TGA Online Clinical Trial Notification Process

Information for Researchers wishing to conduct Clinical Research within the HNELHD

Introduction

The *Therapeutic Goods Administration* has introduced an online version of the Clinical Trial Notification (CTN) form which will require a change in processes by the Research Support and Development Office. Under this process the sponsor will be responsible for registering a clinical trial, signatures will no longer be required for any part of the form – please see the table below for the changes in processes between the paper CTN form and the online submission process.

Section of CTN	Paper Version	Online Version Pharma	Online Version – Investigator Initiated
1: Sponsor	Completed and signed by Sponsor	Completed by the Sponsor	Completed by Investigator and declaration required from Sponsor (who may need to be a representative LHD)
2: Investigator	Completed and signed by Investigator	Completed by the Sponsor	Completed by Investigator
3: HREC	Completed by REGU Staff and signed by HREC Chair/Member	Completed by the Sponsor	Completed by Investigator
4: Authority	Facilitated by REGU Staff to get head of Facility where trial will be conducted: either ELT Member for JHH and JHCH or General Manager of other Hospitals	Completed by the Sponsor but details of contact person required for follow up correspondence	Completed by the Investigator but details of contact person required for follow up correspondence

The following information is provided to assist with the registration of clinical trials reviewed by the Hunter New England Human Research Ethics Committee and/or being conducted in Hunter New England Health facilities.

HREC details:

The following information is required:

HREC Name (Name of the Human Research Ethics Committee (HREC) responsible for ensuring the research proposal is ethically acceptable, and in accordance with relevant standards and guidelines at this trial site)

- **Hunter New England Human Research Ethics Committee (**where that Committee has reviewed the initial ethics submission)

HREC Code (The unique HREC Code issued by the National Health and Medical Research Council (NHMRC) for this HREC). The NHMRC Code for the Hunter New England Human Research Ethics Committee is:

- **EC00403**

HREC Contact Officer (The person who will receive correspondence from the TGA for the HREC (if required) about the CTN). For Hunter New England Human Research Ethics Committee this will be:

- **Dr Nicole Gerrand**

Position - description or title of the HREC contact officer.

- **Manager of the Research Support and Development Office**

Contact phone number (Phone number (including area code) of the HREC Contact Officer).

- **02 4921 4950**

Contact email address of the HREC Contact Officer.

Generic email for HNELHD Research Support and Development Office:

- **HNELHD-HREC@hnehealth.nsw.gov.au**

Approving Authority

The following information is required:

Name of Approving Authority: (Name of the Institution or Organisation, referred to as the 'Approving Authority' where the trial will be conducted).

For HNELHD/CMN this should be:

- The Hospital/Facility where the trial will be conducted.

Approving Authority Contact Officer: (The person who will receive correspondence from the TGA for the Approving Authority (if required) about this CTN)

For HNELHD/CMN this will be:

- Dr Nicole Gerrand

Position: (Description or Title of the Approving Authority Contact Officer)

- Manager of the Research Support and Development Office

Contact Phone Number (Phone number (including area code) of the Approving Authority Contact Officer)

- **02 4921 4950**

Contact email address (of the Approving Authority Contact Officer)

Generic email for HNELHD Research Support and Development Office

- **HNELHD-HREC@hnehealth.nsw.gov.au**

HNELHD as study sponsor

The Circumstances where the HNELHD should act as a sponsor are as follows:

- Where the organisation co-ordinating the trial is an overseas entity, for example the Children's Oncology Group trials
- Where a HNELHD staff member is the Investigator but cannot take on the role of the Sponsor – for example if a clinical trial agreement is required because a pharmaceutical company is providing the trial medication and is requesting access to the study data in return

In these circumstances the CTN will need to be logged by the Research Support and Development Office with input from the Local Investigator. In order for this to occur, an appointment must be made with the Research Support and Development Office. **Please note** the study won't be fully registered until the Chief Executive as given permission for the Sponsor's Declaration to be accepted, and this will be done as part of the Research Governance Process for the study.

Guidance material for the new online CTN form is available on the TGA website.