**Checklist Compliance with HSE RGMS Framework (Sept 2021)**

(draft, September 2022)

**Investigators – Terminology and Indemnity**

Multi-site studies:

The framework changes the terminology of Principal Investigator to Chief Investigator for multi-site studies.

The framework changes the terminology of Lead Co-investigator at the Site to Principal Investigator at the site for multi-site studies.

Single-site studies:

The framework retains the terminology of Principal Investigator for single site studies.

The State Claims Agency have indicated that Principal Investigators should be Delegated State Authority (DSA) clinicians.

Clinicians are healthcare professionals

The HSE is a DSA, Voluntary Hospitals are DSAs, Beaumont Hospital is a DSA

DSA clinicians are clinicians employed by the DSA

**Over to you:**

1. For multi-site studies, check if the principal investigator (previously called lead co-investigator) at the DSA site is a DSA clinician.
2. For single-site studies, check if the principal investigator is a DSA clinician.

**Investigators – Terminology and Controllership**

The framework requires DSA clinicians who hold a dual affiliation to decide which organisation (i.e. the HSE, voluntary hospital, academic/other organisation) they will represent for the whole duration of the research study. **(NB)**

The framework states that this is a vital requirement for the **correct determination of controllership.**

**Over to you:**

1. For all studies, check if any investigators have a dual affiliation / joint appointment and which organisation they will represent for the entire duration of the research study

**Data Controllers**

The framework defines data controllers -  *‘The data controller for a research study is the organisation that determines the purpose and the manner by which personal data are processed for the research study (i.e. ‘Whom’, ‘Why’, ‘How’).’*

This marks a shift away from individuals as data controllers.

(Where two or more organisations determine the purpose and manner by which personal data are processed, these are called joint data controllers)

The framework defines data processors:  *‘A data processor is defined as the organisation that processes personal data on behalf of, and under the instruction of, the data controller (i.e. two distinct organisations).’*

This marks a shift away from individuals as data processors

The framework emphasises that data controllers and data processors are different organisations.

**Over to you:**

1. For all studies, check which organisation is the data controller.
2. For all studies, check if there are joint data controllers (two or more organisations – joint data controllership)
3. For all studies, check which organisations are the data processors (if any)

**Clinical Trials**

The framework defines a clinical trial as a study which seeks to assign participants to one or more interventions.

It states that all clinical trials must have a sponsor, and the sponsor is the data controller for the clinical trial in all cases.

In addition, State Indemnity Guidance (SIG) 10.03 requires that the principal investigator of a clinical trial be a medical practitioner.

**Over to you:**

1. Check if your study is a clinical trial
2. Identify the sponsor for the clinical trial
3. The sponsor will also be the data controller
4. Confirm the principal investigator is a medical practitioner

The State Claims Agency released SIG 10.03 on the 10th May 2022 – The SIG makes compliance with the HSE RGMS Framework a requirement in respect of clinical trials between DSA healthcare enterprises and academic institutions. Importantly, it requires approval of the DSA itself for the trial to proceed.

In Beaumont Hospital, the process for approval of the DSA for clinical trials is outlined here: <https://www.beaumontethics.ie/home/sign_off.htm>

**Studies other than clinical trials**

The framework states that studies which are not clinical trials do not have a sponsor.

These studies have a legally responsible organisation / entity – there may be several legally responsible organisations responsible for different aspects of the study: - *“As there may be one or more legal entities, it is therefore essential that the responsibilities of each entity with regard to the different aspects of the research study are articulated and agreed in advance. These aspects include:*

* *financial responsibility,*
* *responsibility for the indemnity and insurance for the research,*
* *responsibility for compliance with data protection legislation,*
* *responsibility for research misconduct,*
* *responsibility for rights related to intellectual property generated from the research,*
* *responsibility for compliance with HSE policies and procedures and other standards of good practice.”*

**Over to you:**

1. Confirm your study is not a clinical trial
2. Identify which legally responsible entities are involved, and what each organisation is responsible for.

The State Claims Agency plans to release guidance in relation to studies which are not clinical trials, this will include a requirement for compliance with the HSE RGMS framework, and importantly will include a new requirement for approval of the DSA itself for the study to proceed.

In Beaumont Hospital, the process for approval of the DSA for studies is outlined here: <https://www.beaumontethics.ie/home/sign_off.htm>

**Additional Check – Studies taking place in Beaumont Hospital**

(draft, September 2022)

If reviewing a study to check for compliance with the RGMS Framework, please also consider: -

1. Has a DPIA been conducted? Does it need to be reviewed? Does one need to be conducted? It is best practice to conduct a DPIA.
2. Have contracts been entered in to with the hospital? Does a contract need to be entered in to?