Health Research Authority

Generic Document Review Committee:

Policy and Procedure

Author:	HRA Improvement and Liaison Manager
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Owner:	HRA Director of Operations
Scope of Document:	REC staff and members of the Phase 1 Generic Document Review Committee

Background

Clinical trials units, particularly Phase I units, may undertake general, non-trial specific advertising and screening procedures to recruit potential trial subjects, prior to inviting them to participate in a specific trial. Such activities preparatory to research are not part of the conduct of a trial as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004 and, therefore, it is not a legal requirement for such activities to be reviewed by a Research Ethics Committee (REC). However, it is the HRA's expectation that ethical advice regarding any proposed generic documentation or materials for clinical trials is sought from the HRA, prior to its being used, as a matter of best practice. This is to ensure that there is a route available for the review of documentation and materials which do not come directly under the remit of the REC. To ensure consistency such documents are reviewed centrally by the 'Generic Document Review Committee'.

1. Purpose

The purpose of this document is to set out the HRA roles and responsibility in regard to the review of generic advertising and screening materials. This will primarily be for Phase I clinical trials but may also include other clinical trials.

The document sets out the scope of the Generic Document Review Committee, the process for submission for the information of those submitting generic documents for review, the administrative arrangements and the review process, including issuing a decision.

2. Scope

This policy and procedure applies to all requests for the review of generic advertising and screening materials which are submitted to the Generic Documentation Review Committee (from herein referred to as 'the Committee') for ethical consideration. This document applies to HRA staff and members who are involved in managing the review of generic materials but should also be used for reference by clinical trial units.

The scope of the Committee is the review of documentation which is considered to be generic and does not relate to a specific trial. This will be primarily for Phase 1 clinical trials but the Committee may review documentation for other clinical trials on request. The documents reviewed will primarily be external facing documents but other documentation can be considered by the Committee on request. The advice received from the Committee regarding generic study documents is separate to advice received from the REC regarding the ethical opinion of a specific trial. The following are generally the types of documentation and materials which will be reviewed by the Committee however this list is not exhaustive:

- Adverts for radio broadcasts/television advert scripts
- Website scripts/privacy policies
- Patient Brochures
- Frequently Asked Questions leaflets
- Social Media Advertisements e.g. Facebook, Twitter

- Screening information sheets and consent forms
- The HRA template for generic screening information sheets

3. Responsibilities

3.1 Responsibilities of the administrator

3.1.1 Oversight of the generic review mailbox (phase1.advertreview@nhs.net).
3.1.2 Determining whether the documentation fall(s) under the scope of the Committee.
3.1.3 Communicating with the Committee members.
3.1.4 Communicating with applicants.
3.1.5 Ensuring that timelines are adhered to.
3.1.6 Keeping the Committee record spreadsheet updated.

3.2 Responsibilities of the Committee members

3.2.1 Review of generic documentation and materials which are under the scope of the Committee and issuing a decision.
3.2.2 Providing advice to applicants which is in line with guidance published by the HRA.

3.3 HRA Improvement and Liaison Manager (may be delegated to the Deputy HRA Improvement and Liaison Manager)

3.3.1 Ensuring sufficient members are recruited to the Committee and arranging for new members when required.
3.3.2 Providing advice and support to the administrator.
3.3.3 Dealing with concerns raised about generic documentation and adverts in use.
3.3.4 Monitoring the scope of this document.
3.3.5 Monitoring the activities which come under the scope of this document.
3.3.6 Reporting to the Phase 1 Advisory Group.

3.4 Director of Operations

3.4.1 All procedures covered by this document

4. Breakdown of activities

4.1 Administration functions

4.1.1 Upon receipt of a submission, the documentation or materials must be checked to confirm that it/they fall(s) within the scope of the Committee.
4.1.2 If documentation is deemed to be study specific, applicants should be directed to the REC which originally reviewed the study.
4.1.3 Receipt of documents falling under the scope of the Committee should be acknowledged to the applicant by e-mail within 2 working days of the submission being received.
4.1.4 Submitted documents should be sent to the Committee by e-mail within 3 working days of being received. The administrator should inform the Committee of the date a final decision is required by. The decision should be confirmed to the

applicant no later than 10 working days after the documents were initially received.

4.1.5 On receipt of a decision from the Committee, this should be communicated to the applicant within 2 working days

4.1.6 Where a Favourable decision has not been issued and a further response is received from the applicant, the administrator should forward the response to the Committee members which undertook the original review. The Committee should be informed of the date by which a response is required. The final decision should be confirmed to the applicant no later than 10 working days after the response is received from the applicant.

4.1.7 Submitted documents should be logged on the Committee record spreadsheet and issued with a reference number. The spreadsheet should be retained centrally in the shared drive G:\Shared Drive\Operations\PHASE 1 APPLICATIONS\Phase 1 generic review\ Generic Document Review Committee. The spreadsheet must be updated with the reference number, company, date received, date sent to Committee, date of decision issued and if applicable date of the applicant response and further review.

4.1.8 The below mentioned documents should all be saved in the shared drive G:\Shared Drive\Operations\PHASE 1 APPLICATIONS\Phase 1 generic review\ Generic Document Review Committee. The name of the file should be the reference number

a. all documents reviewed by the Committee

b. e-mail correspondence with the applicant, including the acknowledgement of the documents and confirmation of the final decision.

c. e-mail correspondence from the members of the Committee outlining their decisions.

d. further responses from the applicant and the Committee following a ‘not favourable’ decision.

4.2 Committee functions

4.2.1 Committee members should review the documentation and provide a decision on behalf of the Committee within 5 working days. Discussion should take place between Committee members (usually by correspondence or telephone) if necessary in advance of the final decision being confirmed to the administrator by e-mail.

4.2.2 The Committee should reach one of the following decisions after the first review:

a. Favourable - The documents are approved for use in the format presented

b. Not Favourable - The documents would need to be amended before the Committee could confirm the documents can be approved for use

4.2.3 If the Committee issues a ‘Not favourable’ decision, the reasons for this and the required changes should be made explicit in the e-mail to the administrator.

4.2.4 When the Committee receives a response to a ‘Not favourable’ decision, a final decision should be issued within 5 working days of the response being received.

4.3 Membership Requirements and Quorum

4.3.1 Members of the Committee should have at least 2 years of experience as a member of a UK REC service Phase 1 recognised REC.

4.3.2 The members for each review (which could involve one or more than one submission) should be selected from a wider group of members on a rota basis. The rota should be set in advance by the administrator.

4.3.3 A review should be undertaken by a minimum of two and a maximum of three members of the group. Ideally this should be a combination of expert and lay or lay plus members, but this is not mandatory.

4.4 Dealing with concerns about clinical trial documents and adverts

Occasionally the HRA is contacted to raise concerns about generic study documents including adverts for clinical trials. The following process should be followed to investigate any such concerns:

4.4.1 Concerns should be forwarded to the HRA Improvement & Liaison Manager catherineblewett@nhs.net.

4.4.2 It should be established whether the advert relates to a specific study or whether it is a generic advert. If the advert relates to a specific study, the advert documentation on HARP should be compared against the advert about which concern has been raised to see if the advert used has been approved by the REC.

4.4.3 If the advert is generic, the generic review spreadsheet should be checked to see if the advert has been submitted to the Committee for review.

4.4.4 The advert should be reviewed to confirm whether it is in line with the guidance issued by the HRA and the organisation undertaking the clinical trial should be contacted and informed of the outcome.

4.4.5 Based on the outcome of 4.4.2 or 4.4.3 and 4.4.4, a response should also be sent to the person raising the concern.

4.4.6 Details of any issues raised should be included in the information provided to the Phase 1 Advisory Group.

5. Monitoring of activities covered by the procedure

The HRA Improvement and Liaison Manager is responsible for ensuring the monitoring of activities covered by this procedure. This will be undertaken biannually by undertaking a quality control check of five submissions.

6. How lessons are learnt and incorporated into the procedure

The procedure will be reviewed annually. Feedback which is received during this period will be reviewed as part of the review process and any required changes will be made accordingly.

7. Management of Documents and Records

7.1 Documents submitted for review

7.1.1 Each submission should have an individual file on the shared drive G:\Shared Drive\Operations\PHASE 1 APPLICATIONS\Phase 1 generic review\ Generic Document Review Committee

7.1.2 The name of the file should be the reference number which is allocated for that submission. The files are ordered by year, April to March.

7.1.3 The file should contain all e-mail correspondence and all documents submitted for review. When documents have been amended and resubmitted, both versions should be saved.

7.1.4 Files should be retained for at least three years from when the file was opened. All files for a full year should be deleted at the start of the year, April to March, which is three full years after the last file was opened. For example, the file April - March 2014/15 should be deleted in April 2018.

7.2 Generic Document Review Committee record spreadsheet

7.2.1 The spreadsheet should be saved on the shared drive G:\Shared Drive\Operations\PHASE 1 APPLICATIONS\Phase 1 generic review\ Generic Document Review Committee

7.2.2 A separate spreadsheet should be created for each year, April to March, and saved in the electronic file for that year.

7.2.3 The spreadsheet should be retained for three years and deleted at the start of the year, April to March, which is 3 full years after the year to which the spreadsheet relates.

8. Supporting paperwork/forms

8.1 Generic Document Review Committee record spreadsheet

9. Dissemination and publication of the document

This document will be available on the HRA website. Whilst the policy and procedure is internal, the document should be available externally for information to applicants. http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/phase-i-trials/

10. Screening Questions - HRA Equality Analysis and Privacy Impact Assessment

<table>
<tr><td colspan="4">EQUALITY AND PRIVACY SCREENING QUESTIONS</td></tr>
<tr><td colspan="2">FOR EVERY HRA POLICY (defined by the Equality and Human Rights Commission (EHRC) as a function, strategy, procedure, practice, project, or decision) PLEASE ANSWER THE QUESTIONS BELOW TO DETERMINE WHETHER FURTHER ANALYSIS IS REQUIRED.</td><td>YES / NO</td><td rowspan="3">If yes, please complete as required either the HRA Initial Equality Analysis and / or Initial Privacy Impact Assessment Template and copy and paste the completed assessment (s) below. This one document can be found on the Intranet.</td></tr>
<tr><td>Equality</td><td>With due regard to our Equality Duty, could this policy have the potential to have a detrimental impact on anyone with a protected characteristic?</td><td>No</td></tr>
<tr><td>Privacy</td><td>With due regard to the Data Protection Act, does this policy involve the use of Personal Information?</td><td>No</td></tr>
</table>

Document Control

Change Record

Version Status	Date of Change	Reason for Change
V1.1	06.01.2016	Review by Deputy I&L Manager and RES Policy and Support Manager
V1.2	22.01.2016	Review by Committee members
V1.3	19.02.2016	Review at P1AG

Reviewers

Name	Position	Version Reviewed
Charlotte Allen	RES Policy and Support Manager	1.0
Nicola Burgess	Deputy I&L Manager	1.0
Daryl Rees	Committee Member	1.1
John Sheridan	Committee Member	1.1
P1AG	Advisory Group	1.2

Distribution of Approved Versions

Platform (e.g.HRA intranet or website)	Date of Publication	Version Released
HRA website	22 February 2016	1.3