# SESLHD Research Governance: Clinical Trials

# Application for SESLHD Sponsorship

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|  |  |  | **Requirements for SESLHD to consider supporting study sponsorship and potential risk mitigation strategies:** |
| **1** | **Date** | Click here to enter a date. |  |
| **2** | **Title of Clinical Trial** | Click here to enter text. |  |
| **2a** | **Brief summary of proposed intervention and outline of current standard of care.** | Click here to enter text. | This is a brief summary of the current standard of care and need for the intervention (drug, device or procedure). A protocol synopsis can be attached to this application. |
| **3** | **Principal Investigator/s** | Click here to enter text. | You must be an SESLHD employee. (“NSW Health Staff” as per PD2011\_006) |
| **4** | **Department & Institution** | Click here to enter text. | The study is self funded by department/institution. It is not sponsored by a commercial entity or part of a multi-institutional agreement |
| **4a** | **Department / Division Head name and approval** | Click here to enter text.  Yes  No | Senior line management are aware of the study and their sponsorship obligations. Confirming that the CPI has adequate procedures in place for all trial management activities, (e.g. safety monitoring, randomisation, allocation concealment, blinding, data management and analysis) |
| **5** | **Do you hold a current Good Clinical Practice (GCP) Training Certificate?** | Yes  No | You must hold a current GCP training certificate to be a Principal investigator of an SESLHD sponsored clinical trial.  Proof of compliance can be attached to this application. |
| **6** | **Type of Clinical Trial** | Choose an item. | SESLHD HREC & Governance is not authorised to support first in human drugs or devices |
| **7** | **Phase of Clinical Trial** | Click here to enter text. | First in human studies may be referred to an external consultant. |
| **8** | **Product or procedure** | Drug Vaccine  Device Biological  Procedure Education  Other | If drug/device, please provide the name: |
| **9** | **Owner or Product manufacturer:** | Click here to enter text. | If provided by third party a commercial agreement covering manufacturing and/or supply as per applicable standards with the third party must be in place. \*  For part product ownership contracts must be in place to cover IP sharing and third parties’ liabilities. \*  (NSW Health PD2011\_006) |
| **10** | **Describe supply or manufacture of product for trial:** | Click here to enter text. | Attach agreements in place for supply or manufacture of products if applicable. |
| **11** | **Will the product be imported or manufactured in a GMP certified facility?** | Click here to enter text. | Product must be TGA approved or manufactured in GCP facility for all trial phases approved by SESLHD HREC.  If the drug is a natural product and imported from overseas check biosecurity risks. |
| **12** | **Sub Investigators name and institution/employer** | Click here to enter text. | If non-SESLHD employees are Cis, an agreement exists with sub-investigators employers around IP, publications and evidence of insurance coverage for clinical trial activity is required with Site Specific Application. \* |
| **13** | **Trial Sites** | Single  National NSW only  Multi National | SESLHD can act as clinical trial sponsor at other sites within NSW but a CTRA will need to be entered with other sites. No indemnity exists for sites outside NSW. |
| **13a** | **Trial sites details**  **List hospital, state**  **Public or private site** | Click here to enter text. | If this is a multi-site trial, list each of the sites the CPI is collaborating with, including the Principal Investigator’s (PI) name. *An agreement may be required between the SESLHD and each site.* |
| **14** | **Type of Funding** | Investigator Initiated with industry funding  Collaborative group funding  Departmental funding  Grant funding  No funding  Other  Please specify: Click here to enter text. | Attach draft agreements or awards. \* |
| **15** | **Protocol synopsis (please attach)** | **Version No.** | **Date** |
|  | Click here to enter text. | Click here to enter text. |
| **16** | **Investigator Brochure in progress:**  **Please comment** | Click here to enter text. |  |
| **17** | **List third parties required to conduct the study:**  **For e.g. Laboratories outside of SESLHD, statisticians, regulatory consultants.** | Click here to enter text. | Agreement to be entered third parties and addressing as applicable IP sharing, publications and evidence of insurance coverage for clinical trial activity. \* |
| **18** | **Please list any other scientific documentation you wish to submit in support of this trial.** | Click here to enter text. | Attach all relevant clinical, preclinical and animal studies to date. |
| **19** | **Attach Risk Assessment/ describe inherent risks known to date** | Attached: |  |
| **20** | **Any known conflicts of interest?** | Click here to enter text. | Examples include  Financial benefits in the advancement of drug/ device/ biological. Shares held in manufacturer or other third-party providers. |
| **21** | **Contact name** | Click here to enter text. |
| **22** | **Contact Email** (organisational email address) | Click here to enter text. |
| **23** | **Contact Telephone** | Click here to enter text. |

Please read and complete the below if applicable:

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| **Regulatory Approvals:**  **NOTE:** Clinical trials require additional regulatory approvals external to the research ethics and governance process and it is advised that these are sought in parallel once sponsorship is determined.  Therapeutic Goods Administration (TGA): CTN or CTX scheme  <https://www.tga.gov.au/clinical-trials>  For CTX studies a premeeting should be requested with sponsor, PI and TGA.  For Gene and Cell Therapy trials:  GMO licenses through the Office of the Gene Technology Regulator: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dnirclass-2>  BICON import permits through the Department of Agriculture may be required:  <https://www.agriculture.gov.au/import/online-services/bicon/bicon-permit> | If any applications or advice has been obtained, please detail here and attach supporting documentation | Once sponsorship is confirmed a meeting to be organised with TGA to confirm regulatory pathway of CTN or CTX. |

\*If SESLHD takes on clinical trial sponsorship all related agreements must be submitted for review to the SESLHD Research Office