The Role of Model Agreements

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• To provide clarity between, and to legally bind, the Sponsor (as Controller) and the Site (as Processor) as to:
  – How the anonymity of pseudonymised data will be ensured and/or
  – How the Safeguards required to process Personal Data will be enacted

Which “Model Agreements”?
**Which “Model Agreements”?**

- model Clinical Trial Agreement (mCTA)
  - CRO mCTA and Primary Care mCTA
- model Clinical Investigation Agreement (mCIA)
  - CRO mCIA
- model Non-Commercial Agreement (mNCA)
- model Industry Collaborative Research Agreement (mICRA)
- Organisation Information Document
  - Data Processing Only OID
- PIC Data Processing Agreement

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**Purpose of the Model Agreements**

- UK Policy Framework for Health and Social Care
  - Clarity on roles and responsibilities
- Finance, indemnities, IPR, transparency, etc.
- Confirmation of Capacity and Capability
- GDPR Article 28 (3) requirement for data processing agreement
- UK MODEL TEMPLATE AGREEMENTS
  - Consistency, reduced bureaucracy, assurance.

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**mNCA Clauses**

- Recitals
- Definitions
- Obligations of the Parties
- Liabilities and Indemnities
- Confidentiality, Data Protection and Freedom of Information
- Publicity and Publication
- IPR
mNCA Clauses

- Finance and Supplies
- Term and Termination, Agreement and Modification
- Notices
- Assignment and Subcontracting
- Dispute Resolution
- General
- Surviving Clauses and Governing Law

mNCA Schedules

- Summary of Study Arrangements
- Division of Responsibilities and Delegation of Activities
- Study Support Arrangements
- Material Transfer Provisions
- PI Declaration

Confidentiality, Data Protection and Freedom of Information

- Data Protection
- Data Processing Terms
- Data Sharing Terms
- Freedom of Information
- Confidentiality
Data Sharing Terms

- Disclosed only when necessary
- Purpose limitation
  - Limitation on onward disclosure
- Bind Sponsor to GDPR Principles (Article 5)
- Sponsor bound to ensure anyone processing:
  - Understands security obligations and only discloses for lawful and appropriate purposes
  - Has contractual personal accountability, including sanctions for breaches of confidence or misuse

Data Sharing Terms

- Sponsor bound to proactively prevent breaches and respond to incidents and near misses:
  - Limit access to right people for right time
  - Ensure IT access is audited
  - Continual improvement
  - Identify and resist cyber attack and respond to external advice
  - To act immediately on breaches and near misses
- Sponsor bound to use secure and up to date technology
  - Supported software
  - Base cyber security strategy on proven framework
  - Ensure suppliers are contractually accountable for processing
Next Steps

- GDPR mCTA
  - Optional clauses to protect anonymity of pseudonymised data (warranty to not identify, etc.)
  - OR ensure safeguards in place for processing Personal Data
  - UK SW review of IG based on contract, not IRAS
  - UK SW review of IG at the Sponsor level, not study by study
- Revisit mNCA, Organisation Information Document, etc.

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