**DISTRICT HEALTH BOARDS**

**Clinical Trials Checklist**

Name of Clinical Trial Contract: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reference No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please complete the following checklist, and attach informing documents where applicable hereto:

*Please complete the checklist for all clinical trials. The answers to Questions 1, 3 and 11 must be yes, along with no other circumstances requiring the clinical trial to be referred to Marsh, for the clinical trial to be automatically covered under the Professional Indemnity policy.*

# Clinical Trial

1. Is the clinical trial approved by a Health & Disability Ethics Committee (HDEC) or Institutional Ethics Committees (IEC’s) which is accredited by the Health Research Council of New Zealand in

accordance with Section 25 (1) (c) of the Health Research Council Act 1990? ☐Yes ☐No

*An HDEC is a Ministerial committee established under Section 11 of the New Zealand Public Health and Disability Act 2000 for the purpose of ensuring that clinical research meets or exceeds established ethical standards. HDEC’s are required to act in accordance with the procedural rules contained in the Standard Operating Procedures for HDEC’s issued by the Ministry of Health.*

1. Does this Clinical trial require approval under Section 30 of the Medicines Act 1981? ☐Yes ☐No

*If the answer is no, go to Q4.*

1. Has approval referred to in 2 above been received? ☐Yes ☐No

*If the answer is no the clinical trials cover provided under the Professional Indemnity policy will not apply.* ***Refer to Marsh to obtain cover.***

1. Has HDEC determined that the trial is not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled and that participants will be covered

by ACC ? ☐Yes ☐No

*If the answer is no the clinical trials cover provided under the Professional Indemnity policy will only apply where the external sponsor meets the conditions stated under Note 1 below.* ***If it does not refer to Marsh to obtain cover.***

1. Does the contract note the DHB as the “Sponsor” (in name or in assumed liability due to clauses in

the contract), and that ACC does not apply? ☐Yes ☐No

*If the answer is yes the clinical trials cover provided under the Professional Indemnity policy will not apply.* ***Refer to Marsh to obtain cover***

1. For clinical trials initiated in New Zealand will the clinical trial be carried out outside of New Zealand,

either in whole or in part? ☐Yes ☐No

*If the answer is yes the clinical trials cover provided under the Professional Indemnity policy will not apply.* ***Refer to Marsh to obtain cover.***

1. Are there New Zealand Territorial Limits and Jurisdictions? ☐Yes ☐No

*The policy will only apply to clinical trials carried out in New Zealand and claims brought in New Zealand. If the answer is no the clinical trials cover provided under the Professional Indemnity policy will not apply. Refer to Marsh to obtain cover.*

# Clinical Trials conducted for the benefit of the manufacturer

1. Is the clinical trial conducted for the benefit of the manufacturer of the product being trialled ☐Yes ☐No

*If the answer is yes then for the clinical trials cover provided under the Professional Indemnity policy to apply the external sponsor must meet the conditions stated under Note 1.* ***If it does not refer to Marsh to obtain cover.***

1. Is the clinical trial subject to a formal clinical trial agreement between the Insured and the Sponsor? ☐Yes ☐No

*Formal agreement required for all clinical trials. Preference is standard NZ sCTRA,*

|  |  |
| --- | --- |
| 1. Are there clauses which refer to waivers of subrogation and assuming liability?

*DHB policies do not insure liability assumed by agreement where the liability would not have attached without specific agreement. So waivers of subrogation and assuming liability under the contract should be avoided wherever possible. Advise Marsh of any such clauses so that Insurer’s agreement can be obtained* 1. Has the Sponsor arranged Third Party Liability and Professional Indemnity insurance and does this
 | ☐Yes ☐No  |
| cover a CRO (if involved)? *Clauses that simply state that the Sponsor will arrange insurance as required by law are not acceptable.* 12. Has the Sponsor: a) agreed that trial participants will be paid compensation by the sponsor in accordance with The Researched Medicines Industry Guidelines on Clinical Trials Compensation for Injury  | ☐Yes ☐No  |
| Resulting From Participation in an Industry Sponsored Clinical Trial?  | ☐Yes ☐No  |
| b) provided the Insured with a formal indemnity?  | ☐Yes ☐No  |
| c) provided the Insured with evidence of insurance cover held for the trial?  13. Are there any clauses requiring Professional Indemnity cover by the DHB for a specified period e.g. 7  | ☐Yes ☐No  |
| years? *It cannot be guaranteed that cover can be maintained for this length of time.*  | ☐Yes ☐No  |
| 14. Does the Principal Investigator have professional liability insurance or membership of MPS ?  | ☐Yes ☐No  |

*The DHB liability programme specifically excludes cover for SMOs as they are required to have their own insurance .The DHB should confirm that the SMO has medical malpractice cover and that the policy includes cover for clinical trials*

**Note 1**

If a trial does not have ACC cover then it will only be covered by the policy if it meets the following criteria.

The trial is the subject of a formal clinical trial agreement between the Insured and the sponsor of the trial or study whereby the sponsor has:

* 1. agreed that trial participants will be paid compensation from the sponsor in accordance with The Researched

Medicines Industry Guidelines on Clinical Trials Compensation for Injury Resulting From Participation in an Industry

Sponsored Clinical Trial;

* 1. provided the Insured with a formal indemnity; and
	2. provided the Insured with evidence as to insurance cover for the trial

***I confirm that the answers above are true and correct.***

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Name Position

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**FOR DHB** Authorised Signatures on behalf of DHB

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(Chief Medical Officer or equivalent)*  |
| Name     | Position  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |   |

|  |  |  |  |
| --- | --- | --- | --- |
| Signature    | Date  |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |   |  |  *(Chief Executive Officer, Chief Financial Officer or*  |
| Name    | Position |  |  *authorised delegate)*  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |   |   |  |
| Signature  | Date  |  |  |

DHB Comments:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_