ATTACHMENT 1: RISK ASSESSMENT FOR INVESTIGATOR INITIATED CLINICAL TRIALS

Instructions for submission:

- **1 x hard copy of this completed document must accompany a Site Specific Assessment Submission**
- **1x electronic copy of this completed document must be sent to research@nsccahs.health.nsw.gov.au . Please note that submissions will not be processed until a hard copy is received.**
- **1 x hard copy of all mandatory documents listed at Section 2 must be provided for review.**
- **All sections of the Risk Assessment Template must be completed by the Chief Investigator/Principle Investigator of the study. Incomplete Risk Assessments will be returned.**

SECTION 1: CLINICAL TRIAL RESEARCH PROJECT DETAILS

1.1 Name of Public Health Organisation where trial is to be conducted:

Central Coast Local Health District

1.2 Public Hospital Sites to be covered by this Research Indemnity Assessment

1.3 Title and protocol number of clinical trial:

1.4 Human Research Ethics Committee that has approved this trial:

1.5 Trial sponsor:

In the absence of a Commercial Sponsor where the study is Investigator Initiated it is recommended that you list Central Coast Health District as the sponsor.

1.5 Researchers to be covered under this Research Indemnity Assessment:

Name of Researcher	Role in Research	Employment Status
	Chief Investigator	**Eg. Staff Specialist, VMO, Nurse, Allied Health**
	Principle Investigator	**Eg. Staff Specialist, VMO, Nurse, Allied Health**
	[Other, please list]	**Eg. Staff Specialist, VMO, Nurse, Allied Health**
	[Other, please list]	**Eg. Staff Specialist, VMO, Nurse, Allied Health**

1.6 External Organisations Involved with the Research

Name of Organisation	Role in Research	Services to be provided by this organisation for the purpose of the research
	[Eg. Drug company, Manufacturer]	[Eg. Supply of study medications]
	[Collaborative group, Other Area Health Service, University]	[Eg. Supply of monitoring services, funding, insurance, liability coverage.] Include dollar value and type of policy, ie. claims made or claim occurred

1.7 Please provide the membership list of the data safety monitoring board and will it be independent?

Member Name	Role in Committee

1.8 Please list the frequency for which this Committee will meet:

1.9 Please attach a copy of the written operating procedures for this Committee

1.10 Please provide the details of the person or organisation appointed to monitor this research project:

1.10 What are the benefits to NSLHD or CCHD in carrying out the research? (E.g. Financial, public profile, publications, etc)

1.11 Please provide a description of research outcomes and anticipated adverse effects, please ensure that you include statistical data if available:

1.12 Please list the strategies to be implemented to minimise risks, please also attach a copy of the Participant Information Sheet and Consent Form:

1.13 Please provide the details and Amount of Insurance Cover and type of Insurance Cover provided by any of the external organisations listed at Question 2.

1.14 Please complete Risk Assessment Tool provided on the following page.
Complete the Risk Assessment Template based on hazards identified for this trial, which could lead to events that are subject to a claim against the Sponsor. When completing the Template, refer to Annexure A which provides some examples of potential hazards for clinical trials and the NSW Health Risk Matrix, accessed through policy directive PD2009_039 Risk Management – Enterprise-wide Policy and Framework – NSW Health *for determining the risk level for each event.*

SECTION 2: MANDATORY SUPPORTING DOCUMENTATION

2. Please confirm that a copy of the following documentation is attached to support this submission.

- ☐ A complete Site Specific Assessment Application
- ☐ A completed clinical trial risk assessment tool is attached for review
- ☐ Copy of the clinical trial agreement and the indemnity provided (if applicable)
- ☐ Copy of the Research Funding Agreement

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Assessor recommendation:
Comment and make a recommendation based on the risk assessment as to whether the Sponsor's proposed insurance cover is supported with reasons stated.

Assessor's Name:
Signature:…… **Date:**……

Chief Executive: Endorsement of insurance cover:

Signature:…… **Date:**……

RISK ASSESSMENT TOOL

Hazards (Anything from the trial that could lead to an incident or cause harm) **List all hazards which may be subject to a claim against the Sponsor**	**Event** (Incident or harm that could be caused by the hazard)	**Impact From Event Happening**		**Control Strategies**	**Effectiveness of Control Strategies**	**Current Risk Level**			
		NSW Health Risk Categories *(e.g. Clinical Care & Patient Safety, Finance & Legal and Leadership & Management)*	$'000 *(only where applicable*		(A) - Adequate (M) - Moderate (I) - Inadequate	**Note 1** Likelihood	**Note 2** Consequence	**Note 3** Current Risk	**Note 4** Acceptability (A /
1. [eg. Non Compliance with the Research Protocol.]									
2. [eg. Non Compliance with Therapeutic Goods Administration ACT under the Clinical Trial Notification Scheme.]									
3. [eg. Non Compliance with Good Clinical Practice Guidelines.]									
4. [eg. Non Compliance with the requirements of Safety Reporting.]									
5. [eg. Failure to consent patients to the research project.]									
6. [eg. Breach of the Participant Information and Privacy Requirements.]									

For each risk the following profile is to be used based on the NSW Health Risk Matrix accessed through policy directive 2009_039 *Risk Management – Enterprise- wide Policy and Framework – NSW Health*:

Note 1: **Likelihood of Risk Occurring**
Apply the profile of likelihood in accordance with the criteria.

Likelihood: **1** – Rare **2** – Unlikely **3** – Possible **4** – Likely **5** – Almost Certain

Note 2: Consequences if the Risk Occurs
Apply the consequence criteria.

Consequence: **1** – Minimal **2** – Minor **3** – Moderate **4** – Major **5** – Catastrophic

Note 3: Current Risk Rating – Based on the mix of likelihood and consequences

E – Extreme Risk **H** – High Risk **M** – Medium Risk **L** – Low Risk

Note 4: The level of risk is to be assessed as acceptable **(A)** or unacceptable **(U)**.

Annexure A: Some examples of potential hazards for clinical trials

Hazard	Potential event	Points to consider
Intervention	• Expected and unexpected adverse events	• Nature of intervention (e.g. drugs, devices, surgical procedures) • Research clinician's previous experience of intervention • Pre-trial training • Unproven effectiveness or use for new indication? • Development phase, licensing status, clinical experience, and (if drugs) pharmacology. • Novel handling requirements of pharmacy/drug, tissues, equipment • Susceptibility of participant population – disease state, genetics, age, and sex. • Systems to monitor and review adverse events, and act on new information
Clinical management of adverse events	• Effect on participant safety	• Experience of clinician researchers and support available
Clinical management of participant's underlying medical conditions	• Effect on participant safety	• Experience of clinician researchers and support available
Assessment methods	• Effect on participant safety	• Invasive tests over and above routine care • Increased radiological exposure
Consent	• Participants entering the trial without fully informed consent • Failure to act on withdrawal of consent • Data or tissue samples being used or stored without fully informed consent	• Vulnerability of the participant and capacity to give consent, e.g. children, incapacitated adults • Consent process, e.g. timing relative to diagnosis, time to consider, signature • Participant information provided • Experience of those providing participant information and obtaining consent
Privacy	• Failure to protect the privacy of participants	• Data protection and security systems • Anonymisation process