Health Research Authority

Research Summary Deferrals Policy and Procedure

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Background

The Health Research Authority (HRA) has a duty to promote transparency and has committed to a range of activities to improve transparency in health and social care research. Two established methods to support the HRA's transparency agenda are:

- Registration of research onto publicly accessible databases (see section 9)
- Publication of research summaries onto the HRA website

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.

A 'Research Summary' (see Table 1, section 5) refers to the record of a research application published on the research summaries section of the HRA website.

The HRA recognises that in a limited number of circumstances it may be appropriate to allow a deferral of publication of some selected fields within the research summary for a specified time; for example, for reasons of commercial sensitivity or intellectual property protection. In some rare cases it also may be permitted for the research summary to be exempt from publication.

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

Policy

The UK Health Departments' RECs are required by the Governance Arrangements for NHS Research Ethics Committees (GAfREC) to publish a research summary, together with their opinion, for all applications they review. In the case of Clinical Trials of Investigational Medical Products (CTIMPs), it is also a legal requirement for a REC to

publish a summary of its opinion by Regulation 15(9) of the UK Clinical Trials Regulations.

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 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 90 days from the date of the final opinion letter. Table 1 (section 5) shows the contents of the research summary.

This policy allows for requests to defer some fields of the research summary publication. Deferrals can only be valid for a maximum of 12 months. At the end of the deferral period, the research summary will be published unless a request to extend the deferral period has been allowed. In some cases, it is also permitted for the research summary to be made exempt from publication. Exemption of publication would only be permissible where there is very little, or no interest to the public. The number of research summaries receiving an exemption is expected to be minimal. If exemption of publication on the HRA website does apply, the application details may still be released under a Freedom of Information request.

Where a deferral or exemption is in place, a minimum research summary is still published. By allowing deferral or exemption of the publication of some fields within the research summary but not allowing the entire research summary to be deferred or exempt from publication, the HRA aims to ensure that the UK remains an attractive place to undertake research whilst balancing need for transparency within health research.

It is also permitted for some fields to be updated. For example, where there have been numerous amendments to a study, the research summary may be amended to reflect the amendments that have been made.

The HRA reserves the right to review any agreed deferral or exemption on receipt of additional information.

In exceptional circumstances, where there is a greater need for the research community and wider public to see information about research (e.g. during a pandemic), there may be interim deviations to aspects of this policy and procedure. Where any aspects of this policy and procedure need to be changed, this will be communicated on the HRA website.

Procedure

1. Purpose

The purpose of this document is to define the HRA's policy and procedure for the management of research summaries publication, 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 publication of fields within the research summaries

how to request for the research summaries to be updated/amended

2. Scope

2.1 This policy and procedure applies to all applications reviewed by a REC within the UK Health Departments' Research Ethics Service.

2.2 The HRA's Confidentiality Advisory Group (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 policy and procedure.

3. Reference Documents

- Governance Arrangements for Research Ethics Committees (GAfREC)
- The Medicines for Human Use (Clinical Trials) Regulations
- Research Ethics Service Standard Operation Procedures
- Integrated Research Application System (IRAS), including application form, declaration and associated guidance.
- HRA Research Summaries webpage: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

4. Responsibilities

4.1 ‘Deferrals Manager’ refers to the individual at the HRA delegated to manage the deferrals mailbox (study.registration@hra.nha.uk) and procedures outlined in this document, it does not reflect a job title.

4.2 The Sponsor is responsible for:

- 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 in the research summary

4.3 The HRA Deferrals Manager is responsible for:

- monitoring the study.registration@hra.nhs.uk mailbox
- managing requests for deferral or exemption of publication of information within the research summary, ensuring that agreed deferrals or exemptions are processed and recorded according to this policy and procedure
- Updating research summary fields in line with this policy and procedure
- 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 to reconsider decisions in relation to requests for deferral or exemption that are refused by the HRA
- completing and recording quarterly quality checks on a sample of research summaries (deferred and non-deferred) and highlighting any issues to appropriate teams within the HRA

4.4 REC staff are responsible for:

- ensuring that research summaries are published after 90 days from final REC opinion
- ensuring that deferred fields are published after the deferral period has ended
- sending any deferral requests or related queries to study.registration@hra.nhs.uk

5. Breakdown of activities covered by the procedure

The activities described below refer to the HRA Assessment Review Portal (HARP) and the HRA Hub. HARP is a database used by RECs to record and track the progress of research applications submitted to the HRA and HCRW and/or REC. Information held in HARP is held securely and confidentially and access is restricted to authorised users who manage, or review studies, submitted to the HRA and HCRW and/or REC. The HRA Hub is a workspace for HRA staff and is used to record deferral requests.

5.1 Publishing Research Summaries

5.1.1 It is the responsibility of REC staff to publish the research summary on the HRA website no earlier than 90 days from the date of the final opinion letter from the REC. In order to complete the publication, REC staff should action the alert in HARP.

5.2 Updating the Research Summary

5.2.1 It is the responsibility of the sponsor to ensure that the information published in the research summary is correct and reflects the current study, tissue bank or database.

5.2.2 Where a sponsor needs to request an update to the information published in the research summary they should request this, in writing, via email to study.registration@hra.nhs.uk. The request should include:

- identification of the research that is the subject of the request (IRAS ID and REC reference as a minimum);
- clear indication of the fields within the research summary that require updating and the new text that should be published

5.2.3 Ideally, requests to make updates to the research summary should be made within 90 days from the date of the final opinion letter, however requests will be accepted after this period.

5.2.4 Where the request is made after the research summary has been published, the updated information will be made available on the HRA website approximately three working days after the request is processed.

5.2.5 The Deferrals Manager is responsible for reviewing requests received in the study.registration@hra.nhs.uk mailbox. The request will only be processed where all the required information is provided within the request.

5.2.6 The Deferrals Manager is responsible for replying to the request within five days of receipt. Where a full request is sent (i.e. including all the required information) the Deferrals Manager is responsible for processing the request within five days.

5.2.7 Change requests which do not constitute an amendment should be processed by the Deferrals Manager. The Deferrals Manager should ensure that changes are made in HARP where the source data is stored (i.e. In References or Contacts tabs).

5.2.8 It may take three working days for the changes to appear on the research summary section of the HRA website.

5.2.9 REC staff are responsible for considering whether any updates are required to the research summary when processing an amendment, for example, where an amendment involves the change of Chief Investigator this may mean that the contact details in the research summary publication need to be amended. Where a substantial amendment is submitted and includes a request to change to the research summary data fields, the details of the request should be emailed to study.registration@hra.nhs.uk

5.3 Submitting Requests for Deferral or Exemption of Research Summary Publication

5.3.1 All requests should be made in writing via email to study.registration@hra.nhs.uk. If any requests are sent to the REC directly, the REC staff should forward these requests to study.registration@hra.nhs.uk within two working days.

5.3.2 The applicant should submit the deferral or exemption request as soon as possible after REC review. Any requests sent before REC review will not be actioned and the applicant will be asked to re-submit their request after the REC meeting.

5.3.3 The request should be made within 90 days of the date of the final REC opinion letter and should include the following information either in body of the email or it may be included in an attachment.:

- identification of the research that is the subject of the request (IRAS ID and REC reference as a minimum);
- clear justification for the request (whilst there is not a single reason for automatic deferral, the HRA does note the potential commercial confidentiality issues around research).
- clear indication of the fields within the research summary that deferred publication is being sought for (the full title, sponsor organisation and research summary text are the three fields that are usually deferred)
- the timeframe within which the deferred information can be published (note 12 months is the maximum allowed time)

5.3.4 The applicant should be aware that if a deferral request is submitted near to the publication date (90 days after REC opinion letter), then the publication of the research summary may have taken place before the request is processed.

5.4 Processing Requests for Deferral or Exemption

5.4.1 The Deferrals Manager is responsible for reviewing requests received in the study.registration@hra.nhs.uk mailbox and determining if sufficient information has been provided. The request will only be processed where all the required information is provided within the request. If any of the information is missing from the request, then the applicant will be advised of this and asked to provide it. The Deferrals Manager is responsible for replying to the request within five days of receipt. Where a full request is sent (i.e. including all the required information) the Deferrals Manager is responsible for processing the request within five days.

5.4.2 The Deferrals Manager will consider all deferral requests on a case-by-case basis. Exemption requests are not expected to be made regularly. Where all the requested information has been provided in the request and a clear and reasonable justification is provided then this should be accepted.

5.4.3 Where a deferral or exemption request is allowed, the Deferrals Manager should

use the appropriate standard reply (adapted as necessary) to confirm this to the applicant. The email reply will confirm the study details, reason for deferral or exemption, fields which are to be deferred, deferral end date and fields which will still be published. The Deferrals Manager will ensure that the Chief Investigator and REC that reviewed provided the final opinion, are copied into this email.

5.4.4 The Deferrals Manager is responsible for updating the application record in HARP so that the deferred fields will not be published on the HRA website until the deferral end date. The deferral end date in HARP must match the deferral end date provided to the applicant.

5.4.5 Where a deferral or exemption request is not allowed, a justification for this decision should be provided to the applicant. If the applicant is dissatisfied with the outcome they may query this decision in writing to study.registration@hra.nhs.uk who will provide a written acknowledgement within five working days. If required, further advice should be sought from the Head of Policy and Engagement.

5.5 End of Deferral Period

5.5.1 When the deferral period has ended, the deferred fields should be published with the rest of the research summary.

5.5.2 REC staff will be alerted to deferral end dates which are ready to be published via the work area on HARP. REC staff are responsible for actioning alerts regularly to ensure that research summaries are published in a timely matter.

5.6 Requesting a Deferral Extension

5.6.1 Should the applicant require a further extension of a deferral period, they should request this by emailing the HRA (study.registration@hra.nhs.uk), at least 10 working days before the end of the deferral period. The Deferrals Manager will process the extension request as per the process set out in 5.3.1. The maximum time a deferral can be extended for is 12 months.

5.6.2 The Deferrals Manager is responsible for confirming, via email, to the applicant whether or not the extension is allowed. A justification for the outcome should be provided, and if the request is allowed, the new deferral period end date specified in the response to the applicant.

5.7 Recording requests

5.7.1 The Deferrals Manager should ensure that all correspondence relating to research summaries is uploaded onto HARP. Changes to the research summary fields are recorded in the history tab in HARP.

5.7.2 The Deferrals Manager is responsible for updating the Clinical Trial Registration and Research Summaries Deferral log, which is saved on the HRA Hub.

5.8 Research Summary Fields

Table 1: Research Summary fields for research studies (i.e. research that falls into any category of IRAS filter question 2 with the exception of research tissue banks and research databases), research databases and research tissue banks with clarification on which fields can be deferred.

Research Summary Fields	Research Project	Research Database	Research Tissue Bank	Option to defer
REC Name	✓	✓	✓	No (minimum research summary)
REC Reference	✓	✓	✓	No (minimum research summary)
IRAS Project ID	✓	✓	✓	No (minimum research summary)
Contact Name	✓	✓		Yes
Contact Email Address	✓	✓		Yes
Short Title/Title of bank/Title of database	✓	✓	✓	No (minimum research summary)
Full Title	✓			Yes
ISRCTN identifier (if applicable)	✓			Yes
ClinicalTrials.gov identifier (if applicable)	✓			Yes
EudraCT identifier (if applicable)	✓			Yes
Additional Reference Numbers (if applicable)	✓			Yes
Research Summary text (IRAS A6-1)	✓			Yes
Research Type (e.g. research database)	✓	✓	✓	Yes – but only for research projects
Sponsor Organisation	✓			Yes
REC Opinion	✓	✓	✓	No (minimum research summary)
Date of REC Opinion	✓	✓	✓	No (minimum research summary)
Study Duration	✓	✓		No (minimum research summary)
Establishment organisation and address		✓	✓	Yes
Research programme		✓	✓	Yes
Samples/Data collection arrangements		✓	✓	Yes
Human Tissue Authority Storage Licence			✓	Yes

6. Monitoring of activities covered by the procedure

6.1 The Deferrals Manager will conduct quarterly quality checks on a sample of research summaries (deferred and non-deferred) and highlighting any issues to appropriate teams within the HRA.

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 regarding research summaries is welcome via study.registration@hra.nhs.uk.

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

8. Management of Documents and Records

Periodic review of the document and associated forms will be managed through the HRA HUB. Records associated with the process will be retained and destroyed in line with the HRA Records Retention Schedule.

9. Supporting paperwork/forms

- Clinical Trial Registration and Research Summaries Deferral Log (located in HRA Hub)
- Deferrals Standard Responses (located in HRA Hub)
- Registration Deferrals Policy and Procedure (located on HRA website and HRA Hub)

10. Dissemination and publication of the document

This document will be available via the HRA website and on the HRA Hub.

Screening Questions - HRA Equality Analysis and Privacy Impact Assessment

Equality and privacy screening questions

Instructions: For every HRA policy, defined by the Equality and Human Rights Commissions (EHRC) as a function, strategy, procedure, practice, project, or decision, please answer the questions below to determine whether further analysis is required. If the answer is 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.

Category	Question	Answer yes or no
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?	No

Document Control

Change Record

Version Number & Status	Date of Change	Reason for Change
V0.1	Initial draft	To incorporate the current requirements into one document for research community guidance on Research Summaries
V0.4	Draft	Incorporating comments
V0.5	Final draft	Incorporating changes, comments and addition clarity
V0.6	Draft	Incorporating changes, comments and addition clarity
V0.7	Draft	Incorporating changes
V0.8	Draft	Incorporating changes
V0.9	Draft	Incorporating changes, comments and addition clarity
V1.0	2016.10.07	For publishing on the HRA website
V1.1	2019.10.01	Administrative and clarification
V1.2	2020.12.03	Incorporating comments and publishing on HRA website
V1.3	2020.12.10	Formatting changes for accessibility reasons
V1.4	2021.10.06	Ownership moved from HRA Head of Guidance and Advice to HRA Head of Policy and Engagement

Reviewers

Name (name of reviewer and/or management group reviewing)	Version Reviewed
Internal (Draft group (CB, SB, TS (v0-5 JM)	v 0-1, 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
Eleanor Ashworth	V1.1
Eleanor Ashworth	V1.2
Sue Bourne	V1.2
Juliet Tizzard	V1.2
HRA Communications Team	V1.2
Eleanor Ashworth	V1.3
Sue Bourne	V1.3
HRA Communications Team	V1.3
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Distribution of Approved Versions

Platform (e.g.HRA Hub or website)	Date of Publication	Version Released
HRA Website	October 2016	V 1.0
HRA Website and HRA Hub	December 2020	V1.3
HRA Website, HRA Hub, Sharepoint	October 2021	V1.4

Platform (e.g.HRA Hub or website)	Date of Publication	Version Released