Cross-border arrangements for provision of NHS R&D local site-specific information for cross-border studies

As part of the roll out of Health Research Authority (HRA) Approval in England, operational and policy leads from the 4 Nations have worked closely to ensure compatibility of NHS research approval systems across the UK.

As part of this, over the next 6 months, the 4 Nations have committed to review the information required for study approval/confirmation of capacity and capability at the local NHS site level. This is with the aspiration of coming to a common UK position, that supports the timely set-up of studies and that meets the needs of sponsors, research sites, NHS patients and service users.

This review will be facilitated through a series of workshops involving operational and policy leads from across the UK. Until further UK-wide guidance on local information can be agreed and issued, the interim position for management of local NHS site information is as follows:

- Site Specific Information (SSI) forms will continue to be used for setting up studies in the devolved administrations (DAs).

- The above includes research studies that are sponsored/led from England with research sites in a DA, where the DA will continue to use SSI forms.

- Where research studies are sponsored/led from a DA with sites in England, the HRA will accept SSI forms.

- For DA-led studies, the HRA Approval team will facilitate the completion of any additional information requirements in England in order to review the study and will confirm with the sponsor that the information is correct.

- Sponsors from a DA (or authorised delegates) are advised to contact the HRA at the earliest opportunity so that the HRA Approval team can facilitate the review of the research study for English sites.

The above arrangements will be reflected in updates to operational guidance documents, including the HRA Approval Q&A.