Health Research Authority

Confidentiality Advisory Group Standard Operating Procedures

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Contents

1. Introduction

1.1 This document sets out standard operating procedures (SOPs) for the Confidentiality Advisory Group (CAG). CAG is a committee appointed by the Health Research Authority (HRA) which provides independent expert advice to the HRA and the Secretary of State for Health via the Department of Health External Relations Directorate, under the Health Service (Control of Patient Information) Regulations 2002.

1.2 CAG is required to act in accordance with its SOPs and is ultimately accountable to its appointing authority for its governance in this respect.

1.3 The CAG SOPs include information in relation to procedures followed by both CAG and the Confidentiality Advice Team (CAT) throughout the lifetime of an application. They can be used to determine expectations of the CAT, CAG and applicant.

Contact details

1.4 The contact details for CAT are HRA.CAG@nhs.net or 020 797 22557.

Reference documents

1.5 Templates

C01: Observer Confidentiality Agreement

AM1: amendment validation email – not valid

AM2: amendment validation email – valid

AM3: HRA amendment outcome letter

AM4: SofS amendment outcome letter

AR1: Annual review reminder letter

AR2: HRA annual review outcome letter

AR3: SofS annual review outcome letter

FM1: validation email full meeting application

FM2: validation under consideration email full meeting application

FM3: invalid full meeting application

PS1: validation email precedent set application

PS2: validation under consideration email precedent set application

PS3: invalid precedent set application

CAGSF1: CAT advice form

CAGSF2: CAT assessment form

CAGSF3: Non-research application form

CAGSF4: Precedent set member review form

CAGSF5: Annual review template

CAGSF6: Amendment request template

CAGSF7: Application closure template

SL01: Support not required outcome letter

SL02: Final approval outcome letter

SL03: No recommendation, further information required from applicant outcome letter

SL04: Not supported outcome letter

SL05: Provisional approval outcome letter

SL06: Conditional approval outcome letter

SL07: Application closure confirmation letter

M1: CAG meeting minutes template

M2: CAG precedent set minutes template

M3: CAG sub-committee minutes template

M4: CAG chair's action report template

OR1: CAG office report template

CP1: CAG cover paper – complex items

CP2: CAG cover paper – resubmission

1.4 Confidentiality Advisory Group guidance on overarching governance arrangements - this document sets out the overarching governance and framework under which CAG operates.

1.5 Operational Management Guidance on the process for CAG and REC interaction – this guidance defines the process for communication and interaction between the Confidentiality Advisory Group (CAG), Confidentiality Advisory Team (CAT), Research Ethics Committees (RECs) and Research Ethics Service staff.

1.6 Precedent set review process – the precedent set review provides for a transparent and timely review process for applications where precedent advice been set in relation to the key issues engaged by the application. This document sets out the principles and criteria used to determine if an application can be considered under this process. This document is reviewed every 6 months.

1.7 Confidentiality Advisory Group Terms of Reference.

1.8 Confidentiality Advice Team office manual - the office manual is a reference document of the low level details of CAG processes for the Confidentiality Advice Team.

2. Prior to submitting an application

2.1 An applicant intending to submit a new application should contact the CAT prior to completing any application in order to seek advice regarding the following:

- Whether an application to CAG would be recommended for the specified activity.
- Whether an application would be suitable for review through the precedent set process, taking into account the criteria published on the HRA website.

Pre-submission advice

2.2 Prior to formally submitting an application, all potential applicants to CAG can apply for pre-submission advice by submitting a draft application. The CAT will provide an initial assessment of a draft application. Advice can be provided in writing, by phone or in person depending on the nature of advice required, a record of all pre-meeting advice, however provided, should be recorded on the CAT advice form (ref: CAGSF1).

2.3 Pre-submission advice will be provided in line with the validation criteria and further information that may be requested at validation stage as outlined in section 4 below.

Submitting a request for pre-submission advice

2.4 Pre-submission advice should normally be requested by the applicant by email.

2.5 The applicant should submit a completed draft application form including details which are as close as possible to the final application. All research applicants should use the Integrated Research Application System (IRAS). All non-research applicants should complete the standard 'section 251 support' application on the HRA website. If sections are omitted applicants should consult with the CAT prior to the request to ensure that there is adequate information to provide pre-submission advice.

2.6 Pre-submission advice, however sought and provided, must be recorded on the CAT advice form. This form will be used to provide a complete record of all advice provided by CAT and responses from an applicant and should be submitted to CAG members for review with the final version of the application. The applicant should provide their responses to CAT advice on the advice form. A copy of the form will be retained in the application file on the shared drive and uploaded onto HARP.

2.7 Pre-submission advice must be provided by the CAT within 10 working days of the receipt of a draft application form.

2.8 It is up to the applicant when they choose to formally submit the application following pre-submission advice; a copy of the advice form with the applicant responses must be included with the final submission.

2.9 In exceptional circumstances and with agreement from CAT, it will be more appropriate for pre-submission advice to be provided using an alternative process. This will involve situations where, for example, the data collection raises particularly significant or new confidentiality issues and the applicant is seeking an early steer on handling and issues to be resolved that could involve a number of stakeholders. In these instances, it may be agreed that a detailed

briefing paper and subsequent meeting may be the most appropriate method to provide pre-submission advice. Such instances and timescales in these instances will be agreed with the CAT. The advice provided at the meeting should be recorded on the CAT advice form.

3. New applications for review by CAG

General requirements for submission of new applications

An application for review by CAG should normally be made by the applicant seeking to access confidential patient information without consent.

3.1 Under normal circumstances only one application should be submitted in relation to any activity to be conducted within England and Wales; however there may be exceptions where different data flows within the activity add complexities which mean that more than one application is required for an activity.

3.3 All new research applications should be submitted on the standard on-line application form in the Integrated Research Application System (IRAS) (http://www.myresearchproject.co.uk).

3.4 All new non-research applications should be created on the standard 'section 251 support' application form (ref: CAGSF5) available on the HRA website.

3.5 Both research and non-research applications should be submitted electronically to the CAG email address.

Booking an application

3.6 When booking an application the booking checklist should be followed on the HRA website.

3.7 If the applicant is not ready to submit the application including all required authorisations and supporting documentation, the booking should not be accepted. The applicant should be advised to re-book once the application is complete and ready for submission.

3.8 Applicants should be offered the first available meeting slot whether being reviewed via the precedent set process or full CAG meeting. Once the booking has been accepted the member of CAT should record the booking and the applicant should email all documents to the CAG contact email address.

3.9 If the application is not submitted within 24 hours the booking will be cancelled, and the applicant informed by email.

3.10 If a meeting is fully booked (8 new applications) the applicant should be informed of this and offered a booking on the next available meeting. Urgent applications may be accepted under exceptional circumstances if the meeting is full and this will be at the discretion of the Director of Operations and Approval and the Chair of the relevant CAG meeting.

Submitting an application

3.11 Applications forms must be accompanied by relevant supporting documentation. These requirements are set out in application checklists, which are published alongside the CAG form on IRAS for research applications and at the end of non-research application form (ref: CAGSF3). The checklist must be completed by the applicant when submitting an application.

3.12 Document should be provided in either word or PDF format and should be in black and white. Application forms should not include embedded documents.

3.13 The process for submitting non-research and research differs and the process for each is outlined below:

3.14 Non-research

Non-research applications and supporting documentation must be submitted electronically to the CAG contact email address where possible, the applicant should arrange for any necessary declarations to be signed electronically, or signed and scanned to PDF. Where this is not possible, the CAT will accept hard copy signatures.

3.15 Research

Research applications should be saved from the IRAS system in both PDF and XML format and submitted electronically, along with supporting documents, to the CAG contact email address.

4. Validation of applications

4.1 Once a submission is received for either a precedent set or meeting review, the CAT will carry out an assessment to determine whether there is sufficient information provided to confirm that the application is valid, taking into consideration the validation criteria set out in 4.4.

4.2 The purpose of validation is to ensure that there is sufficient and complete information to enable consideration by CAG. An application will not be submitted to CAG for review until sufficient information has been received to confirm that the application is valid.

4.3 All advice provided by CAT prior to CAG review should be recorded on the CAT advice form (CAGSF1).

Validation criteria for new applications

4.4 The points below (a-d) outline the information that must be provided before the application can be confirmed as valid and submitted to CAG for review. These areas refer to the Regulation requirements and clarity of information provided and required for CAG to review and provide advice.

a) Application form has been fully completed, relevant supporting documents have been submitted (listed on IRAS checklist and non-research application form ref: CAGSF3) and the application has been signed or e-authorised.

b) Application is clear and comprehensive, i.e. without the use of overly technical language or acronyms, and all data flows have been adequately explained.

c) The application provided addresses the requirements of the legislative framework including:

- Applicant has clearly detailed the medical purpose in the activity taking place.
- Applicant has set out their considerations of the potential alternatives to the use of confidential patient information that they have explored (e.g. consent or use of anonymised data) and detailed why these have not proved to be feasible.
- Applicant has demonstrated that the requirements of the Data Protection Act 1998 have been considered and that the activity is not inconsistent with the DPA, in line with guidance provided.
- In circumstances where it is unclear if an application falls within CAG scope, the applicant has demonstrated, with reference to legal advice if required, that the activity does fall within scope.

Validation for resubmitted applications

d) Where the application has previously not been supported and is therefore a resubmission:

- Confirmation of previous CAG reference number.
- A covering letter fully explaining how the new application addresses the previous advice outcome from CAG, and how these have been resolved.
- Any changes to study documents must be highlighted, and documents given revised version numbers and dates where applicable.

If these areas have not been addressed the application will not be confirmed as valid for CAG review as the minimum amount of information required has not been provided.

CAT assessment undertaken following receipt of a valid application

4.5 The CAT will also consider and may raise queries in relation to other aspects of the application following receipt of a valid application. These may include but are not limited to:

- Supporting documents have been marked with version number and date in the file name.
- Applicant has confirmed what efforts can be made to inform the public and participants of the activity in order to ensure that the processing of data is as transparent as possible.
- Whether the application has undergone Research Ethics Committee (REC) review and if so whether there are any relevant points arising from the outcome. (The application can be considered by the REC prior to or after CAG advice).
- Confirmation whether the applicant has undergone or begun an Information Governance Toolkit assessment, including whether an improvement plan is in place. Where an improvement plan is in place, CAT should obtain a copy.
- Checking the applicant's registration is valid and up to date on the Information Commissioners Office (ICO) register of data controllers on the ICO website.
- User involvement that has been carried out or planned in relation to the activity.
- Consideration whether further advice in relation to particular aspects of the application is required from an expert advisor (see section 5.41 – 5.46) or legal advice in consultation with the Chair of CAG, and seeking advice where necessary.
- Whether relevant data controller/processor contracts are in place. Copies may be requested if necessary.
- Any other relevant points of clarity.

4.6 Further information will be requested on the CAT advice form at this stage.

Validation process

4.7 Following the initial validation assessment, the CAT will email the applicant (using the relevant standard email ref: FM1, FM2, PS1 or PS2) to confirm whether the application is valid or whether further information is required prior to confirming that an application is valid in line with the criteria in 4.4 above. Requests for further information which are made pre-meeting must be provided on the CAT advice form (ref: CAGSF1).

4.8 If further information is required the validation of the application remains under consideration pending responses and it is the applicant's responsibility to ensure that responses to the request for further information are returned within the specified timescales. The status section should be amended within HARP to reflect that the application is in the validation under consideration stage. The timescales in which a response is required will normally be 7 calendar days. Extensions will be made at the discretion of the CAT. If the information requested is not provided within the specified timescales the application will be declared as invalid (see section 4.18 and 4.19 below).

4.9 Following the receipt of responses on the CAT advice form or an amended application form the CAT may have further queries or advice which will be raised at their discretion either by telephone or email.

Amendments to research application forms prior to CAG review and interaction with RECs

4.10 Amendments to research applications will not normally be requested if the application has already been submitted to a Research Ethics Committee. However, if the extent of changes means that the application form no longer reflects the research protocol the Operational Management Guidance (available on HRA intranet) on the process for CAG and REC interaction should be followed to determine if changes will have any impact on the REC application.

4.11 After confirming an application as valid, the CAT may ask questions on the following aspects:

- Status of REC review
- Status of IGT review

Amendments to non-research application forms prior to CAG review

4.12 Amendments to non-research application forms will be requested where necessary as the application form is not constrained by multiple reviews from different approval bodies.

4.13 Following the receipt of responses on the CAT advice form or an amended application form the CAT may have further queries or advice which will be raised at their discretion either by telephone or email. All advice provided and responses pre-meeting should be recorded on the CAT advice form. (ref: CAGSF1).

Timescales for validation assessment

4.14 CAT will complete the validation assessment of the application within 7 calendar days of receipt.

Decision on validation

4.15 It is the responsibility of the CAT to assess whether or not the application is valid, based upon the minimum criteria specified in 4.4 and to notify the applicant. A valid application may be declared based on the initial application submission documents only or in conjunction with further information provided by the applicant following a request by CAT.

4.16 The relevant date ("the validation date") is the working day on which sufficient information has been received to declare an application as valid. The clock will start on the validation date. The agreement of the Chair is not required to decide if an application is valid.

4.17 Following validation, the CAT will consider, in liaison with the Chair, whether it is necessary for an applicant to attend the CAG meeting and inform the applicant of the time and date of attendance. The need to attend a CAG meeting will be assessed by the CAT and options such as video and telephone conferencing will be offered.

Invalid applications

4.18 Applications will be declared invalid in the following circumstances where the applicant does not provide a complete response to the advice from CAT in relation to the points in section 4.4 above by the requested date and has been informed that the application cannot be confirmed as valid until these have been received.

4.19 The CAT should notify the applicant with confirmation of the reasons why the application is considered not to be valid. The standard email templates should be used for this purpose. (ref FM3 or PS3). The application will not be included on the agenda for the next meeting. The relevant time period for review of the application does not start until a valid application is received.

5. CAG meeting – procedure

General policy

5.1 All valid applications should be reviewed at a full meeting of the CAG held in accordance with the following procedures, except where the precedent set review process is used. Precedent set applications will be reviewed by a sub-committee of CAG.

5.2 Agenda items other than booked applications can include items referred from sub-committees or Chair's action, provisionally approved applications that were required to provide further information to a full CAG meeting or items for consideration/discussion.

Meeting schedules

5.3 The CAG should normally hold at least 10 scheduled full meetings in each year for the purposes of review of applications. Meetings to review applications should normally be held at intervals of between 4 and 6 weeks.

5.4 The schedule of meetings for the year commencing on 1 April should be produced by the CAT by 30 September in the previous year. The schedule should set out the dates of meetings, and the cut-off date for applications to each meeting. All members of CAG should be issued with details of the schedule.

5.5 The cut-off date for applications should normally be no more than 22 calendar days prior to each CAG meeting. Cut-off and meeting dates will be made available on the HRA website.

Allocations

5.6 Members attending a meeting will receive a copy of all applications, unless a known conflict of interest has been declared which means that the member cannot review the application. Lead reviewers and readers will be allocated.

5.7 Allocations will be managed by the CAT and where possible expert members will be allocated applications in line with their area of expertise. A log of allocations will be maintained.

5.8 New applications, resubmissions and amendments will be allocated to at least 3 members (1 lead reviewer and 2 readers). A member should have attended at least 2 meetings prior to being appointed a lead reviewer. Where possible, readers for resubmissions and amendments should be those members who were readers on the original application.

Lead reviewers

5.9 Usually one lead reviewer will be appointed for each application. The lead reviewer will be expected to provide a summary of the main issues raised by that application, and offer their comments and recommendation.

Agenda

5.10 The CAT should prepare the agenda for the meeting. The agenda will include following:

- The date, time and venue of the meeting
- Declarations of interest item
- Applications to be considered at the meeting (new and for further consideration)

- Amendments to be considered at the meeting
- Annual reviews to be considered at the meeting
- Minutes of the previous CAG meeting
- Matters and action points arising at previous meeting(s)
- Office Report by the CAT

5.11 The agenda may also include discussion of the following where appropriate:

- Chair's Report
- Matters relating to the establishment or membership of CAG
- Matters relating to CAG procedures
- Issues relating to the improvement programme of the CAG
- Other items for consideration

5.12 It is important that meetings do not contain so many agenda items as to undermine the rigour of review. The aim is that CAG will review no more than 8 new applications at a meeting but may review other items. The CAG may limit the number of new applications if an agenda item is complex and will require significant discussion.

5.13 In allocating business between the full CAG and sub-committee meetings, the CAT and the Chair should weigh carefully the requirement to give timely advice, the need to conduct CAG business efficiently and with due care, and the overall demands of the agenda on members.

Office Report

5.14 Members should be notified in writing of business undertaken outside CAG meetings, including at least the following:

- Minutes of the advice given or actions taken in relation to amendments by the CAT, CAG members, including Chair and Vice-Chair, under delegated authority, including members involved. This advice should be provided on the relevant template with the next meeting minutes. (ref: M3, M4 or OR1)
- Advice given or actions taken by a sub-committee either at a meeting or in correspondence in relation to a precedent set review applications, including members involved, the decision taken and whether the application was research/non-research (ref: M2).
- Any other issues that the CAT consider to be of interest or relevance to the CAG business.

5.15 The CAT should prepare the report for distribution to Members with the papers for each meeting.

5.16 The office report should normally be distributed with the main papers for the meeting. Once the report has been finalised, any further business that takes place prior to the meeting may be deferred to the report for the following meeting. Where exceptionally the Chair or CAT considers it essential that a matter is reported to the CAG as soon as possible, a further written report may be prepared or verbal report made to the meeting.

5.17 The office report and any attachments are mainly for the information of Members and should not normally require detailed discussion. Members should be allowed to raise any comments about the actions taken on their behalf. Any such concerns should be considered by the CAG and recorded in the minutes.

Readers

5.18 Readers will be allocated copies of full applications and will be expected to offer their own summary of any issues raised by the application that have not been addressed by the lead reviewer. They are expected to have considered the application in full and will be called upon to offer their comments on the application during the meeting.

5.19 Other members, who are neither readers nor lead reviewers for a particular application, will receive a copy of the application and where appropriate will be invited to ask pertinent questions of the lead and other reviewers.

Distribution of papers for meetings

5.20 The CAT should arrange for distribution of the papers (either by post or email, or member portal when available) for the meeting no later than 7 working days prior to the meeting. Papers for the information of Members may be distributed nearer to the date of the meeting or, exceptionally, tabled at the meeting. Under no circumstances should full applications be tabled at the meeting.

Quorum requirements and meeting attendance

5.21 If the Chair is unavailable for a meeting then the Vice-Chair or alternate Vice-Chair will act as Chair, or if all Officers will be absent, the Chair will ask one of the Members to act as Chair or, if necessary, the Members present will agree on a Member to act as Chair for that meeting. An acting Chair's appointment letter should be issued and approved by the HRA Board Secretary & Chief Executive Business Manager if a Member acts as Chair. It is recommended that the Vice-Chair chairs at least one meeting with the Chair in attendance.

5.22 CAG has up to 18 members and the quorum for meetings of the CAG is 7 Members, including at least the following:

- The Chair or, if unavailable, the Vice-Chair or Alternate Vice-Chair or person designated Chair by Members if Chair, Vice-Chair and alternative Vice-Chair are unavailable
- One lay Member

5.23 Members are normally expected to attend in person. However, in exceptional circumstances Members may attend by teleconference or videoconference with the permission of the Chair and CAT.

5.24 The following should not be counted for the purpose of the quorum:

- The CAT
- Observers
- Expert advisors
- Members who are yet to arrive at the meeting, or who have left early

- Members who submit written comments but do not attend either in person or by teleconference or videoconference

5.25 A meeting, or part of the meeting, at which a quorum of Members is not present, may proceed with any other business on the agenda, provided that the Chair (or vice-Chair or alternate vice-Chair) and at least one other Member is present.

5.26 The CAT should keep a record of attendance, indicating which Members were present for the discussion of each application.

5.27 Where the CAT are concerned that a forthcoming meeting may not be attended by a quorum of Members due to foreseen absences, they should consider the following options

- Postponing and re-arranging the meeting, in consultation with the Chair, considering impact on application activities.

- Cancelling the meeting - where it is proposed to cancel a planned meeting, the agreement of the Director of Operations and Approval and Chair must be sought at an early stage.

- Continuing with the meeting and agreeing the advice to be issued at a quorate meeting by teleconference at a later date.

- Co-opting members from CAG2 when possible (*when function resourced*).

Written comments from members

5.28 A Member who is unavailable to attend a meeting may submit comments in writing on any agenda item. These should normally be received by the CAT at least three working days prior to the meeting so that copies may be made available in advance to members. Where later comments are received, they may be tabled at the meeting at the discretion of the Chair. The minutes should record that written comments were submitted from the Member concerned and comments included within minutes, but it should be ensured that specific comments are not attributable to individual members.

5.29 A Member who submits written comments but does not attend the meeting either in person or by teleconference or videoconference does not count towards the quorum.

Declarations of interest

5.30 Members of the CAG are not recruited to represent their organisation or employer, but for their personal expertise and knowledge. Given expert membership and the national role of the Group it is probable that, from time to time, individual Members will have interests, and perceived interests, in the outcome of CAG business. The purpose of this is to mitigate any conflict, or perception of conflict, and to ensure public and stakeholder confidence that impartial and independent advice is provided to the approving bodies.

5.31 Members should declare any perceived or material interests that they have in relation to the purpose, role or remit of the Confidentiality Advisory Group (CAG), in line with the policy and terms of appointment. The purpose of this declaration is to ensure that the functions of CAG can be exercised free of bias that could affect the independence of the group and to protect individual members of CAG from any professional or personal conflict. Declarations will take one of two forms: ‘general’ or ‘specific’. Any declaration of a specific interest might either ‘conflict’ or ‘compete’ with a member’s contribution to CAG advice on a particular matter (e.g. agenda item). Members may leave the meeting for the discussion of the application, stay but not participate in the discussion or stay and fully participate in the discussion depending on the

nature of the interest. The appropriate course of action should be decided at the meeting following discussion with other members. Members may wish to proactively excuse themselves from the discussion and such decisions will be respected and recorded.

5.32 Annually declarations of interest are reviewed and this review documented and uploaded onto HARP.

5.33 During a meeting it is the responsibility of the Member to highlight any conflicts of interest to the Chair. This could be in relation to past or current employment.

Confidentiality of proceedings

5.34 CAG members do not sit on the CAG in any representative capacity and need to be able to discuss freely the application submitted to them. For this reason CAG meetings should be held in private, and members should be encouraged to raise any matters of concern

5.35 The terms and conditions of appointment for members and deputy members include requirements to keep confidential the business of CAG.

Observers

5.36 External observers may be invited to attend meetings with agreement of the Chair and will be arranged by the CAT. External observers must sign a confidentiality agreement.

5.37 External observers should have no vested interest in or scientific or management responsibility for, any applications being considered at the meeting.

5.38 Meetings, or parts of meetings, may also be attended from time to time by representatives of appointing authorities, auditors and HRA staff. The Chair should be notified prior to the meeting.

5.39 Observers should not normally take any part in the CAGs deliberations or advice on particular applications. Exceptionally, they may be invited by the Chair to answer specific questions if they possess expertise that it is thought could usefully inform the deliberations. In this case, the fact of any contribution will be recorded in the minutes.

5.40 If any observer is present, then the Chair should verbally inform any applicant who attends the meeting. The applicant should be given the opportunity to object to the presence of an observer (other than an official observer). If there is an objection, the observer should be asked to leave the meeting room for that item. The attendance of observers should be recorded in the minutes.

Expert advisors

5.41 CAG may seek the advice of an expert advisor on any aspects of an application that are relevant to the formation of final advice offered to the approving body, and which lie beyond the expertise of the members or on which CAG is unable to agree. These expert advisors may be specialists in legal or technical aspects, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups.

5.42 The HRA may also identify that further expert advice is required for CAG following a representation by an applicant and appoint an expert advisor.

5.43 Expert advisors are not voting members of CAG, and should not be involved in the business of CAG other than that related to the application on which their advice is sought.

5.44 The advice of an expert advisor should be sought using one of the following procedures:

(i) CAT or the Chair may write to the expert advisor seeking written advice prior to the meeting. A copy of the advice received should be made available to members prior to the meeting or tabled at the meeting. The substance of the advice should be recorded in the minutes.

(ii) The expert advisor may be invited to attend the meeting in person for discussion of the application concerned. The attendance of the expert advisor and the substance of his/her advice at the meeting should be recorded in the minutes. The expert advisor should not personally question the Chief Investigator at the meeting, or have a vote in the decision taken by CAG.

(iii) The Committee may decide at the meeting to recommend provisional support and seek written advice following the meeting (see 7.39 – 7.45). CAT or the Chair should normally write to the expert advisor within 5 days of the meeting. The written advice received should then be considered promptly in accordance with procedures agreed at the meeting.

5.45 Expert advisors should be required to treat in confidence all information provided about the application, except where already in the public domain, and to return or destroy any application documentation. When an expert advisor is approached to provide specialist advice, the advice given should be recorded in the minutes as given by an expert advisor and will specify their role and organisation. CAT should also record what the Committee decided to do when taking the advice into consideration. When specialist advice is requested after the CAG meeting, prior to a decision being given, the advice provided should be reviewed by a sub-committee.

5.46 The opinion reached by CAG on an application is its own. It may draw on the expert advisor's advice in framing its opinion, including any request for further information, and may indicate to the applicant that it has sought advice from an expert advisor. The original correspondence and any reports from an expert advisor should be retained in HARP for subsequent reference where necessary.

Conduct of business and advice giving

5.47 The Chair of the meeting is responsible for the conduct of the business and for ensuring that the Committee reaches clearly agreed decisions on the advice to be given on all matters.

5.48 The meeting should determine its advice by consensus wherever possible.

5.49 Where a consensus is not achievable a formal vote should be taken by a counting of hands. The advice of the CAG should be determined by a simple majority of those Members present and entitled to vote. A record should be kept of numbers of votes, including abstentions. Where the vote is tied, the Chair may give a casting vote, but should first consider any other options to arrive at a more consensual decision.

5.50 Where any Member wishes to record his/her formal dissent from the advice of the CAG by name, this should be recorded in the minutes.

Responsibilities of the CAT

5.51 The secretariat to the meeting will be the Confidentiality Advice Team (CAT).

5.52 The responsibilities of the CAT in relation to CAG meetings are as follows:

- Preparing the agenda and assessment forms (ref: CAGSF2) for new applications.
- Provision of relevant cover papers for resubmission (ref: CP2) and complex requests (ref: CP1) to ensure that CAG time is best directed.

- Assessment of applications to ensure fit for CAG consideration; raising and pre-emptive issues etc.
- Providing an office recommendation to the CAG on the application outcome.
- Allocating lead reviewers and readers.
- Distributing the agenda and papers.
- Inviting, where appropriate, applicants to attend and making the necessary arrangements.
- Preparing the venue.
- Recording apologies for absence prior to the meeting.
- Ensuring the meeting will be quorate.
- Recording attendance by Members and observers for the discussion of each application.
- Advising the meeting as necessary on compliance with standard operating procedures.
- Advising members as necessary on additional points gained through the CAT assessment or providing clarification where relevant.
- Recording votes where a vote is taken on a decision.
- Preparing the minutes of the meeting for review and approval at the following meeting.

Advice letters

5.53 The letters of advice should be prepared by CAT and sent to the approver within 5 working days of the CAG meeting, sent to applicants within 10 working days and the minutes of the CAG meeting should be prepared by the CAT within 15 working days of the meeting.

Minutes

5.54 The minutes of the CAG meeting should be prepared by the CAT within 15 working days of the meeting. The content of the minutes will be based on the letters.

5.55 The minutes should contain a record of the following, whether in the main text of the minutes or in attachments:

- The members, absent member who have provided written comments, applicants and observers present for the discussion.
- Any interests declared and the detail of the interest and the decision of the Chair on the participation of the Member concerned.
- A summary of the application purpose, why support is requested, what data items are required and the applying organisation
- A summary of the main issues considered

- The advice of the CAG on the application (see section 7 for possible outcomes) and the rationale for advice, including:

  (i) In the case of a recommendation for support, any conditions recommended to be met prior to the start of the study or additional non-binding advice to be given to the applicant.

  (ii) In the case of a recommendation that an application not be supported, the reasons for the advice.

  (iii) Where no recommendation is offered or provisional support is advised, the issues on which further information is required and the action points.

  (iv) The outcome of any vote taken. (Individual votes should be recorded separately from the minutes).

  (v) Where requested by a member and on agreement with the Chair, recognition of formal dissent from the advice of the CAG by a named member, with reasons.

  (vi) Any additional points raised that are not suitable for inclusion in the outcome letter e.g. where the CAG request a specific action arising but not directly linked to an application.

  (vii) Details of advice provided by the expert advisor, along with their role and organisation.

  (vii) Education items will be recorded in the minutes as an education item with the presenter's names, organisation, title of presentation and educational objectives.

5.56 Some issues documented may be solely for information of CAG members and may not be recorded in the formal minutes e.g. where the information is sensitive or not otherwise in the public domain and publishing would prejudice the effective operation of the CAG, or that of the entity providing information to the CAG.

5.57 The minutes should be presented as the outcome of collective discussion. Unless an individual Member requests that a formal dissent is recorded, the minutes should not attribute particular statements to individual Members attending the meeting or providing written comments.

5.58 The minutes should be distributed to all members with the papers of the following meeting of the CAG for formal ratification as a true record. Any necessary revisions should be incorporated in the final version of the minutes. The final version should be signed and dated by the Chair and by a member of the CAT.

5.59 Where revisions are made to the minutes, the Chair should consider the need to write to applicants correcting any inaccuracies or clarifying points made in the letter sent after the meeting. However, no substantially new request for information may be made at this point unless there are exceptional circumstances.

5.60 The minutes of CAG meetings are to be published on the HRA website and freely available to applicants or any other interested party. Copies of minutes should be retained by the CAT.

6. Expedited applications

6.1 On occasion there will be emergency applications made at the request of the Secretary of State for urgent public health matters where processing is being requested under Regulation 3(4).

6.2 On occasion there will be emergency applications made under Regulation 5 which should be expedited as a matter of public interest due to the urgent nature of the activity. CAG will adopt the following criteria when considering whether expedited review of an application is warranted in these circumstances:

- The potential loss of valuable data or data quality, or disproportionate effort being required to capture the data
- The potential impacts of any delay on public health
- The importance of the activity for informing, shaping or defining health policy and service provision

6.3 The applicant will request that the application is expedited in line with the criteria above and the Director of Operations and Approval must provide confirmation that the application can be expedited.

6.4 In these circumstances the CAT should arrange for the application to go for immediate review by a minimum of 3 members (including 1 lay) and an Officer of CAG (Chair, Vice-Chair or Alternate Vice-Chair) by email or telephone. At this stage, members can raise issues about the application and request broader review by additional CAG members.

6.5 The submission format will vary depending on whether the application is for a research or non-research activity:

Non-Research

Applications should be submitted on the non-research application form. It is possible in these situations that the application may not follow the usual format, but may take the form of a written brief. The written brief must include details of the public interest including the benefits to health and social care, data flows, dataset required, purposes for processing and confirmation of security arrangements.

Research

All research applications must be submitted using the IRAS form.

6.7 The Confidentiality Advice Team will advise the applicant directly on the arrangements and oversee the process throughout an expedited review to ensure that the application is reviewed as expeditiously as possible compatible with robust review of any confidentiality issues. The precedent set member review form should be used for this process.

6.8 The Director of Operations may specify the time periods within which each stage of the process should be completed.

6.9 Outcome letters from reviews of expedited applications will follow the normal format; the Confidentiality Advice Team will provide the advice to the approving body (see section 8) on the next working day following advice being given by CAG.

7. CAG advice outcomes

Timescales for outcome

7.1 The target processing time for a full meeting application is 60 calendar days from the validation date.

7.2 The target processing time for a precedent set application is 30 calendar days from the validation date.

7.3 The letters of advice for full meeting applications should be prepared by CAT and sent to the approver within 5 working days of the CAG meeting and sent to applicants within 10 working days. The letters of advice for precedent set application should be prepared by CAT and sent to the approver within 3 working days of the Chair summary being available and sent to applicants within 7 working days.

Possible outcomes

7.4 The CAG should advise one of the following after consideration of an application at a full or precedent set subcommittee meeting:

a) An application meets the minimum threshold of the Regulations and is fully supported
b) An application meets the minimum threshold of the Regulations and is conditionally supported
c) An application meets the minimum threshold of the Regulations and is provisionally supported pending further information
d) No recommendation provided, further information is required from the applicant to determine if the requirements of the Regulations are met
e) No recommendation provided, further information is required from a third party to determine if the requirements of the Regulations are met
f) Support is not considered to be required.
g) An application does not appear to meet the minimum requirements of the Regulations and is not supported (full meeting only)
h) Recommendation not provided, promoted to full meeting review (precedent set meeting only)

7.5 The advice will need to be sent to the approving bodies (see section 8) and the approving bodies will need to take a decision at initial outcome letter stage regardless of the outcome, and each subsequent outcome where CAG has provided additional advice in relation to the same submission, e.g. after 3, 4 and 5.

7.6 The Chair and the Confidentiality Advice Team should ensure that one of the above advice options is given in relation to every application considered at full meeting or via precedent set sub-committee.

7.7 Where the CAG advises that either:

1. An application meets the minimum threshold of the Regulations and is provisionally supported pending further information or,

2. No recommendation provided, further information is required from the applicant to determine if the requirements of the Regulations are met or,
3. No recommendation provided, further information is required from a third party to determine if the requirements of the Regulations are met. The process in 5.41 – 5.46 in relation to seeking advice from expert advisors should be followed.

The Chair of the meeting or sub-committee and the Confidentiality Advice Team should ensure that:

- The further information or clarification required is specifically identified.
- The delegation of responsibility for considering the further information and issuing the CAG's advice is clearly agreed (see 7.25-7.28 below).

7.8 Requests for further information or clarification from the applicant may include recommendations for revision of the application form, provision of further information in the form of a letter or a meeting with the applicant.

7.9 CAG should avoid requesting revision to IRAS forms where these have already been submitted to the REC for review.

Precedent Set review outcomes

7.10 A sub-committee considering a precedent set application can give advice in the same way as a full meeting, including requests for information or clarification that will address straightforward issues.

7.11 However, a sub-committee will not advise the approving body that an application should not be supported. If a sub-committee considers that an application should not be supported, then the application should be promoted to full review in line with 7.53-7.57 below.

Notification of the decision to the Applicant

7.12 All letters (ref: SL01 – SL06) should be in the name of the Confidentiality Advice Manager, Deputy Confidentiality Advice Manager or Confidentiality Advisor who will have delegated authority to report the outcome from Secretary of State and HRA . The supporting advice from CAG will be included.

7.13 The following information should in all cases be included in the letter or in enclosures:

- A summary of the issues considered by the CAG.
- The decision by either the HRA or the SofS following CAG advice.
- Any specific conditions in place and confirmation of whether conditions must be met prior to final approval. Standard conditions of approval are available on the HRA website.
- A list of all documents reviewed at the meeting, giving version numbers or dates.
- A list of the Members who were present for the discussion of the application or who submitted written comments on the application prior to the meeting. The list should indicate lay members.
- Declarations of interest by members, which were material to the application, and whether or not the Member concerned took part in the review and voted on the decision. It is not necessary to give details of the interests, only that a declaration was made.
- The names of any observers present at the meeting.
- A named contact point (normally the CAT) for receipt of queries from the applicant.

7.14 The summary of issues should set out the main issues considered by the CAG when issuing advice. It is not necessary to include all the questions raised at the meeting, such as requests by lay Members for explanation of technical points.

7.15 The letter should not attribute particular comments or questions to individual Members.

a) An application meets the minimum threshold of the Regulations and is fully supported

7.16 CAG may recommend that an application is fully supported if it meets the minimum threshold of the Regulations; in this case no further information will be required from the applicant. Standard conditions will apply and the applicant must provide assurance of satisfactory completion of the Information Governance Toolkit for those organisations processing confidential patient information prior to disclosure taking place. The process for submission and review of the Information Governance Toolkit in relation to CAG submissions can be found on the HRA website.

7.17 The clock will stop when the outcome letter is sent from CAT following HRA decision (research) or to the Secretary of State (non-research).

b) An application meets the minimum threshold of the Regulations and is <u>conditionally</u> supported

7.18 When giving a recommendation of support, CAG may specify any conditions to be met .These should be clearly set out in the decision letter. Conditions can either refer to actions to be taken prior to receiving final support, for example confirmation of a favourable REC opinion or, ongoing actions that should be adopted whilst processing confidential patient information or reported on at a specified time, for example reporting on patient involvement or reducing the amount of identifiers required at annual review stage.

7.19 The clock will stop when the outcome letter is sent from CAT following HRA decision (research) or to the Secretary of State (non-research).

7.20 If the conditions refer to actions to be taken prior to receiving final approval, the applicant <u>must</u> ensure conditions are met prior to approval coming into effect

7.21 CAG should avoid wherever possible attaching conditions where:

- The changes concerned would require further ethical consideration in order for the REC to give a favourable opinion of the research (e.g. significant revision of the participant information sheet)

7.22 The applicant should notify the CAT in writing once the conditions have been met and provide copies of final documentation where appropriate. CAT will then write to confirm final approval to the applicant.

7.23 CAG may also give advice or make suggestions that are not binding on the applicant. These should be clearly distinguished from any conditions specified as part of advice. CAG should only include non-binding advice or suggestions where these are not material to the advice provided i.e. it would not change advice if the applicant opted not to implement them. Where any changes suggested would amount to substantial amendments (e.g. to the study design), the applicant should be advised of the need to notify the REC and obtain a favourable opinion before implementing them.

7.24 If the conditions of approval are not met then final approval cannot be confirmed.

c) An application meets the minimum threshold of the Regulations and is provisionally supported pending further information

7.25 CAG may consider it appropriate to request further information from the applicant before providing final advice, but is able to confirm that the minimum threshold of the Regulations have been met. For example, the applicant may be asked if it would be possible to amend data flows to limit the disclosure of confidential patient information which may result in the details of the data requested being changed.

7.26 The clock will pause when the outcome letter is sent from CAT following HRA decision (research) or to the Secretary of State (non-research); the clock will start once a complete response is received from the applicant (see 7.32-7.34).

7.25 Where the CAG or sub-committee requests further information, it should decide in the initial review the procedures for considering that information and determining final advice.

7.26 These responsibilities should normally be delegated to one of the following:

- Officer of CAG, with support from the CAT;
- Officer of CAG, in oral or written consultation with one or more named Members that were present at the meeting or who submitted written comments on the application;
- Sub-committee involving named members and Officer

7.27 In deciding delegation of responsibility, the significance of the further information and the expertise necessary to assess it should be considered. Consideration should be given whether to involve other members, such as the lead reviewer or a relevant expert member.

7.28 CAG may decide that the further information should be considered at a future meeting of the CAG.

7.29 The applicant is advised to contact the CAT if further advice is required in relation to responding to the request for further information.

7.30 The CAG advice form is not used to record queries, advice and responses following a sub-committee or full review meeting for the application. Responses should be provided in the form of a signed letter submitted by email to ensure a record of the information can be retained with the application.

7.31 At this stage additional new points should not be raised by CAG. On receipt of a complete response from the applicant, CAG should issue its advice to the HRA and SofS on the application (see section 8).

Requirement for a complete response

7.32 If an applicant's response is incomplete or does not appear to fully address the matters raised, then the CAG is entitled to insist on a complete response before issuing its final advice. The CAT should write to the applicant, setting out the further information or clarification still required and the request for further information may be issued more than once if the response continues to be incomplete.

7.33 It is recommended that the CAT contact the applicant (or arrange for an Officer or lead reviewer to do so) to discuss the outstanding points and clarify what is expected. The CAG is not entitled to raise any new issues or concerns at this stage of the process.

7.34 The applicant will be asked for a response to the request for further information within one month. The CAT may extend this period at the request of the applicant where there are reasonable grounds for requiring more time to respond. If the applicant does not respond within two months the application may be withdrawn and a new application will need to be submitted. The clock will start again following the submission of the new application.

d) No recommendation provided, further information is required from the applicant to determine if the requirements of the Regulations are met

7.35 The CAG may consider it appropriate to request further information from the applicant before providing final advice and until further information has been received may be unable to confirm whether the minimum requirements of the Regulations have been met. For example, the applicant may be asked if it would be possible to seek consent for all or part of the cohort.

7.36 The clock will stop when the outcome letter is sent from CAT following HRA decision (research) or to the Secretary of State (non-research).

7.37 In most circumstances where there is insufficient information for a recommendation to be made the application will need to be resubmitted and reviewed at a CAG meeting or by a sub-committee of members. If a submission to a future CAG meeting is required the application will need to be booked on to the next available CAG meeting when the applicant is ready to submit their responses, the clock will be reset to reflect the new submission date and the application will be validated as per a new application and given a new reference number.

7.38 On receipt of the advice and following review, the CAG should issue its advice on the application.

e) No recommendation provided, further information is required from a third party to determine if the requirements of the Regulations are met

7.39 The CAG may consider it appropriate to request further information from a subject matter expert before providing final advice and until further information has been received may be unable to confirm whether the minimum requirements of the Regulations have been met. The provisional advice can either reflect that the application is supported in principle or that CAG is unable to confirm advice at this stage.

7.40 The clock will not stop whilst further information is sought by CAG.

7.41 The CAG is able to draw upon expertise in relation to specific aspects that may affect the advice provided at this stage (see 5.41 – 5.46)

7.42 Where possible and the need is identified, the expert advisor will be asked for comments prior to a CAG meeting where time permits. Where comments have not been sought the applicant will be sent a letter confirming provisional advice pending consultation with another.

7.43 Consultation with an expert advisor should take place as soon as possible and within 5 calendar days of the meeting.

7.44 Delegation of review of the advice should be managed in line with 7.25-7.28 above.

7.45 On receipt of the advice and following review, the CAG should issue its advice on the application to the approver.

f) An application does not appear to meet the minimum requirements of the Regulations and is <u>not supported</u>

7.46 Where the final advice is that an application is not supported then the applicant should be given a full explanation of the CAG's reasons. The applicant should also be informed of the options available for further review.

7.47 When an application is not supported this is normally due to the fact that the threshold of the Regulation requirements has not been met. The reasons will be clearly outlined in the outcome letter to the applicant.

7.48 The clock will stop when the outcome letter is sent from CAT following HRA decision (research) or to the Secretary of State (non-research).

7.49 If further information is required in relation to the advice, the applicant is advised to contact the CAT who can provide further advice.

7.50 If an application is not supported an applicant can resubmit the application if required. (Section 9) If the application has already been resubmitted the applicant may make a representation if required.

g) Support is not considered to be required

7.51 CAG can advise that the activity does not appear to involve the disclosure of confidential patient information and therefore an application is not required.

7.52 The clock will stop when the outcome letter is sent from CAT following HRA approval (research) or to the Secretary of State (non-research).

h) An application is promoted to full review (precedent set applications only)

7.53 Where a precedent set application is considered and there are significant issues requiring wider discussion, the sub-committee should refer the application for further review at a full meeting. The applicant should be informed of this by letter. The reasons for promoting to full review should be made clear to the applicant and further information requested where appropriate.

7.54 When possible, the application should be submitted to the next meeting.

7.55 The clock will change to 60 days in line with timescales for a full meeting application.

7.56 A copy of the letter sent to the applicant and any further information provided should be provided to CAG members with the application.

7.57 If the application is promoted to full review and the applicant requests that the application is not submitted to the next available meeting, the clock start date will be on cut-off date for the next available CAG meeting.

Publication of advice

7.58 The minutes of CAG meetings, indicating the advice offered in relation to each application considered shall be published on the HRA website following ratification at the subsequent meeting.

7.59 The register of approved applications, containing details of all applications approved by either the HRA or SofS, will be maintained by the Confidentiality Advice Team and published on the HRA website and updated every 2 weeks.

8. HRA/Secretary of State approval decisions

8.1 The approving bodies will need to take a decision at initial outcome letter stage regardless of the outcome, and each subsequent outcome where CAG has provided additional advice, e.g. after provisional approval where a sub-group of members provides further advice.

Research applications – HRA approval decision

8.2 A copy of the letter summarising CAG advice will be sent to the nominated HRA approver by email. The HRA approver will respond to the request by email within 3 working days to confirm the decision by the HRA. The decision will be included within the outcome letter from CAT.

8.3 The email confirmation from HRA should be saved within the application folder.

8.4 Where the nominated approver is not available they will inform CAT, with 7 calendar days' notice where possible, and confirm the alternative approver.

Non-research applications – SofS approval decision

8.5 A copy of the letter summarising CAG advice will be sent to the nominated Secretary of State representative by email. The SofS representative will review CAG advice within 5 working days and confirm the decision to CAT by email. The decision will be included within the outcome letter from CAT.

8.6 The email confirmation from SofS representative should be saved within the application folder.

9. Resubmitted applications

9.1 It is open to the applicant to submit a new application relating to the same proposal following CAG advice that an application is not supported. The assumption should be that the applicant is attempting to address the concerns raised by the CAG when advising the previous application was not supported. It should be clearly indicated on the application form that it relates to a proposal that has been previously considered.

9.2 A resubmitted application will receive a new CAG reference number.

9.3 The Resubmitted applications must be validated in line with the criteria outlined in section 4.4(d).

9.4 If significant changes have been made as part of the resubmission a new application form must be submitted.

9.5 At least one resubmission must be made prior to a representation being made against the decision.

9.6 If more than one resubmission is made, CAT or CAG members may determine that it is necessary to have a discussion with the applicant in order to clarify the points raised.

9.7 An applicant may in principle continue to submit applications relating to the same proposal. However, following review of three applications the applicant will be advised of the options for representation and consideration will be taken as to whether further review of the application would serve a useful purpose. In this case the applicant may be advised that the application will not be reviewed and to make a representation in line with the process outlined in representations guidance document.

9.8 The Director of Operations and Approval will determine if the application will not be reviewed any further by CAG at this stage.

10. Amendments to applications given support

Determining the requirement for an amendment

10.1 The list below in 10.8 reflects the type on amendment which may affect the existing support under the Health Service (Control of Patient Information) Regulations 2002. If the amendment request does not fit within any of the specified amendment types below the applicant would be advised to contact the Confidentiality Advice Team to discuss the amendment and required action. Following discussion the applicant may be advised to submit an amendment or provided with confirmation that an amendment does not require review and should be submitted for information only.

Submitting an amendment

10.2 Amendments should be submitted on the amendment request form (ref: CAGSF6) available on the HRA website and emailed to the CAG contact email.

Timescales for review

10.3 The advice outcome should be provided no later than 30 calendar days after a valid amendment request is received. If an amendment is referred to a CAG meeting in line with point 10.13 the applicant should receive an outcome no later than 60 calendar days after a valid amendment request is received.

10.4 An amendment may be referred to a full committee meeting if the amendment differs significantly from the original approval or deviates from the original conditions of approval.

Validation of amendment requests

10.5 Once an amendment is received it should be validated by the Confidentiality Advice Team within 7 calendar days. The validation criteria are outlined below in 10.6. CAT will validate and categorise the request in line with 10.8 below and confirm the route of review for the amendment. The standard email should be used to confirm this to the applicant (ref: AM2)

10.6 Where the points below have not been satisfactorily addressed the CAT will request further information from the applicant and this must be provided before the amendment can be confirmed as valid:

- Amendment request form has been completed and signed.
- The change to the application is clearly detailed – changes are most likely to be in relation to data flows, data items, data sources, purposes of the application, data controller or data processor.
- The justification for the change is clearly detailed.
- Any supporting documents that have been substantially changed should be submitted

10.7 Once an amendment can be confirmed as valid an email (ref: AM2) will be sent to the applicant to outline the assessment method and outcome timescales for the amendment. The amendment validation date is the date when all required information has been received.

Amendment types

10.8 The following lists types of amendments that should be submitted for review. The delegation of review for provision of advice is detailed within brackets and all amendments will require approval from the approving body unless specified:

- Change of data controller or data processer with no change in purposes, data sources, data items or data flows (CAT)
- Change in data sources with no change in extent of data requested (CAT)
- Geographical or cohort size extension where there are no changes in purposes, data sources, data items or data flows (CAT)
- Extension of end date, unless this results in a change to exit strategy (CAT)
- Repeat projects, where an application has already been approved and will now be repeated by the same applicant and there are no changes in purposes, data sources, data items or data flows (CAT)
- Change in identifiable data items requested (Officer)
- Change in purpose of application (sub-committee)
- Change in data flows, for example where an additional organisation requires access to identifiable data (Officer or sub-committee)
- Changes are made to the extent of data requested, e.g. additional datasets or extension of time period covered (Officer or sub-committee)
- Change in contact details (Information only - does not require an approval)

10.9 If an amendment does not fall within any of the criteria outlined above an applicant can contact the CAT to determine if the amendment needs to be submitted to CAG.

10.10 Where an amendment can be reviewed by CAT this review can be carried out by the Confidentiality Advice Manager, Deputy Confidentiality Advice Manager and Confidentiality Advisor.

Amendment consideration process

10.11 Once a valid amendment is received, the CAT will categorise the request to determine delegation of review in line with section 10.8. Once categorised, the CAT will confirm whether the amendment will need to be referred to an Officer of the CAG, sub-committee, committee or whether it can be considered by the CAT.

10.12 If referred to an Officer, they may request that the amendment be referred to sub-committee of members.

10.13 Where a recommendation cannot be made following consideration by the Officer or the sub-committee, the amendment may be referred to the next available CAG meeting and the applicant will be provided with reasons that the amendment cannot be considered via the usual amendment process. At this stage, and if time allows, the applicant will be given the opportunity to provide further information in response to the reasons provided. The anticipated timescales for outcome will be change in line with 10.24 below.

Outcomes

10.14 The potential advice outcomes following the review of an amendment request are:

a) An amendment meets the minimum threshold of the Regulations and is fully supported
b) An amendment meets the minimum threshold of the Regulations and is conditionally supported (either in full or in part)
c) An amendment does not appear to meet the minimum requirements of the Regulations and is not supported.

10.15 The template letters (ref: AM3 and AM4) should be used to report the advice and decision to the applicant

a) An amendment is fully supported

10.16 An amendment is fully supported under the Regulations; in this case no further information will be required from the applicant.

b) An amendment is conditionally support (either in full or in part)

10.17 When giving a recommendation of support, conditions can be specified which may need to be met prior to the disclosure of confidential patient information. These should be clearly set out in the outcome letter. Conditions can either refer to actions to be taken prior to receiving final support or ongoing actions that should be adopted whilst processing confidential patient information or reported on at a specified time.

10.18 If the conditions refer to actions to be taken prior to receiving final approval for the amendment, the applicant must ensure conditions are met prior to disclosure of confidential patient information.

10.19 The applicant should notify the CAT in writing once the conditions have been met and provide copies of final documentation where appropriate.

10.20 Some conditions may require further review by an Officer of CAG or members and the Chair of the sub-committee should ensure that delegation for the consideration of conditions is clear. The advice letter should indicate where this is the case. Further advice provided by CAG should be by letter.

10.21 The CAT can provide further advice to the applicant in relation to working towards meeting conditions and applicants requiring further advice should contact the CAT as soon as possible upon receiving the outcome letter.

10.22 Once the conditions have been met the CAT should issue a final approval letter for the amendment.

c) An amendment does not appear to meet the minimum requirements of the Regulations and is <u>not supported</u>

10.23 Where the final advice is that an amendment is not supported the applicant should be given a full explanation of the reasons. The applicant should also be informed of the options available to progress the amendment.

10.24 This advice is also provided where the amendment cannot be supported as submitted and points of advice for a resubmitted amendment are highlighted.

Reporting

10.25 Those amendments considered by the CAT, Chair's action or by a sub-committee of Members will be reported within the sub-committee meeting minute (ref: M3), Chair's action report (ref: M4) or CAT office report (OR1) at the next CAG meeting.

11. Annual review

11.1 An annual review is required to be submitted annually on the anniversary of confirmation of final approval. It is the applicant's responsibility to ensure that this is submitted.

11.2 The annual review should be provided on the annual review template (CAGSF5) which is available on the HRA website. This should be completed and submitted by the applicant to HRA.CAG@nhs.net.

11.3 Following submission of the annual review the CAT will undertake an assessment of the content and request any further information from the applicant that is required in order for the review to take place.

11.4 Following this assessment the annual review may be reviewed by the CAT or referred to a sub-committee for assessment. The following issues may result in the review being submitted to a sub-committee:

(i) Where standard/specific conditions of approval do not appear to have been met. The applicant should provide an explanation in relation to the issues faced in meeting the requirements.

(ii) Where there are changes to the exit strategy specified within the application so ongoing support is required, for example the applicant specified that consent would be feasible after two years but this has not proved to be possible. In these instances this would be considered an amendment to the original application and an amendment should be submitted in line with section 10.

(iii) Where a new exit strategy is available but the applicant has not engaged with this or has provided reasons why the exit strategy cannot be adopted which requires an assessment by members.

(iv) Where security breaches have been reported.

(v) Where the applicant has been asked to report to CAG on certain issues at annual review stage.

(vi) CAG requested to review the annual review submission at the time of the original application or at the last annual review stage.

(vii) Where the applicant has not provided a clear public benefit in the activity continuing

(viii) If it appears that the application has become inconsistent with the Data Protection Act 1998

11.5 In certain circumstances the sub-committee may consider that it is necessary to refer the annual review to the next CAG meeting for a recommendation, for example where there have been more than 2 amendments across the year or where the proposed exit strategy has not proved to be feasible.

11.6 CAG may recommend an outcome which has an impact of the status of an approved application or amend the recommended conditions of approval.

11.7 Where any changes to the activity are specified, including changes to exit strategy or time extensions, the applicant should be advised to submit an amendment as soon as possible (see section 10) as the annual review outcome cannot be confirmed until this is complete. The clock will pause until the amendment is received.

11.8 The applicant should receive an outcome no later than 35 calendar days after an annual review is received. If an annual review is referred to a CAG meeting the applicant should receive an outcome no later than 60 calendar days after a valid annual review is received. The clock will

pause whilst queries have been raised with applicants and a response is required in order to continue processing the review.

12. Breaches of conditions

12.1 Any breach of specific or standard conditions set within an approval under the Regulations should be reported to the CAT within 10 working days, along with remedial actions taken / to be taken. This is a standard condition of support.

12.2 This should include:

(i) Information in relation to what the breach was and how it occurred

(ii) what action was taken to rectify and mitigate the breach, including details of national guidance followed

(iii) who was informed about the breach

(iv) what actions have been taken to ensure that the breach does not occur again

12.3 The breach should be reported to a CAG Officer in the first instance for guidance on next steps and within the CAT office report (ref: OR1) at the next meeting. The Officer will consider the information and provide advice depending on the nature of the breach. The Officer may request further clarification at this stage.

12.4 CAG will provide a formal advice letter for the relevant approver and send to the applicant. Where the activity is research the letter will be copied to the relevant Research Ethics Committee.

13. Application closure

13.1 An applicant who no longer requires support under the Regulations as they will no longer be processing confidential patient information without consent should inform the Confidentiality Advice Team of this using the application closure template (ref: CAGSF7) as soon as possible. Where the applicant is not the Information Custodian/Chief Investigator named on the application form, it should be ensured that confirmation from the relevant individual is submitted with the closure form.

13.2 Once received the Confidentiality Advice Team should review the information provided, update the approval register and write to the applicant to confirm receipt of the application closure notice using application closure confirmation letter (ref: SL07). If the application is research the letter will be copied to the relevant Research Ethics Committee.

13.3 The application will remain on the approval register on the HRA website for at least 12 months following notification of application closure. A log of those applications marked as expired will be maintained by CAT so that these can be removed in a timely manner.

Storage and retention of documentation

13.4 It is a requirement of the Regulations that the particulars of an application which has been approved should be retained for a long as the confidential patient information is processed and for not less than 12 months after the termination of an approval. Electronic documents only should be retained where possible.

13.5 In line with NRES SOPs, signed final copies of the minutes of full CAG meetings and sub-committee business should be retained for at least 30 years. Where electronic versions are available, paper copies may be destroyed. Draft version of the minutes should be destroyed once the final version has been ratified and signed, together with any written comments submitted by members or manuscript notes taken during meetings.

13.6 Any remaining historic paper files will be retained until these are scanned.

13.7 Where papers recorded are destroyed in accordance with this policy, they should be shredded and disposed of as confidential waste.

13.8 Electronic records of studies will be retained indefinitely.

14. Sub-committee process

Scheduling

14.1 Sub-committees for review of precedent set applications are scheduled every two weeks. The cut-off date for each precedent set sub-committee is no less than 10 calendar days before the meeting.

14.2 Officers of CAG can all Chair sub-committee meetings, a sub-committee is a meeting made up of an Officer of CAG and 2 members.

14.3 Sub-committees can also be established in order to review responses to a provisional outcome, review amendments or annual reviews. These will be ad hoc and will be scheduled as required.

Process for Precedent Set sub-committee

14.4 Meetings will usually be undertaken via email; members will be sent relevant application documents and asked to provide comments on the precedent set review form (ref: CAGSF4). The Officer acting as Chair should also provide their conclusions on the form.

14.5 A member and Chair rota for precedent set sub-committees will be prepared and circulated to members at least a month in advance of commencement and will cover a 6 month period.

14.6 A precedent set sub-committee will be quorate with an Officer of CAG and 2 members.

14.7 Members will be given 7 calendar days to provide their advice to the Chair and copy in CAT; the Chair will provide their summary within 10 calendar days. The outcome letter will be prepared within 7 calendar days of the Chair summary.

14.8 For further information in relation to the possible advice outcomes please see section 7.

14.9 Precedent set review forms should be deleted once sub-committee minutes have been ratified.

Sub-committee minutes

14.7 The minutes of each sub-committee should be submitted to the following CAG meeting. The minutes will include confirmation of the precedent set criteria the application was considered under (if applicable), the Chair and members within the sub-committee and the advice provided. The sub-committee minutes will be signed by relevant Officers at the next CAG meeting.

15. Communication with other review bodies and regulators

Information Commissioners Office (ICO)

15.1 The Information Commissioner's Office is the UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals. It is a requirement that all applications under the Regulations must not be inconsistent with the Data Protection Act 1998 (DPA) although the CAG is not responsible for directly assessing compliance.

Human Fertilisation and Embryology Authority (HFEA)

15.2 On behalf of the HRA, CAG advise the Human Fertilisation and Embryology Authority (HFEA) on applications to use the powers set out in Human Fertilisation and Embryology (Disclosure for Research Purposes) Regulations 2010 ("HFE Regulations") made under Section 33 of the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008).

15.3 The HFE Regulations apply to the whole of the UK. Under the HFE Regulations, certain protected information held on the register of the HFEA may be processed for research purposes subject to authorisation from the HFEA and approval by a REC.

15.4 Communication with the HFEA will follow the standards set out in the Memorandum of Understanding the Human Fertilisation and Embryology Authority (HFEA) and the Confidentiality Advisory Group of the Health Research Authority (HRA) have put in place coordinated arrangements for the processing of applications to access identifiable HFEA Research Register information without consent within this MoU.

Research Ethics Service (RES)

15.5 The Confidentiality Advisory Group and Research Ethics Service have in place management guidelines for interaction, share outcomes and have a collaborative approach to reviewing specific issues within applications where required.

Health and Social Care Information Centre (HSCIC)

15.6 The Health and Social Care Information Centre External Information Governance Delivery Department assess information governance toolkit returns and confirm whether satisfactory for the purposes of an application. CAG applicants should work with the HSCIC in order to ensure that this assurance is provided. It should be noted that the relationship with the HSCIC will change considerably following new statutory powers under the Care Act 2014 to provide advice to the HSCIC.