

Agreement for the conduct of Expert Review of a clinical trial

Alfred Health Alfred Health ABN 27 318 956 319 a body corporate established under the *Health Services Act 1988* (Vic) of Commercial Road, Melbourne 3004 (Organisation)

[name] of [organisation],
Vic 3004 Australia (You)

Background

The Organisation engages you to conduct an independent expert review (**Review**) of the clinical trial set out in the Schedule Details. You agree to conduct the Review in accordance with the terms of this document.

Conduct of Review

- 1 You must conduct the Review of the clinical trial specified in the Schedule Details. The Review consists of the following:
 - 1.1 You must provide a written report to the Organisation that addresses those issues set out under the heading Review Issues in the Schedule Details (**Review Issues**). In that report, you must clearly identify those issues on which you have not or cannot form an opinion, and if possible, the reasons for this. If you have made assumptions in forming your opinion, you should identify them. If you have relied on the opinion of some other person in forming your opinion, you should identify that other opinion. If requested you must rewrite any part of your report that is considered by the Organisation as being ambiguous or unclear or requiring further development.
 - 1.2 You must promptly address any queries raised by the Organisation or its Human Research Ethics Committee (**HREC**) in relation to the Review Issues.
 - 1.3 You must attend any meeting of the relevant HREC at which your written report or other issues concerning your independent expert review are considered, if requested to do so, having been given reasonable notice.
- 2 You must have regard to, and conduct the Review in accordance with, the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* and any relevant laws and guidelines.

Permission to Disclose Personal Details

- 3 You agree that for the purposes of the Review the Organisation may disclose your personal contact details to the principal investigator of the relevant clinical trial and a nominated member of the participating Human Research Ethics Committee (**HREC**).

Consideration

- 4 You will receive the consideration set out in the Schedule Details for conducting the review. If the consideration is a monetary amount, the Organisation will pay you this amount.

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Intellectual property rights

- 5 All intellectual property rights arising out of the performance of the Review will immediately vest in the Organisation.
- 6 You must execute all documents and do all acts and things required by the Organisation to further confirm the vesting of such intellectual property rights in the Organisation.

Confidentiality

- 7 You must not use, copy, disclose, reproduce or make public the Organisation's Confidential Information for any purpose except in accordance with this document. You may use the Organisation's Confidential Information for the purpose of conducting the Review. If you become aware of a breach of this obligation, you must immediately notify the Organisation.
- 8 You must not disclose any of the Organisation's Confidential Information unless one of the following circumstances applies:
 - 8.1 The Organisation has consented in writing to the disclosure.
 - 8.2 The disclosure is required by a court, a binding directive of a governmental or administrative authority or to comply with any applicable law.
- 9 Upon conclusion of the Review, you must return to the Organisation all papers, records and documents in your possession which relate in any way to the relevant clinical trial that were provided by the Organisation or contain the Organisation's Confidential Information.
- 10 Your obligations of confidence set out in this document continue in full force and effect after this document ends.
- 11 In this document **Confidential Information** means any information provided by the Organisation or any of its employees, officers, agents or contractors to you, or otherwise obtained by you, whether obtained before or after execution of this document, in connection with the Organisation, the Review or this document. It includes:
 - (a) all confidential business information, documents, records, financial information, reports, technical information and forecasts which relate to Organisation or the Organisation's business;
 - (b) the Organisation's intellectual property;
 - (c) the terms and conditions of this document; and
 - (d) any information created under or arising out of the conduct of the Review under this document.

It does not include:

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- (e) information which is in or becomes part of the public domain, other than through a breach of this document or an obligation of confidence owed to the Organisation; or
- (f) which you can prove by contemporaneous written documentation was independently acquired or developed without breaching any of the obligations set out in this document.

Conflict of Interest

- 12 You must not undertake any work or perform any services for other parties which may conflict with your obligations as an independent expert reviewer. You warrant that as at the date of this document to the best of your knowledge no conflict of interest exists or is reasonably foreseeable in relation to the performance of your obligations under this document.

Professional indemnity insurance

[Use this clause for Expert Reviewers who have in place individual PI cover.]

- 13 You must maintain professional indemnity insurance that provides cover in relation to the Review for the term of this agreement. You must provide details of your professional indemnity insurance to the Organisation upon request.

[Use this clause for Expert Reviewers who do not have individual PI cover.]

- 14 You have indicated to the Organisation that you do not have in place professional indemnity insurance that provides cover in relation to the Review. The Organisation confirms that you are included as an insured under its professional indemnity policy for the purposes of conducting the Review, provided you comply with the terms and conditions of that policy. You acknowledge that you have apprised yourself of those terms and conditions and agree to comply with them.

Term and termination

- 15 This agreement takes effect on the date of this document and remains in force until you have performed all of the obligations set out in clauses 1.1 to 1.3 (inclusive) or unless terminated in accordance with this document.
- 16 The Organisation may terminate this document immediately if any of the following occurs:
- 16.1 You fail to rectify a breach of this document which is rectifiable within 14 days after receiving a written notice specifying the breach and requiring rectification.
 - 16.2 The Organisation decides not to proceed with the relevant clinical trial.
- 17 If the Organisation terminates this agreement in accordance with clause 16, the Organisation will pay you such portion of the payment amount set out in the Schedule Details as it considers in its absolute discretion represents adequate compensation for any work relating to the Review that you have performed up to that date.

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Schedule Details

Name of Clinical Trial: Full Project Title: A Randomized, Double-blind, Placebo-controlled, Single Ascending Dose Study of the Safety and Tolerability of Intravenously Administered REGN846 in Healthy Volunteers

Review Issues:

- *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.*

Consideration:

Execution

Date:

Signed for and on behalf of **Alfred Health** in the presence of:

.....

Signature of witness

Signature of authorised person

.....

Name of witness (print)

Name of authorised person (print)

Signed by **[insert name]** in the presence of:

.....

Signature of witness

Signature of Expert Reviewer

.....

Name of witness (print)