**C O N T R A C T S – are you entering into research contracts?**

Are there plans to enter into any contracts on foot of this research study, or have contracts already been entered in to? **Y/N** If yes,

|  |  |  |
| --- | --- | --- |
| **Type of Contract** | **Between** | **And** |
| *(e.g. data controller-processor agreement, data controller – data controller agreement, material transfer agreement etc.)* | *(e.g. Beaumont Hospital)* | *(e.g. Royal College of Surgeons in Ireland)* |
|  |  |  |
|  |  |  |

**Noting that it can be difficult to make an assessment as to whether contracts are required, questions to consider are as follows:**

Who / Which organisation did you name as the Data Controller in the Application Form and the DPIA?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 If you named a person, which organisation stands behind this person? \_\_\_\_\_\_\_\_\_\_\_\_

Will the organisation named as Data Controller be entering into contracts with any other organisation? **Y/N**

Revisit the table above after answering these questions…..

Have you indicated in the Application Form or DPIA that you are planning to send data or samples outside the hospital? **Y/N**

Which person/organisation did you state in the Application Form or DPIA that you are sending data / samples to? \_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you named a person, which organisation stands behind this person? \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Will the hospital be entering into a contract with this organisation? **Y/N**

Revisit the table above after answering these questions…..

Have you indicated in the Application Form or DPIA that another person / organisation will be providing a service / assistance in respect of this study e.g. transcription services, storage services (including cloud)? **Y/N**

If you named a person, which organisation stands behind this person? \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Will the hospital be entering into a contract with this organisation? **Y/N**

Revisit the table above after answering these questions…..

Have you indicated in the Application Form or DPIA that this study is in receipt of funding from any other organisation? **Y/N**

Will the hospital be entering into a contract with this organisation? **Y/N**

Revisit the table above after answering these questions…..

Have you indicated in the Application Form or DPIA that this study is sponsored by any other organisation? **Y/N**

Will the hospital be entering into a contract with this organisation? **Y/N**

Revisit the table above after answering these questions…..

**Contracts required under GDPR: -**

1. A data controller-to-data controller agreement

Or

1. A data controller-to-data processor agreement

(these agreements can be annex to the over-arching study contract / agreement)

Such agreements are study-specific and the applicable law is GDPR.

**Not all contracts entered into will be for the purposes of fulfilling GDPR requirements however.**

**“Content of GDPR-Related Contracts or Annexes will include:**

* the terms of the agreement
* regulatory compliance
* obligations of the data controller / processor
* right of audit
* data subjects rights
* liability and indemnity
* resolution dispute with the data subject of Data Protection Commissioner (DPC)
* termination or variation of the agreement
* © Mary Kirwan, Barrister-at-Law,
* CMG Training, Health Research and GDPR, 18 May 2021”

**“Typical headings/points addressed within Data Sharing/Transfer/Processing Agreements include, but are not limited to, the following:**

1.       Definitions e.g. “data”, “confidential information”, “Data Controller”, “data Processor” etc

2.       The terms of the agreement

3.       Confidentiality clause

4.       Obligations of Data Controller and Data Processor

5.       Data Subject Rights

6.       Intellectual Property/Results Rights

7.       Publication e.g. first publication rights etc

8.       Compliance with Applicable Laws

9.       Liability and Indemnity

10.   Representation and Warranties

11.   Right of Audit (if applicable)

12.   Duration of Agreement

13.   Termination of Agreement (may include early termination clause outlining in which circumstances same is permitted)

14.   Assignment clause (usually not permitted)

15.   Force Majeure (if applicable/needed)

16.   Severability and/or Counterparts

17.   Governing Law

18.   Dispute Resolution Clause (e.g. for arbitration or mediation in case of dispute)

19.   General Terms and Conditions, Modifications, Notifications etc

These clauses can be tailored in order to suit the particular agreement being drafted.

- © Róisín Bradley, Barrister-at-Law Candidate, Legal Executive,

* Legal Services Department, Beaumont Hospital, 7th September 2021”