NHS
Health Research Authority

Policy and Procedure for Research Summaries (Including deferral of requests)

Author:	HRA Director of Guidance & Learning
Date of Release:	October 2016
Version No. & Status:	V1.0 Final 2016.10.07
Approved By:	4 Nations Group
Supersedes Version:	V0.9 Draft
Review Date:	October 2017
Owner:	HRA Director of Guidance & Learning
Scope of Policy:	Research Summaries of applications reviewed by a Research Ethics Committee within the UK Health Departments' Research Ethics Service (excluding the Confidentiality Advisory Group)

Background

The Health Research Authority (HRA) is committed to ensure that the UK is a great place to undertake research, including transparency within health research. The HRA and its predecessor organisations have published Research Summaries on its website since May 2008. Research Summaries aim to offer the public and research participants' confidence in the transparency of health research within the UK, enable potential research links to be made, reduce the risk of potential duplication of research and enable more effective use of resources.

In the case of Clinical Trials of Investigational Medical Products (CTIMPs), a Research Ethics Committee (REC) is legally required to publish a summary of its opinion by Regulation 15(9) of the UK Clinical Trials Regulations. This is also required by the Governance Arrangements for NHS Research Ethics Committees (GAfREC) for all applications reviewed by the UK Health Departments' Research Ethics Service. The publication of Research Summaries and REC opinions also supports compliance with requirements under the Freedom of Information (FOI) Act to publish information held by public bodies.

The HRA's Confidentiality Advisory Group (CAG) publish a register of all approved applications and all its meeting minutes on the HRA website (www.hra.nhs.uk). This activity is outside the scope of this policy and procedure.

Policy

'Research Summaries' refers to the record of a research application published on the Research Summaries section of the HRA website. The record contains the fields listed in Table 1 which are obtained from the dataset submitted as part of the application for ethical review. The expectation is that all applications reviewed by a REC within the UK Health Departments' Research Ethics Service will be published on the HRA website no earlier than three months from the date of the final opinion letter. The presumption is that Research Summaries for all applications within the scope of this policy and procedure will be published on the HRA website. The HRA recognises that in a few limited circumstances it may be appropriate to allow for a deferral of publication of some selected fields within the Research Summary, for a specified time period; for example, for reasons of commercial sensitivity or intellectual property protection. By allowing deferral of the publication of some fields within the Research Summary but not allowing an exemption from, or a deferral of publication of the entire Research Summary, the HRA aims to ensure that the UK remains an attractive place to undertake research whilst balancing need for transparency within health research.

Exemption of publication would only be permissible where there is very little, or no interest to the public. This should be requested and not be an automatic exemption. If exemption of publication on the HRA website does apply, the application details may still be released under a FOI request. Deferral (or exemption) from publication of the Research Summary will only be considered where the applicant makes a request in accordance with this policy and procedure. Where HRA agreement has been given to defer or exempt from publication, a minimum Research Summary record will still be published on the HRA website. This will include the short title of the research, REC opinion, date of REC opinion, IRAS ID and REC name. The full title of the research study, contact name, contact email, Sponsor and Research Summary can be potentially deferred. The HRA reserves the right to review any agreed deferral or exemption on receipt of additional information.

The publication of Research Summaries does not replace the REC annual report or fulfil any requirement to register research in a publicly accessible trial registry / database. The HRA's Research Summaries section of the website is not a clinical trial register.

Procedure

1. Purpose

1.1 The purpose of this document is to define the HRA's policy and procedure for the management of Research Summaries, specifically;

- the information that will be routinely included in Research Summaries published on the HRA website and how Research Summaries are managed by the HRA.
- how to request a deferral in publication of fields within the Research Summaries and, by exception, how to request an exemption from Research Summaries inclusion.

2. Scope

2.1 This policy and procedure applies to all applications submitted for review by a REC within the UK Health Departments' Research Ethics Service, following the REC opinion.

2.2 The HRA's CAG publish a register of all approved applications and all its meeting minutes on the HRA website. This activity is outside the scope of this document.

3. Reference Documents

- Governance Arrangements for Research Ethics Committees (GAfREC)
- The Medicines for Human Use (Clinical Trials) Regulations 2004
- Research Ethics Service Standard Operation Procedures
- Integrated Research Application System (IRAS), including application form, declaration and associated guidance.

4. Responsibilities

4.1 The applicant is responsible for:

- Ensuring the completeness and accuracy of information provided in applications submitted for ethical review, including designating a contact person for further information about the research whose details may be included in the Research Summary;
- Notifying the HRA in writing of changes that are required to the information contained within the publicly available Research Summary;
- Applying for a deferral of publication of the Research Summary information, or exemption in exceptional circumstances, as soon as possible and within three months from the date of the final opinion letter, if it is considered that a reason for deferral should apply;
- Notifying the HRA in writing of any change that may have an impact on an agreed deferral or exemption from publication of information in the Research Summary.

4.2 The HRA is responsible for:

- Publication of Research Summary information on the HRA Website, within the scope of this policy and procedure;
- Updates to Research Summary information fields, in line with this policy and procedure, as requested by applicants;
- Ensuring that where a request for deferral of publication of information within the Research Summary, or exceptionally, where exemption from publication is agreed, that the information is deferred / exempt from publication on the HRA Website;

- Reviewing any agreed deferrals or exemptions from publication, where new information becomes available and/or where circumstances change that may affect the justification for deferral or exemption from publication.
- Managing requests for deferral or exemption of publication of information within the Research Summary and recording of requests and updating information contained within the Research Summary in line with notifications made by the applicant.
- Managing requests to reconsider decisions in relation to requests for deferral or exemption that are refused by the HRA.

5. Breakdown of activities covered by the procedure

5.1 Publication of the Research Summary on the HRA website will automatically take place no earlier than three months from the date of the final opinion letter. This includes the data fields listed in Table 1.

5.2 **Deferral of publication**

5.2.1 Where it is considered appropriate to seek a deferral of publication of information within the Research Summary the applicant should make a request, in writing, to the HRA External Assurance Lead (via hra.studyregistration@nhs.net). Appreciating requests may be made to the REC which gave the final ethical opinion, the REC Manager will forward requests to the HRA External Assurance Lead. The request must be made within three months from the date of the final opinion letter and must include:

- identification of the research that is the subject of the request (IRAS ID and REC reference as a minimum);
- the reason for the request;
- clear indication of the fields within the Research Summary that deferred publication is being sought for;
- the timeframe within which the deferred information can be published. [Whilst there is not a single reason for automatic deferral, the HRA does note the potential commercial confidentiality issues around research].

5.2.2 If a deferral request is submitted near to the publication point (three months from the date of the final opinion letter), publication of the Research Summary may take place before the request can be processed.

5.2.3 Without all the required information (listed in 5.2.1), the HRA External Assurance Lead may not be in a position to consider fully the request and as a result be unable to agree to a deferral of publication. In this instance the applicant will be advised with a request to submit the missing information.

5.2.4 Requests for a deferral are considered on a case-by-case basis. Should a deferral request not be agreed, the HRA External Assurance Lead will contact the applicant to advise of this outcome and the reasoning within 5 working days of the request being received.

5.2.5 If the applicant is dissatisfied with the outcome they may query the decision, in writing, with the HRA Director of Guidance and Learning (hra.studyregistration@nhs.net) who will provide written acknowledgement within 5 working days.

5.2.6 Should the applicant require a further extension of a deferral period, they should request this via the HRA External Assurance Lead (hra.studyregistration@nhs.net), before the end of the deferral period. If no request to extend is received, then at the end of the agreed deferral period the information that had been deferred will be automatically published on the HRA website.

5.3 Exemption from publication

5.3.1 In exceptional situations an exemption from publication of information within the Research Summary record may be granted. In the interests of transparency this is likely to be limited to such occasions where the potential interest to the public would not be compromised. The number of Research Summaries receiving an exemption is expected to be minimal. Should an applicant wish to request an exemption from publication on any particular element of information within the routinely published Research Summary or a complete exemption from all fields (noting the exceptional situations for such consideration), they must make a request for exemption to the HRA External Assurance Lead (via hra.studyregistration@nhs.net) as soon as possible, and within three months from the date of the final opinion letter. Where requests are made to the REC which gave the final opinion, the REC Manager will forward requests to the HRA External Assurance Lead. The request must include:

- identification of the research that is the subject of the request (IRAS ID and REC reference as a minimum);
- the reason for the request;
- clear indication of the fields within the Research Summary that exemption from publication is being sought for.

5.3.2 Applicants should note that if an exemption request is submitted near to the publication point (three months from the date of the final opinion letter) publication may take place before the request has been processed.

5.3.3 Without all the required information, the HRA External Assurance Lead may not be in a position to consider fully the request and as a result be unable to agree to an exemption from publication, in which situation the applicant will be advised and asked to submit the missing information.

5.3.4 Requests for exemption are not anticipated as being the norm, and will be considered on a case-by-case basis. Should an exemption request not be agreed, the HRA External Assurance Lead will contact the applicant in writing to advise of this outcome and the reasoning within 5 working days of the request being received.

5.3.5 If the applicant is dissatisfied with the outcome they may query the decision, in writing, with the HRA Director of Guidance and Learning (hra.studyregistration@nhs.net) who will provide written acknowledgement within 5 working days.

5.3.6 If exemption of publication on the HRA website is facilitated, details may still be releasable under a FOI request.

5.4 Revision of Research Summary information

5.4.1 Requests should be submitted in writing to the HRA External Assurance Lead (via hra.studyregistration@nhs.net). Requests should ideally be made within three months from the date of the final opinion letter, however requests will be accepted after this period.

5.4.2 Where the request is made after the Research Summary has been published the updated information will made available on the HRA website approximately 2 working days following the information being processed by the HRA External Assurance Lead. The processing of the request will be undertaken within 5 working days of the request being made.

Table 1. .Data fields taken directly from the research application form, by study type

Data Field	Project based**	Research database	Tissue bank
Short title	Yes	-	-
Full title	Yes	-	-
IRAS ID	Yes	Yes	Yes
Contact name	Yes (Chief investigator)	Yes (Data custodian)	Yes (Tissue Bank manager)
Contact email	Yes	Yes	Yes
Sponsor Organisation	Yes	-	-
Eudract No. (If applicable)	Yes	-	-
ISRCTN No. (If applicable)	Yes	-	-
Clinicaltrial.gov identifies (If applicable)	Yes	-	-
Additional reference No (If applicable)	Yes	-	-
Research summary (IRAS A6-1 Summary of the study)	Yes	-	-
REC name	Yes	Yes	Yes
REC reference	Yes	Yes	Yes
REC opinion	Yes	Yes	Yes
Date of REC opinion	Yes	Yes	Yes
Duration of research project	Yes	-	-
Summary of the application	-	Research database tile Establishment responsible for management of database Data to be stored and data collection requirements Research programme /community support by the programme	Title of Bank Human Tissue Storage Licence Establishment responsible for management of Bank Details of locations at which tissue will be stored Research summary programme/ community support by bank

**** i.e. all project categories in IRAS filter question 2, except for research databases and research tissue bank.**

6. Monitoring of activities covered by the procedure

6.1 A small scale quality check will be undertaken quarterly by the HRA External Assurance Lead.

6.2 Aspects of this policy and procedure will be subject to internal and external audits (including the Health Group Internal Audits) in line with ISO9001:2015 requirements.

6.3 KPI reports will be presented to the Executive Management Team (EMT) on a quarterly basis.

7. How lessons are learnt and incorporated into the procedure

7.1 The HRA monitors feedback from stakeholders, not least through a formal complaints process and user feedback. Any specific feedback around Research Summaries, the process for requesting a deferral or accessibility of the Research Summaries on the HRA website is welcome via hra.studyregistration@nhs.net.

7.2 This policy and procedure will be reviewed annually or more frequently in the event of changes in research regulations, policy or governance frameworks.

7.3 As part of a Quality Management System (QMS), feedback and learning from section 6.1 and 6.2 will be incorporated into improvements.

8. Management of Documents and Records

8.1 All requests for a deferral of, or exemption of, publication of Research Summary fields will be retained in line with HRA Document and Records Management Policy. A log of all such requests will be maintained by the HRA External Assurance Lead. Emails requests from applicants in relation to Research Summaries will be logged on the HARP system and destroyed in line with the HRA Document and Records Management Policy, following the end of study.

8.2 Minor revisions are approved by the document owner and major revisions by UKREDG.

9. Supporting paperwork/forms

- Log of requests for deferral / exemption of publication of research summary fields
- Internal Guidance - Managing requests for deferral / exemption from publication of the Research Summary.

10. Dissemination and publication of the procedure

10.1 This document will be available via the HRA website.

Screening Questions - HRA Equality Analysis and Privacy Impact Assessment

EQUALITY AND PRIVACY SCREENING QUESTIONS			
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.		**YES** / **NO**	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.
Equality	With due regard to our Equality Duty, could this policy have the potential to have a detrimental impact on anyone with a protected characteristic?	No	
Privacy	With due regard to the Data Protection Act, does this policy involve the use of Personal Information?	Yes	

INITIAL PRIVACY IMPACT ASSESSMENT

What is Privacy?

Privacy refers to freedom from intrusion and relates to all information that is personal or sensitive in nature to an individual

	YES	**NO**
Does the policy or procedure have any impact on privacy?	**x**	
If Yes please give details below of the impact and the actions being taken to address any adverse impact. A contact name with email address for each study will be available within the research summary pages, on the HRA website. This information can be updated as requested by applicants.		

If you have answered YES to the questions above and the answers do not mitigate and adequately address the adverse impact, you may need to complete a full PIA.
Please consult the Corporate Secretary.

Full Privacy Impact Assessment required? ~~YES /~~ NO

Author to type in name and date to verify analysis. (If further analysis is required, the Corporate Secretary must be informed).	NAME: T. Smith DATE: 20 November 2015

Document Control

Change Record

Version Status	Date of Change	Reason for Change
Draft v0-1	Initial draft	To incorporate the current requirements into one document for research community guidance on Research Summaries
Draft v0-4	Draft	Incorporating comments
Draft v0-5	Final draft	Incorporating changes, comments and addition clarity
Draft v0-6	Draft	Incorporating changes, comments and addition clarity
Draft v0-7	Draft	Incorporating changes
Draft v0-8	Draft	Incorporating changes
Draft v0-9	Draft	Incorporating changes, comments and addition clarity
V1.0 Final 2016.10.07	Final	For publishing on the HRA website

Reviewers

Name (name of reviewer and/or management group reviewing)	**Version Reviewed**
Internal (Draft group (CB, SB, TS (v0-5 JM)	v0-1, v0-4, v0-5, v0-6
UKREDG	V0-7
4 Nations Group	V0-8
Internal (JK, SO, CB, CD, TS) and DAs (SM, RR, AB)	V0-9
UKREDG	V1.0 Final 2016.10.07

Distribution of Approved Versions

Platform (e.g. HRA intranet or website)	Date of Publication	Version Released
HRA Website	October 2016	V1.0 Final 2016.10.07