

Our Ref: JW/446/sr

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Dear Colleague

Re: NRES publication of research summaries – promoting transparent, ethical research

In May this year I wrote a [letter](#) to inform you of our proposal to publish research summaries of applications to NHS Research Ethics Committees. This is part of our wider agenda to promote transparent ethical research and review. I thought it timely to inform you of the progress we have made and what the next steps are. This letter will be published on our website and can be used as a reference for any queries regarding the publication of research summaries.

Stakeholder engagement

We've continued working with stakeholders following our workshop held last year, '[Ethics behind closed doors?](#)' We have received positive feedback on this project, but acknowledge concerns about commercial sensitivity and intellectual property and are taking these issues forward responsibly.

The National Research Ethics Service (NRES) held two events in August to plan and implement this important initiative and there are further events planned on 10 and 24 September. These will be open to researchers and REC members.

Those at the meetings felt that the title "Research Summary" (as opposed to Lay Summary) was a much clearer description of what we intend to publish. As a result one of the main outcomes from the events was to change the title to "Research Summary" and to ensure it is written in plain English.

Early stage implementation

At present we receive inconsistent research summaries, written in a variety of styles and for this project to succeed, clarity and consistency will be paramount. To start with, we will therefore manage their review centrally to develop future guidance. This will allow us time to test and develop guidance to improve the summaries and make them fit for purpose.

The website with the research summaries (within the NRES website) will go live in September as planned and we hope to have up to 100 research summaries at the time of the launch, with more being added on an ongoing basis.

The early stage implementation process is described below. It is independent of the REC's ethical review. The steps are to:

- Identify clinical trial applications submitted after 1 May 2008 (when the intention to publish was first included within the applicant declaration);
- Review each research summary against our current framework;
- Write to each investigator, reminding them of the intention to publish three months from favourable opinion and suggesting revision.

This process will ensure that there are 'no surprises'. Applicants will have already signed the declaration on the ethics form but will receive further notification of the intention to publish and will be able to raise any concerns regarding publication or timing of publication and provide feedback on the procedures. Although this process will at this early implementation stage be managed centrally, the letter will be copied to the REC that is undertaking the ethical review for their information.

The structure of the research summary

The published research summary will consist of the:

- Short study title;
- Contact details for the Chief Investigator (A2*, parts of);
- Disease (A15*);
- Study design and timing of the study (A7*, A21* A69*);
- Trial registration details (if available) (A5-1* A50*);
- Status of REC decision;
- The summary as submitted by the applicant and agreed through the process described above (A6-1*).

**References in the brackets refer to ethic sections within the IRAS application form.*

The fields will be uploaded from the application form via the Research Ethics Database and on to the NRES website.

This will be a separate, searchable section of the NRES website that will be accessible from all sections of the NRES website. We will also consider ways to make this information available to others as appropriate.

Next steps

In the first stage we will test guidance and incorporate this within our Standard Operating Procedures. At a later stage, our intention is that RECs will undertake the review of research summaries, alongside, but separate from the ethical review.

We acknowledge the resource and training issues of this initiative and will not expect RECs to undertake this task until training and resources are in place. It is our ultimate intention to publish research summaries for all applications submitted to RECs.

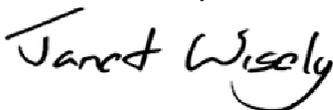
This is work in progress; we will record all feedback from RECs and researchers and adapt the process accordingly.

Summary of ethical opinion

NRES is taking forward a separate but linked piece of work to develop a framework for a summary of ethical opinion. We are currently testing if it is possible to draft a summary of the ethical opinion from the REC minutes.

I hope this information is useful. We will continue to update you on progress and you are welcome to sign up for one of the [forthcoming events](#). The research summary is only one element of full trial registration which NRES strongly encourages. Publication of the research summary will make a significant contribution to transparency as research design and results are of no value if they are not available to patients, the public and other researchers.

Yours sincerely



Dr Janet Wisely
Director
National Research Ethics Service (NRES)