Model Clinical Trials Agreement

as implemented by Royal Brompton & Harefield NHS Trust
Introduction

January 2003 mCTA published as Jointly Developed by ABPI and DH implementing recommendations made by Pharmaceutical Industry Competitiveness Task Force (PICTF);

Predates the implementation of the Medicines for Human Use Clinical Trials Regulations of 2004 but takes account of the expectations of the Clinical Trials Directive of 2001/20/EC

In applying the contract RBH takes note of the ambit of the Clinical Trials Regulations (e.g. contracting outside of the EEA)
Document Components

Documentation (including associated documents)

- Model Clinical Trial Agreement (April 2003)
- Appendix 1 – Copy of finalised Protocol
- Appendix 2 – Timelines for Parties
- Appendix 3 – ABPI Compensation Guidelines
- Appendix 4 – ABPI Form of Indemnity
- Appendix 5 – Financial Arrangements
- Appendix 6 – Conditions applicable to the Site Principal Investigator

Also have attached the Guidance for R&D Managers in NHS Trusts and Clinical Research Departments in the Pharmaceutical Industry (2003)
Scope and Aims

Aims of mCTA
- Improve UK’s international competitiveness through expedited arrangements - model CTA
- Facilitate timely completion of contractual documents.

Scope
- Use of model CTA is not mandatory but is recommended - any alternative CTA should address terms contained in model CTA;
- Use only in commercially sponsored research involving NHS Trust patients;
- Covers Clinical Research involving medicines (not devices);
- Applicable to all Phase II to IV trials;
- Applicable only to Phase I if subjects are selected due to a known or suspected condition or illness relevant to the study
Form of contract – Things to watch out for

1. Proper parties to the agreement (ie legal entities contracting) NOT investigator but NHS Trust as party to the agreement. The NHS Trust is responsible for the patient care and not individual investigators (NHS corporate governance);

2. ensure sponsor is established in the EEA or has UK legal representative;

3. if CRO involved, include both CRO and Sponsor as parties to the agreement

4. company name, registered address and registered company number (http://www.companieshouse.gov.uk/- to verify) – helpful to ensure that you are contracting with the correct entity – NOTE: company may change its name but registered company number will remain the same;

5. authorised signatory to the agreement – ie Director of Research/ Chief Executive on behalf of NHS

6. Ensure all appendices are included in the final agreement for execution
Clause 3.6 - provides that terms in the protocol will apply where they are inconsistent with the terms of the agreement therefore need to review terms in protocol to look out for areas that may be inconsistent with the agreement and see if they are acceptable eg:

- publication - (restrictive rights to publication may be inconsistent with NHS Research Governance guidelines),
- termination clauses - (there may be further reasons for termination by the sponsor in the protocol and these may not provide for NHS Trust to be ‘compensated’),
- any conditions for payments or withholding of payments – cross check with Financial Arrangements in Appendix 5 etc.
Indemnity provisions

• Liabilities and Indemnity – forms of indemnity, insurance, guidelines, NHS insurance coverage:

• Clause 5 – indemnity by Sponsor of any claims against NHS Trust for personal injury (including death) of participant is essential;

• Appendix 4 - ABPI Form of Indemnity – use template and it is strongly advised that this is not altered by either party
Indemnity ctd.

- Appendix 3 – ABPI Clinical Trial Compensation Guidelines – use template. It is strongly advised that this is not altered by either party.

- Note that the compensation guidelines are not intended to be legally binding and we are relying on the good faith of the Sponsor to apply the guidelines when a claim for compensation is made.

- No fault compensation – i.e. no need to establish negligence of sponsor for compensation to be paid however, caveat is that sponsor will not indemnify NHS Trust where injury/death is the cause of NHS Trust’s negligence.

- Insurance – provision in mCTA to decide on the level of insurance. Amount dependent upon perceived risk of trial but usually £1 to £2 million per occurrence;
Insurance

- Proof of Insurance – can request production of copy of insurance certificate to confirm insurance limits and currency although insurance certificates generally state that they are for information purposes only and not to be relied on as statement of coverage.

- Clause 5 provides for reciprocal indemnity for claims related to damage to property. NHS Trusts may not have appropriate insurance cover to provide such indemnity. Would try to negotiate removal of the provision of indemnity on part of the NHS Trust or to limit liability to say the maximum contract price or cost of equipment etc., depending on the type of property envisaged.

- Intellectual property – ensure that ownership or transfer of any IP to Sponsor are those directly related to study not incidental discoveries of researchers/ NHS Trust;

- ensure that patient records, doctor’s notes etc are not part of the documents usually referred to in this clause;
• Data storage – ensure that storage of data exceeding NHS Trust or regulatory requirements are at the cost of the sponsor especially when the periods for storage of data may vary depending (eg where sponsor is applying for FDA approval);

• access to personal data – Data Protection Act applies – there must be consent and more importantly data shared with sponsor must be in an anonymised format.

• Early Termination – Sponsor may wish to terminate the agreement / clinical trial for commercial reasons (other reasons set out in clause 12). Clause 12.6 specifies that in the event of termination for reasons other than those set out in the agreement, the sponsor shall make a compensatory payment as set out in Appendix 5. Include a provision for the level of compensation but ensure that it does not become a penalty (ie a sum far exceeding the losses suffered by early termination).
• Clause 10 and Appendix 5 - Financial Arrangements

• Look out for clauses that withhold payment and ensure that the conditions for withholding payment are not too onerous;

• Similarly, condition for payments for screening costs etc of ineligible patients – depends on each trial, recruitment, and at times;

• Insert appropriate compensatory payment clause per clause 12.6 here.

• FDA Financial Disclosure - Increasingly, sponsors are incorporating FDA Financial Disclosure forms for signature of the Investigator. This is covered by declaration in Appendix 6 so preference would be to remove such forms.