NHS
Health Research Authority

Generic screening of potential Phase 1 trial participants: Guidance for using the HRA Generic Screening Information Sheet and Consent Form template

Clinical trials units frequently undertake general, non-trial specific screening procedures ("generic screening") to recruit potential trial participants, prior to inviting them to take part in a specific clinical trial. The Health Research Authority (HRA) has developed a template information sheet and consent form for organisations undertaking this type of generic screening activity in the UK. The template and linked guidance has been developed in consultation with the HRA's Generic Document Review Committee and representatives from the Phase 1 Advisory Group.

The HRA generic screening information sheet and consent form template is to be used for the generic screening of healthy volunteers only. It should not be used for enrolling potential participants into a particular trial. All trial specific documentation (including Participant Information Sheets and Consent Forms) must be submitted to the Research Ethics Committee and must be ethically approved. Guidance for producing trial specific Participant Information Sheets and Consent forms is available on the HRA website: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/phase-1-clinical-trials/

Using the HRA generic screening information sheet and consent form template

It is not a legal requirement for generic screening documents to be reviewed by a Research Ethics Committee however, it is the HRA's expectation that:

Either the HRA generic screening information sheet and consent form template is used

-Or ethical advice regarding generic screening materials is sought from the HRA, prior to its' use, as a matter of best practice.

If the HRA generic screening information sheet and consent form template is used in its published form, there is no need to seek ethical advice regarding the template from the Generic Document Review Committee. If you make any changes to the document (other than the insertion of your logo and organisation name and indicating which tests will be included), the HRA template generic screening information sheet and consent form should be submitted to the Generic Document Review Committee (phase1.advertreview@nhs.net) in order to obtain ethical advice. For example, if you wanted to include additional assessments not listed in the document or amend the standard wording. Please note, if you choose to include sputum induction or a skin prick test as part of generic screening, this would need to be submitted to the Generic Document Review Committee along with written justification for including these tests as specified on the template.

The template is a supporting document and not a mandatory document. Other versions of generic screening information sheets and consent forms may continue to be used however; it is expected that these are submitted to the Generic Document Review Committee in order to seek ethical advice.

How to use the HRA template:

- It is recommended that you download a copy of the HRA generic screening information sheet and consent form template from the Phase 1 section of the HRA website when preparing the document in order to ensure that you are using the most up to date version
- Remove the HRA logo and replace with the logo of your organisation.
- Add a date and version number to the footer section of each page. A title can also be added to the footer if different variants of the generic screening information sheet are used within the same unit.
- Insert the name of your organisation where indicated in red type.
- Specify which assessments will be included as part of the generic screening by removing any of the rows containing tests which will not be included. Remember to also amend the numbering in the left hand column.
- A signed copy of the HRA generic screening Participant Information Sheet and Consent form should be provided to potential participants.
- Completed copies of the HRA generic screening Participant Information Sheet and Consent form should be held securely and in accordance with the Data Protection Act.

After a period of 12 months, potential participants should be asked to complete a new generic screening information sheet and consent form if they are still interested in participating in future clinical trials.

Suggested revisions to the published template will need to be approved by the Phase 1 Advisory Group.

Please contact Charlotte Allen, Research Ethics Service Project & Support Manager (charlotte.allen2@nhs.net) if you have any questions regarding the use of the template.

The HRA website material is a statement of the HRA understanding. Whilst the reader is encouraged to seek further clarification from the HRA in respect of any queries via the queries line, it will be for the reader to take their own legal advice as to what their legal duties are.