid Percentage
Valid	Strongly agree	12	80.0	85.7
	Agree	2	13.3	14.3
	Total	14	93.3	100.0
Missing	System	1	6.7	
Total		15	100.0	

**It is preferable to have only one form to complete if applying to multiple committees Crosstabulated With  
The form is better than that previously used**

			The form is better than that previously used					
			Strongly agree	Agree	Neither	Disagree	Strongly Disagree	Total
It is preferable to have only one form to complete if applying to multiple committees?	Strongly agree	Count	2	3	4	2	1	12
		Expected Count	1.8	3.7	3.7	1.8	.9	12.0
		% within The form is better than that previously used	100.0%	75.0%	100.0%	100.0%	100.0%	92.3%
	Agree	Count	0	1	0	0	0	1
		Expected Count	.2	.3	.3	.2	.1	1.0
		% within The form is better than that previously used	.0%	25.0%	.0%	.0%	.0%	7.7%
	Total	Count	2	4	4	2	1	13
		Expected Count	2.0	4.0	4.0	2.0	1.0	13.0
		% within The form is better than that previously used	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

**It is preferable to have only one form to complete if applying to multiple committees Crosstabulated With  
The form was easy to complete from a technical perspective**

			The form was easy to complete from a technical perspective				
			Strongly agree	Agree	Neither	Disagree	Total
It is preferable to have only one form to complete if applying to multiple committees	Strongly agree	Count	2	6	2	4	14
		Expected Count	1.9	6.5	1.9	3.7	14.0
		% within The form was easy to complete from a technical perspective	100.0%	85.7%	100.0%	100.0%	93.3%
	Agree	Count	0	1	0	0	1
		Expected Count	.1	.5	.1	.3	1.0
		% within The form was easy to complete from a technical perspective	.0%	14.3%	.0%	.0%	6.7%
	Total	Count	2	7	2	4	15
		Expected Count	2.0	7.0	2.0	4.0	15.0
		% within The form was easy to complete from a technical perspective	100.0%	100.0%	100.0%	100.0%	100.0%

## APPENDIX D - LETTERS FROM PILOTING COMMITTEES



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

HSE South,  
Waterford Regional Hospital,  
Dunmore Road,  
Waterford,  
Ireland.

Telephone 051 848000  
Fax 051 848572

Ms Ursula Ryan,  
Project Lead,  
Working Group for Common Ethics Application Form,  
AMNCH/SJH Research Ethics Committee.  
Dublin.

22<sup>nd</sup> July 2010.

**Re: Pilot phase of the Common Ethics Application Form.**

Dear Research Ethics Common Form Pilot Working Group,

The Research Ethics Committee, HSE, South East have been involved in the piloting phase of the Common Ethics Application Form from February 2010 to June 2010. The Research Ethics Committee reviewed applications submitted on this form at their meetings in March, April, May and June. In tandem the Chairperson and the Research Ethics Committee Coordinator reviewed applications on this form for studies that were granted expedited approval.

The form was discussed at each monthly meeting. Applicants to the REC, HSE, South East encountered substantial difficulties with the Intelligent Word form and it was agreed that this format was not suitable and would not be used in the South East. This related purely to the technical difficulties applicants had in accessing and downloading the form.

The Committee reviewed 5 applications submitted on the Common Form and the Chairperson and Research Ethics Committee Coordinator reviewed a further 7 applications. The total number of forms reviewed totaled 12.

The Research Ethics Committee has agreed to adopt the Common Application Form, in the WORD version for the HSE, South Eastern area subject to regular reviews and updates. The Committee recognise the need for speedy responses to applicants requests for ethical approval and subsequent research and are committed to providing a quality, timely service which, we believe, this form endeavours to support.

Yours sincerely,

**Dr Paula Lane.**  
Chairperson,  
Research Ethics Committee, HSE, South East.

*Waterford Regional Hospital Mission Statement:*  
"Together we will provide quality patient care delivered by skilled and valued staff through the best use of available resources".



**Mater Misericordiae  
University Hospital**

Sisters of Mercy

**Ospidéal Ollscoile  
Mater Misericordiae**

Síúrácha na Tríocaire



Eccles Street, Dublin 7, Ireland.

Tel: +353 1 8032000 Fax: +353 1 8032404 Email: [muh@mater.ie](mailto:muh@mater.ie) Web: [www.mater.ie](http://www.mater.ie)

*Not for prescription purposes*

Common Health Research Ethics Committee Application Form Working Group

**RE: Common Health Research Ethics Committee Application Form for all Health-Related Research not covered under the Clinical Trials of Medicinal Products for Human Use Legislation (S.I. No. 190 2004)**

30<sup>th</sup> June 2010

Dear Working Group

Following the review of approximately seven research studies that have used the above application form in recent months the Mater Misericordiae University Hospital and Mater Private Hospital Research Ethics Committee are in favour of its use.

We look forward to the further development of this form and the guidance document in the near future.

Yours sincerely

Mr Malcolm Kell  
Chairman Research Ethics Committee

*'Commitment to Excellence'*

Directors: Mr. John Morgan (Chairman), Sr. Kevin Boten, Mr. Fionn Clarke, Mr. Don Mahony, Sr. Margherita Rock, Sr. Martin Cowley, Prof. Conor O'Keane, Ms. Mary Day, Mr. Brian Conlan, Sr. Eugene Moran, Dr. Anthony Clarke, Sr. Kevin Murphy, Dr. Nuala Healy, Ms. Caroline Pigott.

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THE NATIONAL CHILDREN'S HOSPITAL

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TELEPHONE: +353 1 4147000

Common Health Research Ethics Committee Application Form Working Group.

**Re: Common Health Research Ethics Committee Application Form for all  
Health Related Research not covered under the Clinical trials of medicinal  
Products for Human Use Legislation (S.I. 190 2004).**

July 30<sup>th</sup> 2010.

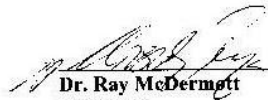
Dear Working Group,

The SJH/AMNCH Research Ethics Committee has participated in the pilot of the  
common ethics form from January 2010 to date. Applications using the form have  
been received and reviewed at our meetings throughout the year.

The form has been discussed at these meetings and with the Chairman and Vice  
Chairman at various stages throughout the pilot and it has been agreed to continue  
using the pilot form.

Our Ethics Committee sees the benefit of having a common application form and  
would welcome the development of an online version of the form which, it is felt, will  
further streamline and improve the application and review process for all concerned.

Yours sincerely,

  
\_\_\_\_\_  
**Dr. Ray McDermott**  
Chairman  
SJH/AMNCH Research Ethics Committee.

1-6701001



**UCC**

Coláiste na hOllscoile Corcaigh, Éire  
University College Cork, Ireland

An Coláiste Leighis agus Sláinte  
College of Medicine and Health

Roinn na Dochtúireachta Ghinearálta  
Department of General Practice

Brookfield Health Sciences Complex  
University College Cork,  
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F +353 (0)21 4901605  
E gp@ucc.ie  
www.ucc.ie

June 24, 2010

Ms. Gillian Vale,  
Ethics (Medical Research) Committee,  
Beaumont Hospital,  
Dublin 9.

Dear Research Ethics Common Form Working Group,

The Irish College of General Practitioners' Research Ethics Committee participated in the pilot of the common ethics form from February to June 2010. Applications using the form were received for our meetings in February, April and June and in total we reviewed 24 applications which used the form at these meetings.

We discussed the form at each of these meetings and at our April meeting agreed that we were willing to continue with the pilot but only using the plain WORD version (not the intelligent WORD form) due to the technical difficulties encountered by applicants. We are remaining in this process because we can see the benefit of having a common form and eagerly await the development of the online version which will permit the deletion of sections as necessary etc. The guidance document accompanying the form is a valuable resource for all.

Yours sincerely,

Professor Colin Bradley,  
Chair, ICGP Research Ethics Committee

Colin P. Bradley, M.D., M.Sc. (Hons)  
Head of Department

Ollscoil na hÉireann, Corcaigh  
National University of Ireland, Cork