Research Ethics Committee Perspectives

on the second anniversary of the
Research Ethics Committee Standard Application Form (RECSAF)

Background:
A standard research ethics committee application was launched and made available for use in September 2010. Approximately 30 medical research ethics committees [RECS] in the Republic of Ireland have considered whether or not to adopt the research ethics committee standard application form [RECSAF] since its launch.

This document contains the perspectives of some of those committees, both in relation to their rationale for choosing either to adopt the RECSAF or not; and the impact, if any, adoption has had.

Perspectives - our rationale for adopting the standard form:

Our rationale for adopting the standard form was, first and foremost, to facilitate researchers in undertaking multisite research studies. Secondary, but also very important reasons, included...[the]...better quality of application form, standardisation, ...[and]...that the form was validated and informed by agencies such as the data commissioner, state claims agency etc.

The rationale for adopting this form is as follows:
1. Questions posed in the form address the needs of potential research that may be undertaken within St. Francis Hospice.
2. Structure of form: easy to use and is accompanied by clear instructions for use.
3. User friendly – with the option to delete parts of the form that are not relevant for a particular organisation.
4. It is likely that researchers may have used this form for healthcare research in another site, so they are likely to be more familiar with the form, as opposed to using a form that is organisation specific – reducing the possibility of errors or omissions in the form.
5. Expertise associated with those compiling the form – was from a broad source of skills – enhancing the breadth and depth of the questions posed in the form.

The Committee’s rationale for adopting the standard form was that it meets their criteria and that it benefits both the Researcher and this Hospital, by standardising the forms and application process, particularly for multi-site trials.

“[This committee].....decided to use the new form as it was more comprehensive than our previous application form.”
We adopted the standard form because it benefits both the researcher and the reviewers, by standardising and asking specific questions, which results in more detailed information, which is required to adequately review the application... [and because of] ...the attraction of eventually moving to an on-line form.

The RECSAF is a standardised format which allows researchers to complete one form to distribute to relevant REC’s rather than the multiple forms that were previously required, thus expediting the application process.

The RECSAF is a rigorous and comprehensive document.

The RECSAF was developed by professionals working in the field of ethics and was informed by experts in specific areas, e.g. Data Protection Office, Clinical Indemnity Scheme, Radiotherapy and Paediatrics.

The RECSAF is supported by a comprehensive Guidance Manual which was also developed with expert input.

The form is concise running to 24 pages, or 12 if double sided.

Certain sections may be deleted if not applicable, thus shortening the form further.

The RECSAF is a national, standardised document.

The RECSAF is reviewed regularly (annually)

The RECSAF has the future potential to be adapted into an on-line electronic format.

The RECSAF, once adopted and with the necessary assurances in place, could allow REC’s to adopt a single site approval mechanism for research studies akin to the current system under the EU Directive (2004)

Perspectives: our rationale for not adopting the standard form:

The Committee... reviewed the Research Ethics Committee Standard Application Form when it was proposed and, at the time, the Committee... felt that the form provided little additional benefit to the current form in use; it was not considered appropriate for children and was too long and complex.
**Perspectives – the impact of adoption:**

| From the point of view of the RCPI ethics committee, it has reduced the work involved in reading submissions as it ensures the applicants have thought about the issues that often caused problems in ethics review and that they have also had to provide ethical solutions. All in all it has enhanced the efficiency of the committee and also ensures that because of the format that all concerned can be assured that the more common ethical issues are dealt with. |

| Another advantage of the common form is that once a researcher has learned how to complete this form their subsequent applications, even if to other ethics committees, will be easier as the form will be familiar. |

| There was some initial disquiet about the length and seeming complexity of the form which has diminished as people have got used to it;.....[It]...has resulted in longer applications and, in most instances, this increases the likelihood of all the required information being provided. |

| The benefits of standardisation for researchers and committees far outweighed any loss of autonomy for individual Clinical Research Ethics Committees. |

**Perspectives – the form:**

| The RECSAF is clear, thorough and reasonably user friendly. Most people / applicants using it have no concerns. |

| The committee... [is]...generally satisfied with the form, and it appears to be working well. |

| We have not encountered any major problems with the form. It is however very long and can put people (and administrators) somewhat off when simpler projects are submitted........there is too much wasted space on the form with lists of sections etc - it means that excessive paper is used for printing and filing. |

| “[Our committee finds the form]...... a bit cumbersome at times. As and when the web electronic form is available (if possible) that would delete sections automatically that are not needed we would feel that this would be preferable.” |

| We have received no complaints about the form but have been asked to introduce a shorter version for students/trainees, which we have not done as we feel the same ethical questions/information still need to be considered. |
**Perspectives – the future:**

We are happy to continue using the common form and to help further the improvements in streamlining the process.

An on-line version, as originally proposed, in which sections not required would disappear, is still very desirable.

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Irish College of General Practitioners Research Ethics Committee  
Mid Western Regional Hospital Complex Research Ethics Committee  
Our Lady’s Children’s Hospital Ethics (Medical Research) Committee  
Rotunda Hospital Research Ethics Committee  
Royal College of Physicians in Ireland Public Health and Occupational Medicine Research Ethics Committee  
Sligo General Hospital Research Ethics Committee  
St. Francis Hospice Research Ethics Committee

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