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DRUG/DEVICE TRIAL SUBCOMMITTEE (DTS)

TERMS OF REFERENCE

1. Role:

The role of the Drug/Device Trial Subcommittee (DTS) is to scientifically review all research protocols investigating drugs and devices which are submitted to The Royal Children's Hospital Human Research Ethics Committee (HREC). It is the role of the DTS to advise the HREC on matters relating to scientific, medico-legal (and in some case ethical) issues associated with clinical drug and device trials conducted on The Royal Children's Hospital (RCH) campus.

2. Reporting:

The DTS is accountable through the RCH HREC to the RCH Board of Directors and the National Health and Medical Research Council (NHMRC).

3. Terms of Reference:

The functions of the Drug Trial Subcommittee shall include the following:

3.1.1. review of new protocols from scientific, medico-legal and where necessary ethical and regulatory viewpoints;
3.1.2. confirmation of appropriate risk management processes in drug device trials, i.e. Data Safety Monitoring Boards, expertise of researchers assessing adverse events etc;
3.1.3. review of protocol modification;
3.1.4. review of serious adverse events during use of investigational drugs;
3.1.5. review of revised investigator brochures or product information;
3.1.6. provision of recommendations to the RCH HREC;
3.1.7. consideration of other matters referred to the DTS by the RCH HREC

The terms of reference shall be reviewed from time to time by the Committee to ensure ongoing relevance.

4. Conflict of Interest

At the commencement of each meeting the Chair will call on all present to declare any potential conflict of interest for any of the listed agenda items. A decision will then be made as to whether that conflict of interest will prevent that member from participating in discussion and/or subsequent deliberation.

5. Membership

5.1. The following shall constitute the Committee

- The Chair

- Medical staff representatives from various specialties to reflect type of drug/device trial submissions
- Pharmacy Department representative
- Clinical Pharmacology representative
- Statistician / Epidemiologist
- Additional members with specific expertise as required
- Ethics and Research Department representative (Director & Secretariat) (Attendees)

5.1.1. The Chair or their representative to an attendee of the RCH HREC.

6. Meetings:

6.1. Each person appointed as a member of the Committee shall be entitled to one vote and in the event of an equal vote the Chair shall have the casting vote

6.2. A quorum shall consist of two (2) members, including one (1) clinician plus one (1) pharmacist/clinical pharmacology representative.

6.3. The Committee may invite any person to attend a Committee meeting in order to facilitate business.

7. Objectives:

The objectives of the Drug Trial Subcommittee will include:

- Initial review of all clinical trials to be conducted at The Royal Children's Hospital to ensure they are designed in a safe and scientifically valid manner;
- Ensure compliance of the protocol with the National Health and Medical Research Council guidelines, and the current Therapeutic Goods Administration "Note for Guidance on Good Clinical Practice" for Guidelines for Good Clinical Practice (GCP), and appropriate regulatory requirements and guidelines pertaining to the conduct of clinical trials in Victoria and Australia
- Foremost consideration to be given to the welfare of the participant, volunteer and their family, and to protect their rights, privacy and confidentiality.

8. Meeting Frequency

The Committee shall meet monthly (11meetings per year), in general one-two weeks prior to the RCH HREC.

Developed:	**February 2004**
Developed by:	**Director, Research Development & Ethics**
Date of last Review:	**February 2013**
Date of next Review:	**February 2016**