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13 July 2021

Dr Marisa Mason
NCEPOD Chief Executive
Ground Floor Abbey House
74-76 St John Street
London
EC1M 4DZ

Dear Dr Mason,

Application title: **The Child Health Clinical Outcome Review Programme (CH-CORP)**
CAG reference: **21/CAG/0085**

Thank you for submitting a **non-research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State for Health and Social Care on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 17 June 2021.

Secretary of State for Health and Social Care decision

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

The application,

1. to support a core methodology of data collection for The Child Health Clinical Outcome Review Programme (CH-CORP); of disclosing confidential patient information regarding all eligible cases from participating healthcare providers to the National Confidential Enquiry into Patient Outcome and Death (NCEPOD),

selecting a sample, and using confidential patient information to follow-up with clinicians involved in the patients care by way of questionnaire (completed online in pseudonymised format), and to disclose relevant copies of extracts from the patient's case notes from treating clinicians to NCEPOD,

2. and also for the described core methodology to be used to undertake the 'Transition from child to adult services study',

is conditionally supported, subject to compliance with the standard and specific conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

This Healthcare Quality Improvement Partnership (HQIP) commissioned non-research application from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) set out the purpose of undertaking a rolling programme of topics under the Child Health Clinical Outcome Review Programme (CH-CORP) core methodology, which aims to review the organisation of, and clinical care provided to children and young people up to their 25th birthday, by undertaking confidential reviews of case notes. Previous related applications for specific studies in this area include 15/CAG/0210 and 18/CAG/0127, however this application falls under a new contract with HQIP and it has been set up in a rolling manner so applicants apply a core methodology but start a new topic each year, as is undertaken as part of the Medical and Surgical Clinical Outcome Review Programme (PIAG 4-08(b)/2003), where CAG have supported the core method and applicants submit an amendment with a new protocol for each new study started. The application activities are carried out across England, Wales, Northern Ireland, Guernsey, Jersey and the Isle of Man; however, the CAG remit extends only to data generated in England and Wales.

This application is for the Child Health Clinical Outcome Review Programme (CH-CORP) core methodology, to allow NCEPOD to run confidential enquiries to improve the quality of care for future young people. Although aiming to identify areas for improvement, NCEPOD will also highlight examples of good practise, and provide tools to help providers make changes and monitor the impact they are having. The recommendations made by NCEPOD over the last 30 years have had considerable impact on healthcare.

This application is additionally for their first proposed study; 'Transition from child to adult services study'. The purpose of this study is to explore the barriers and facilitators in the process of the transition of young people with complex chronic conditions from child to adult health services. There is evidence that for many young people with complex conditions and their families, this can be an apprehensive time as it is often associated with a dislocation of care and a deterioration in health and wellbeing.

Applicants plan to use standard NCEPOD retrospective questionnaire and case note review methodology on a sample of patients from various healthcare providers, who match the inclusion criteria for a specific study. Confidential patient information relating to all eligible patients will be reported to NCEPOD from participating healthcare providers via a patient identification spreadsheet. This data is entered onto the NCEPOD database, and a pseudonym applied unique NCEPOD number. From this, the data will be sampled for

those to be included in the study. The patient identifiable data for those not included in the study are kept until all sampling is done, just in case re-sampling is required, and then removed from the database at the earliest possible opportunity as it is not needed.

The clinician(s) involved in the patient's care are then notified that they need to complete a questionnaire, and return copied extracts of the case notes, to undergo peer review. The NHS number and date of birth alongside the NCEPOD number is used to enable clinicians to identify the correct patients, and the questionnaire is returned back pseudonymously via the online questionnaire system, using only the NCEPOD number. Depending on the study, case notes will be requested from all relevant healthcare services. If a young person is identified and tracked across a number of care settings, case notes will be requested from all organisations. Case notes are returned in an identifiable format, and upon receipt at NCEPOD, patient identifiers are removed by the NCEPOD team as soon as possible after receipt but no later than two months, if not already done so. Care providers are encouraged where possible to remove patient identifiable data, however the applicants understand this does represent an additional burden to the direct care team.

A multidisciplinary group of clinical case reviewers will be recruited to assess the case notes and questionnaires and provide their opinion on what went well and what did not go well during the care under review. NCEPOD staff will ensure there is a mix of specialties at each meeting from across the UK. Note that all patient identifiable data are removed from case notes before being seen by case reviewers. The set of case notes is only identified by the 'NCEPOD number' allocated to the case.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

For the **Child Health Clinical Outcome Review Programme (CH-CORP) overall;**

Cohort	In general, patients from birth up to their 25th birthday will be eligible for inclusion. However, the inclusion criteria will be specific for each topic and will be highlighted in the amendment form when each study protocol is submitted. Support is also in place for those who are deceased.
Data sources	Case notes from all organisations that provide care to patients aged 0-24 years, such as, but not limited to; secondary/tertiary care, community care. primary care, mental healthcare, independent healthcare or hospices
Identifiers initially collected for all patients	This could include but are not limited to the below; 1. NHS number 2. Hospital number 3. Date of birth 4. Sex 5. Diagnosis and/or procedure code

	6. Date of admission 7. Source of admission 8. Date of discharge/death 9. Additional healthcare organisations 10. Potentially partial postcode if an aspect of a study was very focused on deprivation
Identifiers required for linkage between organisations purposes (sampled patients)	This information will be used to notify the clinician who needs to complete a questionnaire, or the local contact at the healthcare provider who will send/scan copied case note extracts to NCEPOD. • NHS number • Hospital number • Date of birth • Sex • Date of admission – where applicable • Date of discharge – where applicable • NCEPOD number – for future pseudonymisation where possible • NCEPOD 'site identification – for future pseudonymisation where possible
Identifiers required for analysis purposes	For the clinical questionnaires and case reviewer data – no identifiers are needed as all data are linked by the NCEPOD number only. Note that NHS number is removed.
Additional information	**Case note review** For each sampled patient included in the case review, NCEPOD will obtain copied extracts of the relevant parts of the patient's notes to allow the peer review process to take place. Each protocol will specify what is needed and for what time period. NCEPOD have access to all the information within the returned case notes and also use the case notes to identify other providers of healthcare services for each patient, that might be relevant to the patient pathway, and to whom NCEPOD would want to send a clinical questionnaire or request additional notes. On receipt of the case notes all patient identifiable information will be removed and substituted with the NCEPOD number. All case notes are securely destroyed at the end of the study.

For **Transition from child to adult services study specifically;**

Cohort	All patients aged 13-24 years, with a complex chronic condition, transitioning from child to adult health services and provided care between 1st October 2019 - 31st March 2021 (approximately 123,564 patients) Patients will be randomly selected from a larger sample for questionnaires (4000 patients) and case note reviews (1000 patients). Note these figures account for response rates.

Data sources	Case notes from all organisations that provide care to patients aged 13-24 years with a complex chronic condition, including primary care, community care, and secondary/tertiary care Notes requested relating to Transition will include: • Clinic letters • Discharge summaries • Transition documentation (including 'Ready Steady Go' and Transition plans) • General multidisciplinary team notes • Education, Health and Care Plans (where available) • Moving on Passport/Transition passport • Care plans • Treatment escalation plans
Identifiers initially collected for all patients	1. NHS number 2. Hospital number 3. Date of birth 4. Sex 5. Diagnosis and/or procedure code
Identifiers required for linkage between organisations purposes (sampled patients)	• NHS number • Hospital number • Date of birth • sex • Date of admission – where applicable • Date of discharge – where applicable • NCEPOD number – for future pseudonymisation where possible • NCEPOD 'site identification – for future pseudonymisation where possible
Identifiers required for analysis purposes	For the clinical questionnaires and case reviewer data – no identifiers are needed as all data are linked by the NCEPOD number only

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The Members were very supportive of this application, agreeing that there is no doubt about the medical purpose, and the clear public interest in this overarching approach. The CAG also agreed on the medical purpose and public interest for the specific 'Transition' application, noting that the transition period is fraught and difficult to negotiate.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Minimising flows of identifiable information

The Committee commented that the current methodology of disclosing confidential patient information appeared to be via encrypted spreadsheet, which was then sent from nhs.net email address to nhs.net email address. The CAG realised that this is a standard methodology but felt that it was subject to human error and feels out-dated.

Members queried if the applicant had considered revisiting how the data flows were undertaken, considering improvements in data security and technology over the years, as it may be possible for a more secure method to be used to transfer data. Safe and secure alternatives such as secure file transfer protocols (secure FTP) could be a good alternative, although noting that CAG do not prescribe these specifics, and the applicant is advised to discuss this level of detail with information governance experts.

Furthermore, the Committee recognise that this issue is potentially one that sits with HQIP as the commissioners, and therefore the applicant is not expected to change this methodology as part of this application. However, the Members would like some assurance that the methods of disclosing confidential patient information would be re-visited to explore if there were more secure alternatives available and the Members be provided with feedback at annual review.

- Feasibility of consent

The applicants provide a number of reasons to justify why consent is not feasible, including the large sample size of the initial case reported information, the potential for some patients to be deceased, the retrospective nature of the activity, and the potential for sample bias through operation of a consented process as this would need to be taken by treating clinicians. The CAG were content with these justifications and considered that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to identify a sample of eligible patients, and then to undertake linkage between different organisations who may have treated the same patient, and to ensure that clinician questionnaires and case notes can be linked. The applicants have considered pseudonymisation of notes at the healthcare sites; however, this would be a burden on those returning notes and may also lead to errors and failure in linkage to the questionnaires. Analysis is undertaken on pseudonymous data, that the reviewers are unable to re-identify. The only time that an individual case is isolated, is where a case review raises such a concern that current patients could be at risk. These cases are referred back to the Medical Director/ Responsible Officer of the healthcare provider concerned in order that appropriate action may be taken. This approach was

given support by the GMC in 1998 and 1999 and was ratified by the NCEPOD Steering Group in March 2001, September 2003 and April 2006. More recently this process has been adopted by HQIP across all Clinical Outcome Review Programmes. This meets the requirements laid down by the GMC in Good Medical Practice.

The Committee were content that the activity could not be undertaken in a less disclosive manner and using pseudonymised or anonymised information would not be a practicable alternative.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

For the **Child Health Clinical Outcome Review Programme (CH-CORP) core methodology;**

In general, local contacts are provided with a general poster about NCEPOD to be displayed in clinical areas – this is also available in Welsh. This is also displayed on the NCEPOD website. A general privacy notice is also displayed on their website.

Prior to data collection for individual studies, NCEPOD will contact all healthcare providers and provide a specific poster and patient information leaflet, for display in waiting areas or to be given to clinicians to provide to patients. Social media is used to advertise that the activity is taking place – Twitter and Facebook being the most commonly used. Links are added to the website (*www.ncepod.org.uk*) where the same poster and patient information can be found, as well as information on opting out. Patient groups and third sector organisations are asked to help share information about the study. These organisations will be listed on the study specific communications plan as they will vary depending on the topic under review.

All patient facing material will state how to opt out of the study, including poster and patient information leaflets, which will be displayed on NCEPOD website and in local clinical areas. The national data opt out will also apply.

The Members were content in general with the standardised notification and opt out approach. However, it was noted that the general NCEPOD poster for clinical areas and the website does not explain what NCEPOD is, and it was felt that this useful information should be included.

It was also noted that the communication approach should vary from sub-study to sub-study depending on the ages of the children and young people involved, and it is likely in these cases that only one poster and information leaflet may not be appropriate for all age groups. It was also noted that as some of these children may be very young, there may also need to be notification materials created that are aimed specifically at parents or carers. The Committee considered that in these cases there may occasionally be times where a child may wish to opt out, but the parent wishes for their data to be retained, or vice versa, although noting that this would be a very rare occurrence. The CAG were therefore interested in the policy position of the applicant regarding conflicting opt outs.

For **Transition from child to adult services study specifically;**

Information regarding this activity will be made available via the NCEPOD website and sub-study specific posters are provided to participating hospitals/GPs to inform patients that data may be collected. A Patient information sheet is additionally provided for clinicians to provide to patients. A communication plan has also been provided, which contains a list of organisations to contact to help share information about the study. This would include providing organisations with some text they could put in a newsletter, attending online/physical meetings held to talk about the study and tagging them in social media posts on both Twitter and Facebook to help promote the work both with patients/parent carers and healthcare professionals.

The poster provides detail of how a patient can opt-out – this is by contacting NCEPOD directly via post, email or telephone. The patient information sheet also provides an opt out option, and additionally the national data opt out will apply.

As per the core methodology, the CAG were content with where the notification would be displayed, and the use of social media, and how the opt out option will work. They did however have some comments on the content of the notification, considering that a poster aimed at a 13 year old may greatly differ in content to one aimed at a 24 year old, however, the applicant had tried to use only one poster and information leaflet, which may have had the unintended effect of sacrificing clarity for simplicity. For example, the phrasing regarding data being put into a 'big pot' may be perfect for 13 year olds but may be oversimplifying for a 24 year old. The Committee are not prescribing that the applicant must split the patient notification for the transition study into 2 separate notifications, however they do request for a plain English review of the transition notification materials to ensure the language is clear and informative without being condescending or ambiguous. Members again noted that they would like a description of NCEPOD to be included on the transition poster, noting it is explained well in the leaflet.

The CAG also commented that the phrasing regarding 'we will see what works well and see what does not work well' sounds a little like research, and would like the revised transition notification materials to be clear that this activity is a non-research activity.

<u>Patient and Public Involvement and Engagement</u>

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

For the **Child Health Clinical Outcome Review Programme (CH-CORP) core methodology;**

NCEPOD has a panel of eight 'permanent' lay representatives involved across work programmes who sign off protocols and review data before publication as well as participating in the study advisory groups.

The applicant ensures patient input for each individual sub-study by inviting patients to sit on the study advisory group as part of the design process. Patient focus groups/interviews are undertaken at the start of a study to get a wider feel for the themes that should be reviewed. Patient representative/third sector organisations help the applicant engage with patients (e.g. Local Reporters, and relevant charities), and anonymous online surveys are undertaken to get a wider view of patient experience.

The applicants have asked their users thoughts on using identifiable data without consent with regards to the core methodology. Initial responses are positive, and more responses may be returned. The CAG were content with the level of patient and public involvement undertaken, however they would like some feedback regarding any further comments returned, as the applicant has noted that more responses are expected. The applicant has also noted that for all future sub-studies, exploring the use of confidential patient information without consent will be built into patient and public involvement undertaken in order to build up comments of support and recognise any areas of concern that could be addressed.

The Committee also were interested in the turnover of the eight permanent lay representatives, querying at which point a lay person becomes an expert.

For **Transition from child to adult services study specifically;**

For the Transition study, focus groups were held with parent and carers of young people and there are patient representatives on the study advisory group. The findings from the focus groups were shared at the first study advisory group meeting, and the themes that participants felt were important have fed into the study objectives. All young people and parents or carers involved have been made aware of the study method and no concerns have been raised about the use of patient data. However, as the question was not explicitly asked, the applicant has again (as a response to queries) asked the study advisory group and focus group participants thoughts on using identifiable data without consent with regards to the transition study. The one initial response is positive, and more responses may be returned. The CAG were content with the level of patient and public involvement undertaken, however again, they would like some feedback regarding any further comments returned, as the applicant has noted that more responses are expected.

Exit strategy

Each item of identifying information is deleted at the earliest opportunity during each specific study. Three months after publication all electronic data are anonymised, and all paper data are securely shredded. The patient identifiable data for those not included in the study are kept until all sampling is done, just in case re-sampling is required, and then removed from the database at the earliest possible opportunity as it is not needed.

NCEPOD was commissioned for a three-year contract starting on January 1st 2020, and with a possible extension for a further two years starting in 2023. Support is requested on an ongoing basis, in line with other applications of this type.

The members were content with this exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Support extends to data generated in England and Wales only.

2. Please re-visit the methods of disclosing confidential patient information to explore if there are more secure alternatives available and provide feedback at annual review.

3. Please update the general NCEPOD poster to explain what NCEPOD is and provide an updated version to CAG within one month from the date of this letter.

4. Please provide some more detail on whether different approaches will be considered for different sub-studies, specifically regarding age appropriate patient notification, how you will differentiate between parent/carer and children notifications, and a statement regarding the policy that will be followed regarding any conflicting opt-out requests (from a parent/carer and their child), within one month from the date of this letter.

5. Please revise the transition notification materials to ensure the poster explains what NCEPOD is, ensure there is no suggestion of research activity, and re-consider the language used to ensure they are written in plain English, and provide updated versions to CAG within one month from the date of this letter.

6. Please provide any detail regarding turnover of the eight permanent lay representatives, within one month from the date of this letter.

7. Please provide any further patient and public involvement feedback surrounding the use of confidential patient information without consent, that is noted as expected for both the core methodology and the transition sub-study, when it is available.

8. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **2019/20** DSPT review for **National Confidential Enquiry into Patient Outcome and Death (NCEPOD)** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 5 July 2021)

   Due to the number of participating care providers involved it is the responsibility of NCEPOD on behalf of HQIP, as controller, to ensure that all organisations disclosing confidential patient information to NCEPOD meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

As the above conditions have been accepted and are met or will be met in a later response, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is

also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **13 July 2022** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing. Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published 'Register of Approved Applications'. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting are as follows.

Document	*Version*	*Date*
Application form_21CAG0085_NCEPOD		20 May 2021
Attachment B_21CAG0085_Data flow diagram		
Contract of employment confidentiality clause		
HQIP letter of support NCEPOD CH CORP		20 May 2021
Protocol_Transition from child to adult healthcare services		May 2021
Transition Communication Plan.pdf		
Transition patient identifier spreadsheet.xlsx		
Transition patient identifier spreadsheet_sampled patients.xlsx		
Transition patient identifier spreadsheet_sampled patients.xlsx		
Transition to Adult Healthcare_Poster.pdf		
PIAG 4-08(b) 2003 NCEPOD amendment outcome letter refreshed application		1 October 2013
15CAG0210_s251_final_approval_(Non_Research)		24 February 2016
18CAG0127 Conditionally Supported		15 October 2018

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

No conflicts of interest were declared.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

On behalf of the Secretary of State for Health and Social Care

Email: cag@hra.nhs.uk

Included: List of members who considered application
Standard conditions of support

Confidentiality Advisory Group meeting attendance
17 June 2021

Members present:

Name	
Professor William Bernal	CAG alternative vice-chair
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Mr. Myer Glickman OBE	CAG member
Dr Katie Harron	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Laura Gordon	HRA Confidentiality Advisory Group Assistant
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Observer

Health Research Authority

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Secretary of State for Health and Social Care, is subject to compliance with the following standard conditions of support.

The applicant and those processing the information under the terms of the support will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.

4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.

6. Activities must be compliant with the General Data Protection Regulation and relevant Data Protection Act 2018.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken/to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.