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 required.

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 required 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 and, where applicable, the Local Clinical Research Network) 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 required.

## 1. Overview

1.1. The term "*Formal Confirmation of Capacity and Capability*" refers to the type of confirmation given by an NHS organisation in England 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 in place of an agreement.

1.2. For studies where it is deemed that formal confirmation of capacity and capability is not required, the sponsor should notify the relevant participating NHS organisations in England of the study. 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. A reason must be provided to the sponsor.

1.3. The sponsor will specify the date upon which confirmation of capacity and capability will be assumed (unless the NHS organisation communicates that it will not participate in the study or requires more time to make arrangements). This date will be in line with the information provided in the HRA letters and will normally be a specified number of days from the date on which the sponsor formally notifies the participating organisation by providing then with a complete local information pack. In other cases (e.g. urgent public health studies), the HRA might specify an immediate implementation date.

1.4. It is important to note that the sponsor MUST notify the participating organisation of its intention to assume confirmation of capacity and capability after the defined number of days, by provision of the full local information pack to the local research management function (e.g. R&D office and, where applicable, Local Clinical Research Network) AND (where applicable) the local research team. Failure to do so (including failure to wait for the specified number of days, or otherwise to receive formal confirmation from the participating organisation, before commencing research activities) would breach the terms of the HRA Approval as applicable to commencing research at that organisation.

1.5. Participating organisations may choose to confirm their readiness to participate in the study in advance of the deadline by email to the CI/sponsor, once HRA Approval is in place. This is encouraged, as in many cases there will be no need on the part of the participating organisation to allow the specified number of days to elapse.

1.6. Although there are circumstances in which organisations are not required to formally confirm their capacity and capability, it may still be the case that some activity is needed to assess and arrange their capacity and capability to deliver the study. The statement that no formal confirmation is required is simply an acknowledgement that, for certain types of study and certain activities at site, the assumption is that the participating NHS organisation will have the capacity and capability to commence involvement in the time frame specified, placing the onus on the participating organisation to 'opt-out' (or request more time to make arrangements) where this is not the case. For example:

1.6.1. A questionnaire study sent to NHS staff as participants should not entail any assessing or arranging of capacity and capability at an organisational level 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, to be taken with respect to normal local management processes, 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.

1.6.2. 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.

1.6.3. Studies were an existing participant is transferred to another NHS organisation so that it is not possible to know in advance 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 formal confirmation should be required. Organisations will be expected to put the required arrangements in place to ensure that the participant can remain in the study.

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 required to formally confirm capacity and capability. Where formal confirmation from all or some of the participating organisations is not required, the letter will also specify the timeline for these organisations to object or request more time to consider, following provision by the sponsor of the full local information pack.

2.2. Where formal confirmation from all or some of the participating organisations is not required, the HRA will inform the sponsor of its responsibility to notify all participating NHS organisations in England **to which this applies**, so that that they may put in place any arrangements to ensure their participation in the study.

2.3. The sponsor will be directed to 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. The letter will provide a url to access an excel sheet of the contact details and a password that enables access. This password is updated on a monthly basis.

2.4. The sponsor will also be directed to send the local information pack (under cover of the same email sent to the R&D office, as per the R&D Forum contact details) to the local research team (where these is one) and to the Local Clinical Research Network, if the study is on the NIHR portfolio.

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

2.6. 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.

2.7. 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.

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

2.9. 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.

2.10. 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 assurance 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 (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 should be provided to participating NHS organisations in England by the sponsor, and the deadline for organisations to object or request more time to consider will commence, for those organisations, from the date that the sponsor provides the full local information pack.

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 sponsor 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 required as evidenced by the HRA Approval Letter.

4.4. The email from the sponsor informing participating organisations should provide a deadline (in line with the HRA Approval letter) to object or request more time to consider. The 35 day deadline will start from the date that the sponsor provides the full local information pack.

4.5. Sponsors and the newly added NHS organisations in England should work collaboratively as per 2.7-2.9 if any further clarifications are requested.

4.6. Where an NHS organisation is ready to commence their role in the study, 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 (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).