QH HREC Administrators and Research Governance Officers Network Meeting
Clinical Trial Agreements

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Overview – Session 1

- Introduction to clinical trial agreements
  - Medicines Australia standard agreements
  - VMIA “standard” agreements
- Schedule 4/7 amendments
- Frequently encountered issues
“Institution” – the hospital

“Sponsor”, “CRG” or “Organisation” – the company, organisation or individual taking overall responsibility for the trial

“Investigator” or “Principal Investigator” – the primary researcher, employed by the Institution

“Protocol” – the document setting out scientific/clinical details for how the trial is to be run
To produce a set of uniformly accepted standard clinical trial research agreements that can accommodate requirements of individual pharmaceutical companies through amendments in Schedule 4/7.
The standard agreements

- Medicines Australia - standard clinical research trials agreement for:
  - commercially sponsored trials
  - contract research organisations (CRO)
  - collaborative research group (CRG) studies

- Victorian Managed Insurance Authority (VMIA) - Investigator initiated agreement

- Medical Technology Association of Australia (MTAA) - Standard clinical investigation research agreement (CIRA) for use in device trials
Commercially sponsored

- To be used for all commercially sponsored clinical trials where the local sponsor is an Australian company or the Australian subsidiary of the pharmaceutical company providing the investigational product

Contract Research Organisation (CRO)

- To be used where the Sponsor is an international entity without an Australian affiliate

Collaborative/Cooperative Research Group (CRG)

- To be used where an academic and/or non-commercial collaborative research group is the Sponsor
Investigator initiated

- Can be used for investigator initiated trials which cannot be accommodated under the CRG agreement

Clinical investigation research agreement (CIRA) for use in device trials

- Developed by MTAA, VMIA, NSW Health and Qld Health
- Can be used for device trials which cannot be accommodated under the other standard agreements
Clinical trial agreements - structure

- Party details
- Legal terms
  - Study, roles and obligations of parties and Principal Investigator, payments, Equipment, Investigational Product, Confidentiality, Privacy, Publications, IP, Term and Termination, Disputes, Assignment
- Execution page
  - Principal Investigator signs to acknowledge agreement, not as a party
Clinical trial agreements - schedules

- Key information
- Payments
- Indemnity
- Insurance
- Guidelines for compensation for injury
- Study protocol
- Special conditions - Schedule 4 (CRG) or 7 (commercially sponsored and CRO)
Clinical trial agreements – use of Schedule 4/7

- Include additions/changes to standard terms and conditions
- Incorporate unique operational issues relevant to Sponsor
- Should not be used to substantially rewrite terms and conditions
- Schedule 4/7 conditions which have not been pre-approved by QH/NSWH/VMID require legal sign-off
Frequently encountered issues

- Foreign laws
- Liability and indemnity
- Naming an additional party
- Payments
- Insurance
- Publication rights
- IP
- Protocol
- Investigator
- Subcontracting
- Privacy and transborder data flows
Our experience

- Drafting
- Reviewing/advising
- Standard Schedule 4/7 amendments
- Non-standard clinical trial agreements
• Lessons learned from former processes
• Share knowledge and reduce duplication
  • Centralised database of approved clauses
  • Distribution through email group
• Maintain contact with NSW and Vic Health
• Streamline transfer of existing preapprovals into new contract structure
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