New template clinical research agreements published by the Health Research Authority

Published 28 February 2022

The Health Research Authority ("HRA") has published its eagerly awaited template agreements for commercial non-interventional research being carried out at NHS sites. These are the first UK templates designed for this purpose.

The HRA has also prepared a template confidentiality agreement, which it encourages sponsors to use with NHS sites in order to formalise the early sharing of information in connection with proposed clinical research.

Non-interventional study agreements

The HRA has developed two template agreements for commercial non-interventional research with NHS participants throughout the UK:

- The 'mNISA', which is entered into between the sponsor and the NHS site; and
- The 'CRO-mNISA', a tripartite agreement for use when the sponsor has engaged a contract research organisation.

As with the existing HRA template agreements, the mNISA and the CRO-mNISA are designed to be used without modification, in order to reduce the time, cost and resources needed to set up commercially sponsored studies.

This aim is in line with one of the key themes of the Department of Health and Social Care's 'UK Vision for Clinical Research Delivery', namely to ensure that the UK is seen as the best place in the world to conduct streamlined, efficient and innovative research.

The templates are designed to be used for non-interventional research involving pharmaceuticals or medical devices, and are based largely on the existing HRA templates for industry-sponsored clinical trials and investigations. As to be expected, however, there are some important differences in how the NISA and CRO-mNISA address issues such as liability, indemnities and compensation for study participants.

The HRA is strongly encouraging all sponsors and NHS sites to begin using these templates now, without modification, for maximum speed and benefit in relation to the set-up phase of commercial non-interventional research.

Confidentiality Agreement

The HRA has also prepared a template confidentiality agreement to govern the sharing of confidential information between the sponsor and prospective participating NHS sites prior to execution of a clinical research agreement.

The HRA's aim is, again, to help make the early sharing of information, for feasibility and site set-up purposes, clearer, more consistent and efficient, in line with the UK Vision for Clinical Research Delivery.

NHS sites and sponsors may of course have their own standard confidentiality agreements but HRA's intention is to provide a 'recommended template' with the aim of reducing negotiation time between sites and sponsors and promoting greater consistency of terms across sites.

Accessing the templates

All 3 templates are available via HRA's Integrated Research Application System ("IRAS") website.

The templates are published as 'consultation in use documents' and feedback is encouraged to the relevant contacts in each of England, Wales, Scotland and Northern Ireland, as set out on the IRAS website.

Authors

Andrew Johnston
London - Walbrook
+44 (0)20 7894 6532
ajohnston@dacbeachcroft.com

Alison McAdams
London - Walbrook
+44 (0)20 7894 6588
amcadams@dacbeachcroft.com

Olya Melnitchouk
London - Walbrook
+44 (0)20 7894 6596
omelnitchouk@dacbeachcroft.com

DAC BEACHCROFT