**Quotes from the HSE National Office of Research and Development Framework for the Governance, Management and Support of Health Research (RGMS Framework), Sept 2021**

**Research Ethics Opinion**

‘Research Ethics opinion should be independent and separate from institutional governance’

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**Identifying Data Controllers and Processors**

**‘**Data protection law requires clear, factual and formal identification of controllership (e.g. sole / separate / joint controllers, data processors).

* page 18

**NB** ‘The sponsor…takes responsibility as data controller for the clinical trial’

* page 18

‘The HSE is always the data controller of the personal data it holds for the performance of its statutory functions, including the provision of healthcare. An employee of the HSE will act as an employee of the data controller in the normal course of their duties (e.g. healthcare, clinical audit, quality management) but NOT always for research.’

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‘The HSE is not the data controller for personal/health data held in Section 38 acute hospitals which are legally independent organisations with respect to compliance with data protection legislation.’

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‘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’). ‘

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‘If the organisation takes these decisions with another organisation, they must specify the nature of their respective controllership (i.e. separate or joint controllers).’

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‘Controllership is determined based on the factual elements and the circumstances of the research study, and the type of controllership determines the roles and responsibilities of the organisation.’

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**NB** ‘A PI employed by a healthcare delivery organisation (i.e. hospital, community or national services) acts as the employee of the data controller and is not, (in his own right), the data controller of personal data held by the organisation employing them. In such cases, the PI acts on behalf of the data controller and is responsible, along with the data controller, for ensuring compliance with GDPR and S. 36 (2) (Health Research) of the Data Protection Act 2018 and subsequent amendments.’

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‘In limited circumstances it is possible for the PI to act as data controller if not acting as an employee of the HSE.’

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**NB** ‘Where HSE staff hold a dual affiliation, they must decide which organisation (i.e. the HSE, or the academic/other organisation) they will represent for the whole duration of the research study, and this determination must be done and confirmed in writing with the RGMS before the start of the research study. This is a vital requirement for the correct determination of controllership between the collaborative organisations.’

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‘A data processor is anyone who processes personal data on behalf of the data controller following strict instructions. Data processors should solely process data as requested by the data controller, and must be a separate legal entity from the data controller. A processor becomes a controller if it does not follow the controller’s instructions.’

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**NB** ‘Where an employee of the HSE collaborates on a research study with a third-party, the HSE governance arrangements should ensure that such a situation is appropriately registered. An appropriate determination of controllership must be done based on factual elements and the circumstance of the research study to determine if the HSE (and the PI or researcher it employees acting on its behalf) acts as a controller or processor for the purposes of the research study.’

* page 27

‘For the avoidance of doubt an employee of the HSE cannot act as a data processor of personal data for the provision of healthcare.’

* page 27

‘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).’

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**NB** ‘Disclosure of personal data that is held by the HSE to a third party is a processing operation, but such disclosure does not make the HSE a data processor.”

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**Plans in respect of data governance**

“The implementation of the framework will require the development of **Research Offices** at local, regional and national levels to coordinate these services and support staff to obtain the relevant approvals, **as well as streamlined involvement of the relevant Data Protection officers for the host services when required**.”

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• <https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf>