Health Research Authority

Collaborative working between sponsors and NHS organisations in England for HRA Approval studies, where no formal confirmation of capacity and capability is expected.

This document provides information supplementary to the Initial Assessment Letter and/or the Letter of HRA Approval for sponsors and NHS organisations undertaking a study where there are participating NHS organisations in England that are not expected to formally confirm capacity and capability.

This document applies only to working with NHS organisations in England. Where the research also includes NHS organisations in Northern Ireland, Scotland or Wales, the sponsor should set up the study in accordance with the guidance provided by the relevant nations. For non-NHS organisations, the sponsor should work with the individual organisations to obtain management permission to proceed.

It is critical that the sponsor involves both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study.

This document provides an overview of what formal confirmation of capacity and capability means, the implications of not giving formal confirmation and details on what should happen upon issue of the initial assessment letter and HRA Approval letter. It also provides guidance on how to add new participating organisations in England where no formal confirmation of capacity and capability is expected.

1. Overview

1.1. The term "*Formal Confirmation of Capacity and Capability*" refers to the type of confirmation given by an NHS organisation to state that it is ready to commence and deliver a particular study. Such confirmation may be provided either by execution of the agreement to be used in the study or agreeing by email to the statement of activities, where this is used as the agreement.

1.2. For studies where it is deemed that formal confirmation of capacity and capability is not expected, the HRA will notify the relevant participating NHS organisations in England of this and the sponsor will be entitled to assume the participation of these

organisations, without their formal confirmation, unless they elect to opt out of the study or request additional time to consider their involvement. In most cases, the HRA will specify that organisations have 35 days from the issue of the Initial Assessment Letter (or HRA Approval letter where no initial assessment is issued) to consider opting out, or requesting additional time to consider, after which their confirmation will be assumed. In other cases (e.g. urgent public health studies, the HRA might specify a shorter timescale).

1.3. However, participating organisations can confirm their readiness to host the study in advance of the deadline by email to the CI/sponsor, once HRA Approval is in place. This is encouraged.

1.4. Although organisations are not expected to formally confirm their capacity and capability, they may still undertake some activities to assess and arrange their capacity and capability to deliver the study. For these types of studies it is expected that the NHS organisation will take part in the study. For example:

1.4.1. A questionnaire study sent to NHS staff as participants may not entail any assessing or arranging of capacity and capability by the NHS organisation. The sponsor's study team will send the questionnaire directly to identified staff within the NHS organisation. The staff members may be identified by a variety of means but the employing NHS organisation is not asked to provide contact details. It is the decision of each staff member whether they are able and willing to complete the questionnaire. Normal departmental management processes should be followed to determine whether the necessary time to complete the questionnaire is appropriate. No formal confirmation is expected.

1.4.2. An external researcher conducting focus groups with NHS staff as participants will be expected to entail a little assessing (e.g. "do we have the right staff members to participate?") and a little arranging (e.g. booking a room for the focus group, ensuring staff members are aware) but, even so, no formal confirmation would be expected.

1.4.3. Continuing care organisations in a study where it is not possible to know up front which organisations will be participating. Well-designed studies of this type should not expect capacity and capability to be significantly different from that which might be expected to already be in place. As such, there should be no assessing or arranging of capacity and capability to be undertaken, and no institutional agreement should be expected. Organisations will be not be expected to give formal confirmation of capacity and capability, and will be given time to object (if for example they do not in fact host the relevant care service).

These are examples only and there will be other scenarios.

2. Initial Assessment Letter

2.1. The Initial Assessment Letter issued by the HRA will confirm whether all, or some types of, participating organisations are not expected to formally confirm capacity and capability. Where formal confirmation from all or some of the participating organisations is not expected, the letter will also specify the timeline (normally 35 days) for these organisations to object or request more time to consider.

2.2. Where formal confirmation from all or some of the participating organisations is not expected, the HRA will directly notify all participating NHS organisations in England **to which this applies**, to ensure that they have the full period allotted in order to consider their participation in the study, should they need it.

2.3. The HRA will use the R&D Forum website contact details for this notification - so it is imperative that these are maintained up to date by NHS organisations.

2.4. The Initial Assessment Letter (and/or HRA Approval letter) will provide clarity on what activities will be undertaken at participating NHS organisations.

2.5. Whilst the HRA is undertaking further assessments in order to issue a letter of HRA Approval, NHS organisations will have time to, where relevant, assess and arrange capacity and capability.

2.6. Where NHS organisations seek further clarity in order to assess/arrange capacity and capability, they should contact the sponsor to request the relevant information. This does not mean that NHS organisations should routinely request all study documentation.

2.7. Sponsors should work collaboratively with any NHS organisations which request further information to assess/arrange capacity and capability.

2.8. Where an NHS organisation is ready and able to do so, and HRA Approval is in place, the HRA encourages the organisation's research management function to confirm by email to the CI and sponsor that the research may proceed in advance of the no-objection deadline.

2.9. Where an organisation confirms by email that the research may proceed in advance of issue of the HRA Approval Letter, the research should not begin until the Letter of HRA Approval has been issued.

3. Letter of HRA Approval

3.1. The HRA will issue a Letter of HRA Approval to the CI and sponsor when able to do so. It will provide final confirmation regarding all areas of assessment, including whether formal confirmation of capacity and capability is expected.

3.2. The sponsor should provide this letter to all of their participating NHS organisations in England (including the local research team – and for most studies which do not require formal confirmation of capacity and capability the local research team will comprise of a local collaborator at most, the research management function supporting the organisation and, where applicable, the LCRN).

3.3. In some circumstances, the HRA may issue an HRA Approval letter without needing to issue an Initial Assessment letter. In these cases, the HRA Approval letter will be provided to participating NHS organisations in England **to which this applies** by the HRA, and the deadline for organisations to object or request more time to consider will commence from the date of the HRA Approval Letter.

3.4. Where the deadline from issue of the Initial Assessment Letter to object or request more time to consider has passed by the time the Letter of HRA Approval is issued, the sponsor should provide the HRA Approval letter to their participating NHS organisations in England and may commence the study at those organisations which have not objected or requested more time to consider.

4. New Participating Organisations

4.1. Unless otherwise stated in the Initial Assessment Letter and/or the Letter of HRA Approval, HRA Approval applies to those organisations listed on the IRAS form.

4.2. Following HRA Approval, if the sponsor wishes to add further sites to the application an amendment should be submitted.

4.3. The HRA will inform the newly added participating NHS organisations in England that they have been added to the study through an amendment, and that formal confirmation of capacity and capability is not expected.

4.4. The email informing participating organisations will provide a deadline (normally 35 days) to object of request more time to consider. The 35 day deadline will start from the date of the confirmation of continued HRA Approval letter.

4.5. Sponsors and the newly added NHS organisations in England should work collaboratively as per 2.5-2.7 if any further clarifications are requested.

4.6. Where an NHS organisation is ready and able to do so, the HRA encourages the organisation's research management function to confirm by email to the CI and sponsor that the research may proceed in advance of the no-objection deadline.

4.7. Where an organisation confirms by email that the research may proceed in advance of the deadline, the sponsor may commence the research at that organisation once a letter confirming continued HRA Approval has been issued.

4.8. The sponsor should provide the letter confirming continuing HRA Approval for the amendment to all of their participating NHS organisations in England (including the local research team – and for most studies which do not require formal confirmation of capacity and capability the local research team will comprise of a local collaborator at most, the research management function supporting the organisation and, where applicable, the LCRN).