

Our Ref: JW/440/sr

8 May 2008

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Dear Colleague

The publication of lay summaries, and from later in the year the REC summary of opinion, is a key part of our agenda to increase the transparency of decision making.

We held a workshop, 'Ethics Behind Closed Doors' last year which included representation from a wide range of stakeholders. The outcome of the workshop is that many interested parties are now working with us to develop this important area of work. It also ensures that we are able to fulfil our obligations with regard to publication of a summary of opinion and freedom of information.

We announced our intention to publish the lay summary after the workshop last year and have put in place a project team to take this forward. In January we added this in guidance on IRAS. We will now publish lay summaries for trials submitted from May this year. We are currently working up more detailed guidance for researchers and RECs. This open letter describes some key principles that have been agreed:

- we expect all relevant questions to be answered, and for A6 the response to fall within guidance provided on IRAS. However, comments and discussions regarding this, within the context of suitability for its purpose for publication, will be held separately to the ethical opinion and will not delay or confound final approval.
- where the applicant fails to provide a suitable lay summary, and does not provide a revised lay summary, we will publish the original A6 response and note in the corresponding REC summary of opinion that the REC did not consider the lay summary fit for purpose.
- we expect to publish the lay summary 3 months from when the final decision is made by the REC, however applicants will be able to negotiate an extension to this where there are issues regarding intellectual property or commercial sensitivity.
- we appreciate that there will be some concerns regarding publication, however, it is worth noting that under Freedom of Information the Strategic Health Authorities who hold the REC information, in applying necessary tests regarding disclosure, are more likely to release minutes of REC meetings than withhold them. Our intention through the publication of a lay summary, drafted by the applicant, is to be able to refer to these as having met appropriate sharing of information in many cases.
- we review a wide range of studies. We will apply this policy to all and as such hope to build on existing agreements and requirements such as registration details, UKCRC and UKCRN requirements.

- trial registration is strongly encouraged, research design and results are of no value if they aren't available to patients, the public and other researchers. We ask if a trial has been registered, or if there is an intention to register and if not why not. However at the moment, trial registration is not a condition of a valid ethics application or a requirement for a favourable ethical opinion.

Yours sincerely

A handwritten signature in black ink that reads "Janet Wisely". The signature is written in a cursive style with a prominent flourish at the end of the last name.

Dr Janet Wisely
Director
National Research Ethics Service (NRES)