



# **Igniting our potential**

**UK Clinical Research Collaboration**

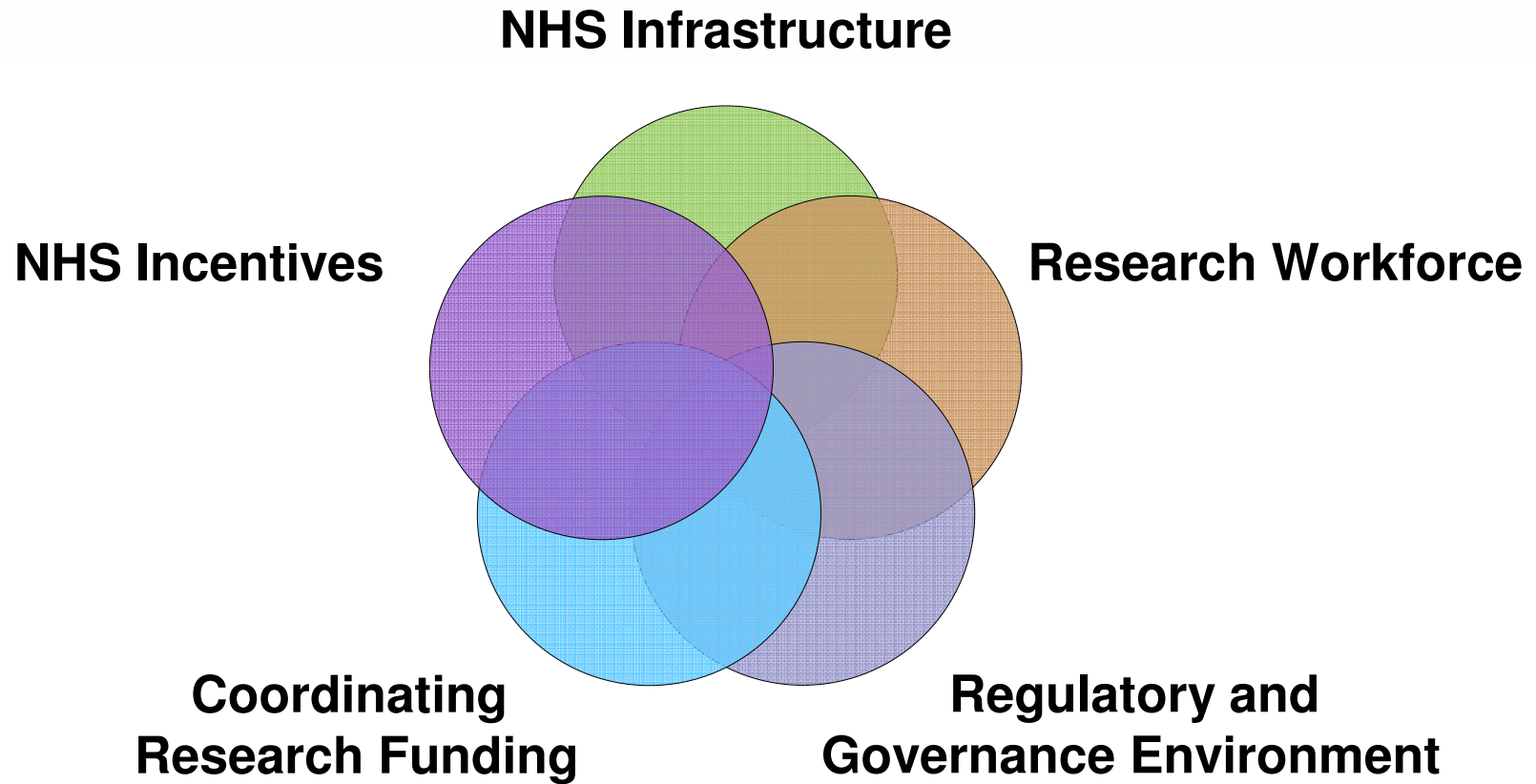
**The model non-commercial agreement**

**NHS R&D Forum Conference  
13<sup>th</sup> May 2008**

# Outline of session

- ▶ Background and context
- ▶ Use of the agreement
- ▶ The clauses and schedules
- ▶ Discussion and questions

# UKCRC Activities



# Streamlining the R&G environment

## ▶ **Bottle-necks and barriers**

- ▶ Lack of consistency and duplication with administration and IT processes
- ▶ Variation in interpretation of regulations

## ▶ **Focus of activities under the UKCRC Umbrella**

- ▶ Streamlined approach for R&G Applications
- ▶ Research Passport for Honorary Contracts
- ▶ Restructuring NHS R&D Permissions
- ▶ Suite of model agreements
- ▶ Consistent approach to advice provision
- ▶ Early engagement with regulatory change

# UKCRC Model Agreements (1)

## ▶ **Why are they needed?**

- ▶ To document the roles and responsibilities of the parties involved

## ▶ **What is the issue?**

- ▶ Negotiating agreements between sponsors and sites carrying out research can lead to long delays and variation

## ▶ **Why is it important?**

- ▶ Supports efficient study set-up
  - ▷ Time
  - ▷ Cost
- ▶ Works with and supports other activities to improve the R&G environment

# UKCRC Model Agreements (2)

- ▶ **Suite of model (template) agreements:**
  - ▶ Pharmaceutical and biopharmaceutical clinical trials (mCTA)
  - ▶ Clinical trials employing a contract research organisation (CRO; CRO mCTA)
  - ▶ Clinical investigation of medical devices (mCIA)
  - ▶ Non-commercial research in the Health Service (mNCA)

# Development of the mNCA (1)

- ▶ Project Group
  - ▶ Medical Research Council
  - ▶ Medical Schools Council
  - ▶ NHS R&D Forum
  - ▶ UK Clinical Research Collaboration
  - ▶ UK Health Departments
  - ▶ Representatives from universities and networks
- ▶ Supported by Mills & Reeve

## Development of the mNCA (2)

- ▶ Involved multiple stakeholders
- ▶ Consultative process
- ▶ Very complex project
  - ▶ Stakeholder views
  - ▶ Building consensus
  - ▶ Negotiation
  - ▶ Changing environment

# Scope of the mNCA

- ▶ Between non-commercial Sponsor(s) and site
  - ▶ Non-commercial Sponsor(s) developed protocol
  - ▶ Site carrying out research
- ▶ UK-wide
- ▶ “Multi-purpose” (clinical trials, device studies, patient data, research using human tissue etc)

## The mNCA is not designed for:

- ▶ Commercial research
- ▶ Collaborative studies e.g. where site has contributed to protocol design
- ▶ Research involving patients (or their data) when treatment outside the NHS
- ▶ Independent GPs undertaking research on behalf of PCT
- ▶ Use by individual employee carrying out research in personal capacity

# Format of the mNCA

- ▶ Agreement
  - ▶ Standard clauses to give consistency
  - ▶ Schedules to give flexibility
- ▶ Guidance
  - ▶ Detailed information on use
  - ▶ Completion of the agreement
  - ▶ Explanation of clauses



## The model non-commercial agreements

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Gill Thomas



The right direction for legal advice,  
wherever you are.

# The legal provisions

- **Overview of the terms and conditions**
- **The difficult issues**
  - Liabilities and indemnity
  - Publication
  - Intellectual property rights

# Structure of the legal terms (1)

- **Definitions**
- **Study governance**
- **Obligations**
- **Liabilities and indemnities**
- **Confidentiality, data protection and freedom of information**

## Structure of the legal terms (2)

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- **Publicity**
- **Publication**
- **Intellectual property rights**
- **Financial and supplies management**
- **Term**
- **Suspension or early termination**

## Structure of the legal terms (3)

- **Modification and authority of co-sponsors**
- **Force majeure**
- **Notices**
- **Assignment and subletting**
- **Dispute resolution**
- **General**

# Liabilities and indemnity

- **General approach to liability issues – party responsible for any loss/injury takes legal liability**
- **Indemnity**
  - Limited in scope
  - Where all parties are NHS bodies
- **No cap on liability**
  - The exception to this rule
- **Exclusion of liability for economic losses etc**

# Publication

- **Balancing different interests of Sponsor/NHS Organisation**
- **First publication by Sponsor – but an obligation to do so**
- **Sponsor must consent to NHS Organisation publishing – but must act reasonably**
- **Acknowledgement of obligation on NHS bodies to publish under RGF**

# Intellectual property rights (1)

- **Definition of intellectual property rights – in Guidance**
- **Ownership of Intellectual property rights: Sponsor**
  - Sponsor's pre-existing intellectual property rights
  - Intellectual property rights arising directly out of the study
- **Ownership of Intellectual property rights: NHS Organisation**
  - Its pre-existing intellectual property rights
  - Improvements, clinical procedures, intellectual property rights arising indirectly out of the study

## Intellectual property rights (2)

- **Third parties involved in carrying out research**
  - model assignment
- **Property in biological material**
- **Use of intellectual property arising from the study**

## In summary

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- **User friendly**
- **Concise**
- **Robust**

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▶ Questions?

<http://www.ukcrc.org/activities/modelagreements.aspx>

[www.ukcrc.org](http://www.ukcrc.org)