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Information Governance Information for Organisations Participating in Research Studies – Joint Statement (HRA, RRDN and R&D Forum)

From:	The Health Research Authority (HRA) in its role as provider of a unified national system for the governance of health and care research. Supported by the RRDN and the NHS R&D Forum (to share with their networks), and in alignment with ICO approved guidance
To:	Organisations providing health and social care services - especially those in primary care (GPs) - their R&D staff, and their DPOs
Key Messages:	● You should rely on assurances in IG matters reviewed as part of HRA/HCRW Approval when participating as a research site, based on which: ○ You should **not** need to carry out or ask to see study specific DPIAs where any high risks have been mitigated already and reviewed as part of the (HRA/HCRW approved) study design; ○ You should **not** modify template agreements except as set out in the Approval Letter. **Organisations that undertake their own modifications create additional risks to their organisation as they will not be indemnified by the HRA and HCRW.** ● Take reassurance from a new IG standards framework under development for digital service providers requiring data protection by design and default when processing data for research studies (including in respect of data extraction from GP systems)

Introduction

Information governance (IG) is all about how to manage, use and transfer information safely and securely. This is as true for health and social care (HC) research activities as other types of HC activities. However, IG in research has a distinct national oversight infrastructure compared to other types of HC activities. This infrastructure enables those involved in delivering and managing research, including data professionals (such as Data Protection Officers (DPOs)), to rely on IG assurances provided as part of study approval, and accordingly to act differently than they might otherwise do in a non-research setting.

We are looking at ways to increase awareness in such staff of the standards and processes relating to IG in HC research, with whom we share a common goal of making sure confidential information is used safely and securely in research. We want to do more to make sure that IG guidance is clear and consistent for everyone doing HC research. This will make it easier for people to do research that people can trust. At the same time, it should reduce duplicate work in the system related to local (site-level) checks and reviews being carried out in respect of HC research, not least by streamlining variability of IG interpretations and processes based on aligned assurances. It also complements work we are doing to standardise and coordinate research approvals.

This document is a starting step in this ambition. It sets out the existing processes for IG compliance, and describes how IG is assessed by dedicated staff, and assurances provided, as part of HRA and Health Care Research Wales (HCRW) Approval. It also introduces new

plans to better achieve simple and consistent compliance with IG standards for research across the NHS.

A summary of existing IG guidance

The HRA is the body nominated to publish guidance on the implementation of the UK GDPR and the supplementary Data Protection Act 2018 for HC research. This guidance was co-developed between HRA and the Information Commissioner's Office (ICO) and is linked below. It outlines the areas in relation to which IG assurances can be drawn.

First, the HRA's GDPR guidance interprets UK GDPR, to help organisations understand the specific provisions relating to research and their implications for the delivery of research in the UK. This guidance is aimed specifically at researchers and study coordinators managing individual research projects, as well as containing important information for those delivering and supporting studies at sites. It includes guidance on data protection impact assessments (DPIAs) intended to avoid sites duplicating reviews carried out at a sponsor (data controller) level to ensure compliant research studies through design and default. More detail is included in the complementary technical guidance relevant at an organisational level for NHS R&D offices, university research offices, company senior managers, DPOs, IG leads and security architecture leads.

Alongside this guidance, the HRA publishes several templates containing standard transparency wording to be made available to research participants to ensure they have the legally-required information about processing of personal data for research studies they are invited to participate in. See, for example, Patient Data and Research leaflet - Health Research Authority (hra.nhs.uk). These templates were also developed with streamlining considerations in mind – in particular, to avoid sponsors and participating sites developing lots of different forms for researchers to complete.

HRA and HCRW Approval brings together the assessment of governance and legal compliance of prospective research studies, undertaken by dedicated staff, together with the independent ethics opinion by a Research Ethics Committee (REC). HRA and HCRW Approval includes a study-wide review conducted to UK-wide agreed standards. It is designed to provide NHS organisations with assurances that approved studies would be compliant with relevant laws and other applicable standards, when conducted in accordance with the approved documents. Accordingly, the UK Study-wide governance criteria are the criteria that studies must meet and against which HRA and HCRW (or our devolved administration partner organisations, where a study is led from another UK nation) review studies in order for us to issue approval. These criteria are published for reference by research sponsors and by other key parties who support researchers seeking HRA Approval to support their study design and submission. Updated in 2021, further detail was added to the criterion 'Compliance with Data Protection law and data security issues assessed' to clarify the assurances that should be taken from HRA and HCRW Approval.

In summary, HRA and HCRW Approval includes a review by dedicated staff of compliance with data protection law and IG standards on behalf of participating NHS organisations. The assurance provided by Approval therefore provides protections for all parties, alleviates burden on sites and sponsors by providing reassurance (thus removing a need for duplicate reviews), and brings greater speed and efficiency to research set-up and delivery. Indeed, NHS organisations that undertake their own site-level reviews create additional risks to their organisation as they will not be indemnified by the HRA and HCRW.

IG survey

We recently shared a survey about existing IG arrangements for research across the NHS. This survey was designed to gather information on why organisations participating in HRA and HCRW Approved research are undertaking additional local IG reviews that may not be

necessary, and where such additional reviews are occurring at a participating NHS organisation level.

The survey was also intended to promote greater awareness of the updates already made to the study-wide criteria around IG compliance, and to assess whether further clarifications would prove useful either to the study-wide criteria or the outputs of HRA and HCRW Approval.

For example, we have already identified a need to clarify further why it is not necessary for participating NHS organisations to modify the wording of model agreements. Another area for clarification regards DPIAs not being necessary at a site-specific level for each study ((because the sponsor need only undertake DPIAs at the level of their quality management system, via their sponsor policies and via the processes by which they design and manage their research portfolios). In respect of both areas, the Approvals review process provides assurance that IG compliant research has been designed according to standard processes and templates in alignment with the study-wide review criteria. **As such, any high risks to individuals will have been mitigated by data protection by design and default (through appropriate technical and organisational measures being required), and additional reviews (including DPIAs) are unnecessary to assess and demonstrate compliance with IG principles and obligations.**

The HRA is finalising its analysis of the survey and will be engaging with respondents, both to understand the issues reported in due course and to publish new or updated guidance as necessary.

New IG guidance around GP software installation and data extraction

We have also identified confusion around the requirements relating to data extraction from electronic health records. This is an area that HRA and HCRW Approval does not cover where it concerns potential sites providing access to data before a study begins. However, we plan to publish new guidance to help potential sites (in particular, GPs considering taking part in research requiring the extraction of data) undertake the necessary local checks, including security arrangements, relating to installation of a particular piece of third-party software on their own electronic health systems.

Such guidance will set out the criteria that should be met (to ensure IG standards are upheld) by any third-party digital service provider processing data for a purpose for which the potential research participating organisation (i.e., the GP) is data controller. These criteria should also be considered as part of a data processor agreement concluded in advance of participation. Every digital service provider should also be able to demonstrate they meet the necessary standards, including via production of a DPIA that their policies and processes are IG compliant to provide reassurance for sites on IG issues when considering participation. (Again, this should preclude the need for study-specific DPIAs).

It is intended that such guidance will also align with plans for creation of an HRA-approved IG standards framework for third party digital service providers as part of the Find, Recruit and Follow-up (FRF) programme. That programme aims to harness the potential of health data and digital tools to support effective, efficient trial delivery and wider participation in research across the UK (as outlined in The Future of UK Clinical Research Delivery and its associated implementation plan).

A new national IG group to provide advice on study specific issues

A new group will be established this year to provide advisory IG support to health and care research participating organisations based in England and Wales. This new group will act as a point of national advisory expertise and escalation, providing support with IG and data related issues through a single, direct referral route via your local RRDN or Lead RRDN. The aim is to promote consistency of advice and reduce duplication of queries across different stakeholders.

For more information, please email Dr Alison Knight, the HRA's Data and Privacy Specialist (alison.knight@hra.nhs.uk), who is also a member of the Health and Care IG Panel Working Group.