Health Research Authority – new approval process for research

08 March 2016

HRA Approval is the new approval that will be required for all research to commence in the NHS in England. It is a new process that comprises of a review by a Research Ethics Committee (REC) as well as an assessment of regulatory compliance and related matters undertaken by staff of the HRA located in centres around England. It will include study-wide review in line with UK-wide agreed standards and also new assurances including the coordination of clinical support assurances for radiation and pharmacy.

Once HRA Approval is in place and local capacity and capability is agreed, sites will be able to confirm with the sponsor their readiness to recruit and the study will be able to start at that site.

Applications for HRA approval are made using IRAS (Integrated Research Applications System) and are e-submitted directly to the HRA through IRAS. From the end of March 2016, the combined form on IRAS will be adopted UK wide and a new format for site information will be provided for the UK. For commercial studies, the local information will be significantly reduced and there will be no requirement to submit SSI forms in England. The HRA will continue to test suitable formats for site information for all study types.

Study documents for sites will be provided directly from the Sponsor or via their study teams. HRA studies will not appear in the NIHR CSP module which will be closed to new studies from 31 March 2016.

** For all studies which are currently going through the existing approval process (particularly those using CSP for portfolio studies) HRA and CRN are encouraging the submission of completed SSI forms to allow this process to continue and avoid having to restart the process using the new HRA approval system. Therefore any study with an SSI form submission outstanding should, where possible, be submitted. Please contact your Research Governance Coordinator to discuss your study as soon as possible.**

All new non-Commercial studies will require a completed Statement of Activities and a Schedule of Events, with all the research activity required by sites to run the study itemised and all costs attributed. R&D will need to work with Investigators in order to complete these
documents, and they will need to be in place before submission to HRA. There is the potential for this new process to require more front-loading of work to be done prior to submission to HRA and sites, but this may make the actual set up at sites easier.

Where CUH are to be participating in a research study as a host site, PI’s and R&D departments will be asked earlier about their participation, and the completed document sets received should enable quicker set up as all the research activity will be identified. Cost attribution via the Statement of Activities will ensure funds are available to research sites for non-commercial studies, much as the existing commercial costing template does for studies led by industry. Model agreements are advocated to help with efficient contract review and changes made to these contracts will be highlighted as having the potential to delay study start up.

R&D are currently working on our plans for the local capacity and capability review for new studies together with looking at our processes for Sponsor review. For multi-centre studies with over 10 sites a Study Coordinator will need to be in post to manage the process of study document dissemination.

At this stage, studies solely for educational purposes are not yet included in HRA Approval whilst the HRA continues to collect views on appropriate ways of managing this study type.

If you have any queries or questions or are planning a new study, please email research@addenbrookes.nhs.uk

Further information, guidance documents for applicants, guidance for NHS organisations, illustrative examples, including the new Statement of Activities and opportunities to provide feedback to the HRA are all available on the HRA website

CUH R&D website pages will also be updated to reflect these changes and you can also find R&D contact details for the Governance Coordinators on these pages.