

1. Clarification of 'Date Site Selected' for studies not receiving HRA Initial Assessment Letter.

In certain circumstances for studies other than clinical trials, the HRA will not issue an Initial Assessment Letter, where the HRA Approval for a study can be issued within the same time frame as undertaking the initial assessment. Therefore, by definition, the local information pack to enable confirmation of capacity and capability will not include this letter. In these cases, the HRA Approval letter should be provided as part of the local information pack. This is in accordance with the definitions, which provide for the HRA Approval letter to be included, where available.

As an interim measure following the full implementation of HRA Approval - and the very large number of applications received - the HRA has temporarily adapted processes to suspend issuing initial assessment letters in some cases, including some clinical trials, and move directly to approval. Where this is the case, and the sponsor has chosen to send the local information pack whilst awaiting HRA Approval, the provision of the local information pack from the sponsor is still expected to reflect the documents submitted in the HRA Approval application and the date that this pack is sent can be considered by the site as the 'Date Site Selected'. Sites are expected to use this information to commence and inform their local set-up. A substitute HRA communication, such as the HRA Approval letter, is not required to commence arranging local capacity and capability. A retrospective HRA Initial Assessment letter will not be issued, as it provides no added value after the HRA Approval letter has been issued.

2. Clarification of 'Date Site Selected' for sites added to HRA approval studies via amendment.

The provision of the HRA amendment validation letter does not provide any additional information to enable local capacity and capability activities for a new site added via an amendment. Sites are expected to commence arranging local capacity and capability based on the local information pack from the sponsor which reflects the current document versions, including any submitted with the amendment to the HRA. This pack does not need to include the HRA amendment validation letter. The date of sending of the pack should be reflected in the 'Date Site Selected' data field. Local set-up is expected to commence prior to HRA Approval and therefore the same principle applies to amendments: the site should issue confirmation of capacity and capability (where required) once the HRA has approved the amendment. For the purpose of completing PID returns, if a delay in completing site set-up occurs as a result of HRA amendment processing, this can be captured by selecting 'A – Permissions Delayed/Denied' and including a brief explanation in the comments section.