

1.2.9 Sample letter to external expert reviewer

date

address

AlfredHealth

55 Commercial Road
PO Box 315 Prahran
Victoria 3181 Australia
Telephone 03 9076 2000
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Dear

RE: Project [no] [title]

Thank you for agreeing to review the above research project. If you have any concern about completing the review please contact me.

We would like your opinion on the safety aspects of administration the drug [xxxx], which has not previously been tested in humans. The drug is a [brief description]. It is being developed for the management of [brief description].

The review we require consists of a brief report (2-3 pages in length), based on information provided in the investigator's brochure and trial protocol. The focus of the review is on:

- sufficiency of evidence (including pre-clinical testing) to support administration into humans;
- identification of risks to participants (short and long term) and recommended measures to minimise these;
- the starting dose, dose range including maximal dose, timing of dosing within the cohort and between cohorts (dose escalation)
- any questions that you consider important to ask the researchers.

I have attached the following files to assist with your review.

- Trial protocol
- Investigator's brochure

In addition to your report we require that you maintain confidentiality and declare any conflict of interest. This is set out in the covering e-mail. Following your review, please delete the documents provided.

Our insurer, the Victorian Managed Insurance Authority (VMIA), requires that if you have your own professional indemnity that you please forward us a copy. In the event that you do not have professional indemnity insurance, VMIA will provide you with indemnity. To do so, we also require a copy of your CV.

Please forward your review via email. Ideally we would like this in two weeks, prior to the Ethics Meeting scheduled [insert date]. The review will be paid for by the Alfred Ethics Unit at a total of \$xx inclusive of GST. Please remember to submit an invoice for the review.

Yours sincerely,

s 47F (s 47F) on behalf of

s 47F (s 47F)
The Alfred Hospital

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