This guidance relates to Research Ethics Committee (REC) and NHS arrangements. This is a rapidly evolving situation and guidance will be
1. New studies relating to COVID-19

An expedited review process is available for studies relating to COVID-19 where there are public health grounds for rapid review. The full process for fast-track reviews is set out in the Standard Operating Procedures for Research Ethics Committees.

2. Amendments to existing studies to address COVID-19

- 2.1. Studies where the sponsor wants to add in testing for SARS-CoV-2 for safety purposes
- 2.2. Studies adding new COVID-19 elements

3. Amendments to existing studies impacted by wider COVID-19 response

- 3.1. Changes instigated by sponsors across the study
- 3.2. Changes instigated by individual sites due to clinical requirements
• the NIHR to be classified as an urgent public health study by the Chief Medical Officer
• other regulators, for example the MHRA if the study requires clinical trial authorisation

If an expedited review is agreed, the service can arrange for the application to be reviewed at a scheduled meeting, or for an existing REC to hold an extraordinary meeting, or for a new REC to be formed to consider a particular application.

For studies taking place in the NHS (and/or HSC), the UK study-wide assessment will consider any arrangements to expedite study set-up across NHS organisations.

The Confidentiality Advisory Group provides an expedited review for studies that will involve use of confidential patient information without consent.

2. Amendments to existing studies to address COVID-19 elements

There are a number of possible scenarios where there may be a need to rapidly amend an existing study.

• All amendments requiring submission should use the usual email route, clearly marking them with the subject header: IRAS ref# Amendment - COVID-19, so that they can be expedited.
• For non-substantial amendments, the template non-substantial amendment form may be used. It is acceptable for the form to only be authorised by the sponsor.
For multi-centre studies in Scotland or Northern Ireland, amendments should be provided to the national coordinating functions for dissemination to the participating R&D offices as usual. Sponsors should continue to share with the PI/delivery teams.

For single centre studies all correspondence to sites should be copied to R&D/I department and the PI/delivery teams.

- In England and Wales All correspondence to sites should be copied to R&D/I department and the PI/delivery teams

- Where indicated below, the sponsor should include the category and confirm that no assessment is required. Any amendments meeting these criteria do not need to be sent to HRA/HCRW but should be provided to sites as above.

2.1. Studies where the sponsor wants to add in testing for SARS-CoV-2 for safety purposes

This may be implemented for example where studies include taking samples, and safety checks need to be implemented so that the appropriate protection is put in place for sample handling. Such arrangements should be treated as an urgent safety measure with subsequent notification in the usual way. Consider using a separate specific information sheet to provide information about additional tests rather than modifying an existing Participant Information Sheet.

2.2. Studies adding new COVID-19 related elements

This could include amendments to add sub-studies or components, e.g to enable epidemiological analysis of COVID-19, or to add patients with COVID-19 to an existing trial of a treatment.
COVID-19 Response

There are a number of possible scenarios where there may be a need to rapidly amend an existing study with no COVID-19 related aspects, but due to the wider impact of COVID-19 on NHS staffing, restrictions on movement of people or in response to Government advice. Guidance is given for each scenario below. All amendments that need to be submitted to a review body should be sent through the usual email route. All amendments should be sent to sites in accordance with the guidance above.

Safety of patients of course remains a priority. If the safety of a participant is at risk because they cannot complete key safety checks, then consideration to discontinuing that participant must be considered. Where necessary, urgent safety measures may be implemented first and notified subsequently.

The MHRA provides more detailed guidance on handling of particular scenarios for clinical trials.

3.1. Changes instigated by sponsors across the study

3.1.1. Studies where sponsors need to change their site monitoring arrangements, or make changes to administrative arrangements to reduce burden or physical contact with sites

Any such changes should not increase the burden on NHS sites.
Such changes should be handled as a non-substantial amendment that does not require HRA/HCRW Approval or R&D agreement. For studies involving the NHS/HSC, these should be marked by the sponsor as category C and not requiring assessment and sent directly to sites following the instructions above. These should be implemented at sites on the date specified by the sponsor.

Sponsors should consider what monitoring needs to be done in real time, and what checks can be undertaken later, taking a risk-based approach. Where a change to access to confidential patient information will arise as a result of changes to remote monitoring, the revised participant information sheet and consent form, along with the risk assessment justifying the changes to access to confidential patient information, should be submitted as a substantial amendment. Such amendments will be categorised and assessed according to existing guidance, but the process will be expedited. They should be sent to sites following the instructions above. These should be implemented at sites on the date specified by the sponsor.

3.1.2. Studies making changes to how or when patients are seen to avoid exposing patients or to reduce burden on clinical services

a) In some cases changes will be deemed by the sponsor to reduce risk of potential exposure to COVID-19 by participants, for example changing participant site visits to phone calls or postal questionnaires. Sponsors must not make any such changes that would create additional burden to NHS staff or resources. These should be handled as a non-substantial amendment that does not require HRA/HCRW Approval or R&D agreement. For studies involving the NHS/HSC, these should be marked by the sponsor as category C and not requiring assessment and sent directly to sites following the instructions above. These should be implemented at sites on the date specified by the sponsor.
3.1.3. Studies where treatment or investigational medicinal product need to be sent by courier direct to participants or other alternative mechanisms of provision

Sponsors must assess the risks relating to the product and consider any shipping and storage arrangements. Participants must consent verbally to providing contact details for shipping purposes. Where participants are self-isolating or in quarantine, arrangements for a nominated person to collect product may be implemented with the participant’s verbal consent. Any such temporary arrangements should be handled as a non-substantial amendment that does not require HRA/HCRW Approval or R&D agreement. For studies involving the NHS/HSC, these should be marked by the sponsor as category C and not requiring assessment and sent directly to sites following the instructions above. These should be implemented at sites on the date specified by the sponsor.

3.1.4. Studies where sponsors need to implement a temporary halt to all or some of the study or extend the duration of a study due to COVID-19.

Sponsors must decide when they need to implement a formal temporary halt. For CTIMPs the MHRA provides advice. For non-CTIMPs consider reporting a formal halt if there are safety considerations for existing participants, or actions that sites need to take.

Simply pausing recruitment does not need to be reported as a temporary halt, although sponsors should record such decisions for their records.

For CTIMPs, in the scenarios where MHRA has advised this would be substantial amendment, such amendments will be categorised and assessed according to
agreement. For studies involving the NHS/HSC, these should be marked by the sponsor as category C and not requiring assessment and sent directly to sites following the instructions above. These should be implemented at sites on the date specified by the sponsor.

3.1.5. Studies that need to be closed
For any studies not involving provision of treatment to participants, a notification to the REC or study-wide review (for non-REC studies) should be provided, and an end of study report should subsequently be provided.

For any studies involving provision of treatment to participants, careful consideration should be given to post-study care. If this cannot be in line with the information provided in the participant-information sheet, a substantial amendment should be submitted. Such amendments will be categorised and assessed according to existing guidance, but the process will be expedited. They should be sent to sites following the instructions above. These should be implemented at sites on the date specified by the sponsor.

3.2. Changes instigated by individual sites due to clinical requirements
Sites may need to make rapid changes to manage clinical situations. The priority should be the safety of patients. For CTIMPs, the MHRA expects any protocol deviations to be documented.

3.2.1. Studies where sites need to suspend recruitment
Sites must raise such issues with the sponsor as early as possible if this is likely to occur. No further action by sites is required except where instructed by sponsors.
Sites must raise such issues with the sponsor as early as possible if this is likely to occur.

Where possible such arrangements should be handled prospectively, and, where required, submitted as an amendment. In cases where there is no time to arrange for such review, changes should be implemented as urgent safety measures and reported retrospectively. In any such situation the impact on participants should be considered and arrangements made to cover this, for example additional transport.

Where participant visits can be done remotely rather than face to face this does not need to be reported as an amendment, although it may be appropriate to record this if it might affect the study data, for example subjective interview responses.

Where individual sites need to arrange to courier treatment to patients, this does not need to be reported as an amendment, but should be agreed with the sponsor and a risk assessment documented.

If patient visits need to be moved, the options are to set up as a sub-contracted site of the existing site if oversight can be maintained by the existing site, or to set up new sites, or to implement direct home care arrangements by the sponsor. For study types where addition of new sites is a substantial amendment, existing guidance for submitting a substantial amendment for new sites should be followed. In all other cases, existing guidance for non-substantial amendments and addition of new sites should be followed.

Establishing subsidiary sites is a non-substantial amendment. These should be handled as a non-substantial amendment that does not require HRA/HCRW Approval or R&D agreement. For studies involving the NHS/HSC, these should be marked by the sponsor as category C and not requiring assessment and sent directly.
occur.

For any studies involving provision of treatment to participants, careful consideration should be given to post-study care. If this cannot be in line with the information provided in the participant-information sheet, a substantial amendment should be submitted. Such amendments will be categorised and assessed according to existing guidance, but the process will be expedited. They should be sent to sites following the instructions above.

3.2.4. Studies where Principal Investigator(s) are taken off a study

If the absence will be greater than one month the REC should be notified. If the Principal Investigator will be absent for greater than three months alternative arrangements should be put in place.

For further queries please contact:

- HRA Queries line: queries@hra.nhs.uk. Out of hours: 020 7104 8322
- MHRA Clinical Trials Unit Helpline: clinicaltrialhelpline@mhra.gov.uk or 020 3080 6456.

<table>
<thead>
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<th>Version number</th>
<th>Date</th>
<th>Changes made since previous version</th>
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<tr>
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<tr>
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<tr>
<td>2</td>
<td>17 March 2020</td>
<td>Section 2 – clarification about arrangements for provision of amendments. Section 3 – includes link to MHRA blog. Section 3.1.1 – additional information on monitoring. Section 3.1.4 – clarification on when a sponsor should report a formal temporary halt. Section 3.2.1 – clarification of distinction between site temporary halt and sponsor temporary halt. Section 3.2.2 – additional scenarios included</td>
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<tr>
<td>2.1</td>
<td>20 March 2020</td>
<td>Link to MHRA guidance updated following new MHRA guidance. Section 2 - clarification about non-substantial amendment form. Section 3.1.4 - wording clarified. Section 3.2 - additional information about protocol deviations.</td>
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<tr>
<td>2.2</td>
<td>26 March 2020</td>
<td>To add a new link to the NIHR’s guidance on public health emergency research, as approved by the Chief Medical Officer</td>
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Back to covid-19 research

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<th>Email Address</th>
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Guidance about COVID-19 for sponsors, sites and researchers - Health Research Authority

Research planning
Best Practice
Policies, Standards & Legislation
Learning
Confidentiality
Advisory Group registers
Research summaries

Approvals and amendments
What approvals and decisions do I need?
Amending an approval
Managing your approval

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What we do
Who we are
Committees and services
Consultations
Partnerships
Governance
News & updates
HRA Latest
Vacancies
Glossary

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