Health Research Authority

COVID-19 COPI Notice

Final report June 2022

Introduction

On 01 April 2020 the Secretary of State for Health and Social Care issued a general notice (COPI notice) under the Health Service Control of Patient Information Regulations 2002 to support the response to the COVID-19 pandemic. The notice provided a common law legal basis for NHS Trusts, Local Authorities and others in England and Wales to process confidential patient information (CPI) without consent for COVID-19 public health, surveillance and research purposes. As part of this COPI notice it was also a requirement for organisations to process CPI for COVID-19 purposes, whereas under Regulation 5 it is permissive. This enabled activities that relied upon the use of confidential patient information without consent to begin without review and advice provided by the Confidentiality Advisory Group (CAG), though NHS favourable ethical opinion was required for research.

The expiry of the COPI notice has been extended a number of times over the last two years. The table below summarises the main timelines and expiry dates for the COPI notice.

Date	Event
01 April 2020	COPI notice published with expiry of 30 Sept 2020
06 August 2020	Expiry extended to 30 March 2021
10 February 2021	Expiry extended to 30 September 2021
10 September 2021	Expiry extended to 31 March 2022
14 February 2022	Expiry extended to 30 June 2022

The COPI notice expired on 30 June 2022 and has not been extended further. However note that a specific COPI notice for the OpenSAFELY database has recently been issued until 31 October 2022.

This report summarises the activities of the Confidentiality Advice Group (CAG) and the Confidentiality Advice Team (CAT) whilst the notice was in effect and in preparation for its expiry. It also provides a summary of the applications that transitioned to Regulation 5 support on expiry of the notice on 01 July 2022.

Informal advice of activities relying on the general COPI notice

In April 2020 in response to the COPI notice HRA staff quickly set up an 'informal advice' process where Approvals staff alerted the Confidentiality Advice Team (CAT) to research activities relying on the COPI notice. It also provided CAG the opportunity to review the REC application documents available for applications relying on the COPI notice and offer informal advice to applicants on the steps they would need to consider should they need to submit an application to transition to Regulation 5 support on expiry of the notice.

This enabled the CAT to maintain a log of research activity relying on the COPI notice and maintain oversight, as described below. However, this was not replicated for non-research activities with partner organisations, which meant there was no central record and subsequently proved difficult for CAT to understand what non-research activities required to transition. Indeed, our final partner organisation only confirmed there was no non-research activities to transition on 28 June 2022, with significant uncertainty until this date.

Between April 2020 and July 2021, the CAT arranged 64 informal advice meetings for CAG to review these applications. The meetings were held in addition to standard full and PS CAG meetings.

A total of 89 research applications were reviewed by CAG through the informal advice process. A summary of the key themes of use of CPI under the COPI notice, without the requirement for CAG advice are as follows:

- Uncertainty on whether the use of CPI without consent for the purposes of the activity was in the public interest. This is an important consideration and was compounded by many applications not undertaking patient and public involvement on this aspect. However, some activities did provide excellent patient and public involvement evidence that demonstrated PPI can be done in an emergency situation.
- No evidence of steps taken to inform patients and the public of the use of CPI without consent. Transparency is a key principle under CAG to ensure that as far as possible there are no surprises to patients and the public about the use of their data.

Other themes that arose to support the above were:

- Lack of clarity on the flows of identifiable information – e.g. what identifiable data items are used and between which organisations.
- Concerns that data is not being deidentified as soon as possible, and why the amount of identifiers used are necessary. Linked to this, many applications had no apparent exit strategy on using CPI without consent.
- Lack of justification on why consent cannot be sought, instead of reliance on the COPI notice

Preparation for expiry of the COPI notice

In preparation for the expiry of the COPI notice the CAT undertook a number of activities to ensure that, as far as possible, all research and non-research applicants using the COPI notice were identified and supported to transition to Regulation 5 support where required and appropriate.

Identifying studies

Along with information already held on applications reviewed through the informal advice process, the CAT undertook a data trawl across the HRA management systems to ensure that all applications relying on the COPI notice had been identified based on the information provided to the HRA. This data trawl identified an additional 13 studies relying on the COPI notice.

Communication

In Autumn 2021 the CAT contacted all applicants identified as relying on the COPI notice. The purpose of this contact was to ascertain whether applicants would be continuing to process CPI beyond the expiry date and to provide guidance on how to prepare an application to CAG to transition to Regulation 5 support, should this be required and be the most appropriate permanent legal basis.

The table below provides a summary of the number of applicants contacted and outcome of the contact.

Total number of applicants contacted (identified through informal advice process and HRA data trawls)	102
Total number of new* COVID-19 studies identified as relying on the COPI notice	3
Number of applicants not requiring transition**	89
Number of applications received and will transition to Regulation 5 support on 01 July 2022***	14
Number of applications received and will not transition to Regulation 5 support on 01 July 2022***	2

*new = studies started between Nov 2021 and Feb 2022

**reasons for not requiring transition included - processing of CPI completed, study not started or no breach of confidentiality (under direct care or consented)

***see Appendix A for a summary of these applications

A webpage was created on the HRA website to provide guidance for applicants on how to prepare and submit an application to CAG to transition to Regulation 5 support. A series of key messages were also sent out to key stakeholders and through HRA communication channels to ensure that the relevant research and non-research communities began preparing for the expiry of the notice. Key messages included:

- Asking applicants to contact CAG of they were relying on the COPI notice and had not been contacted by CAG by November 2021
- That Regulation 5 support was not the only alternative legal basis, others include obtaining patient consent, deletion of identifiable data and Regulation 3 support
- To use the remaining time in the lead up to the expiry to seek a permanent legal basis if the processing of CPI was to continue on expiry of the notice

Common themes during CAG review of transitioning applications

There were a number of common themes arising during CAG review of transitioning applications which lead to an initial outcome of either conditional or provisional support. These themes are detailed below.

Patient and public involvement

One of the key considerations for CAG is whether the use of CPI without consent for the purposes of the activity is in the public interest. The CAG expects to see this evidenced in applications through patient and public involvement work. Although applicants had carried out patient and public involvement for the study as a whole, many had not extended this to include testing the acceptability of processing CPI without consent. This was likely due to reliance on the COPI notice for this element of the study and lack of requirement to do this. Guidance was produced for applicants to ensure that CAG expectations around patient and public involvement were addressed in their application. Whilst some applicants had made some effort towards meeting CAG expectations it was often the case that not enough people had been involved and not enough people had been involved with lived experience. Therefore, a common condition of support was to carry out further, higher quality patient and public involvement work.

Patient notification

Transparency is a key principle under CAG to ensure that as far as possible there are no surprises to patients and the public about the use of their data. As such the CAG expects to see evidence of how the applicant intends to notify patients of the activity as far as is reasonably possible e.g. through posters in hospital departments, notification on a Trust or study specific website or other routes as appropriate to the research. As above, patient notification materials were often missing or did not meet CAG expectations on the quality of the content due to the reliance in the COPI notice and lack of requirement to have this in place until an application was submitted to CAG.

Study progress and justification for continuing

An initial finding during the CAG review of the first few applications was that information had not been included on the progress of the study to date, in particular the processing of CPI and also the justification for continuing to process CPI after expiry of the COPI notice. It was therefore challenging for the CAG to know what support was being requested for at the point of expiry of the notice. Guidance was updated after this finding to request that applicants submit a cover letter with their application to provide information on study progress and clarity on what support was requested for at the point of the COPI notice expiry.

The National Data Opt-Out

The National Data Opt-Out was not applicable under the COPI notice. All applications transitioning to Regulation 5 support confirmed that they would apply the National Data Opt-Out on expiry of the notice, with the exception of RECAP (22/CAG/0001) as the data collection had already been completed under the COPI notice. PEACH (21/CAG/0119) requested not to apply the National Data Opt-Out and this approach was supported by CAG, however the study did not transition to Regulation 5 support as processing of CPI was completed before the expiry of the notice.

Wales

The COPI notice in Wales continues to provide a legal basis until 30 September 2022, when it expires. Seven applications have transitioned that involved processing in Wales. For these activities, Regulation 5 support is in place for English processing, and the COPI notice will continue to apply for Welsh processing until 30 September 2022.

On expiry of the Welsh COPI notice Regulation 5 support will apply to the entirety of the application.

Lessons learnt and next steps

The considerations by CAG, an independent body, on the public interest of the activity (supported by patient and public involvement) as well as the patient notification are key to maintaining public trust in the safe and effective use of their confidential medical data. The informal advice process and review of transitioning applications highlighted that many activities had not fully considered these aspects, as well as alternative methods of processing or data minimisation, which had the potential to impact on this trust if this continued.

Whilst many patients during the pandemic understood the importance of the use of their data during COVID, the role of CAG is vital to maintaining that public trust and confidence moving forwards, and is one that we wish to promote to patients and the public moving forwards.

Nevertheless, we are taking steps to improve the service and generate a positive user experience. Examples of current improvement activities include:

- Piloting a coordinated approach between CAG and REC. This enables the applicant to submit the applications at the same time and for reviews to be conducted in parallel. Communications at each time point are coordinated to provide a single output to the applicant on the status of the reviews. This is expected to reduce the overall time to gaining HRA & HCRW Approval from submission but also importantly improve user satisfaction.
- As part of this the following are also being tested:
    - A new question set in preparation for inclusion in future IRAS. Doing so now enables CAG to receive the necessary information for review whilst applicants provide more relevant information than currently without being overburdened.
    - Applicants attending CAG meetings to discuss their application. Historically in CAG this has only happened when CAG felt the applicant attending is warranted (e.g. particular issue for resolving). However, it is expected to bring positive benefits, and aligns with recommendations in the Goldacre review.
- Updating public facing guidance for applicants. Doing so will enable applicants to have a clear understanding on when an application should be made to CAG and the CAG expectations before applying, and can incorporate this into their application for consideration.
- Review and update of the precedent set criteria, and other approaches to CAG review to consider what types of applications should use different routes of review under Regulation 5. This will allow CAG to focus on those applications where their expertise adds value in a way that is proportionate to the application type.

Appendix A

Applications supported by CAG in preparation for transition

The following 14 applications transitioned to Regulation 5 support and were published on the CAG register on 01 July 2022.

CAG reference	Study title	CI and Organisation
22/CAG/0001	RECAP: Remote COVID Assessment in Primary Care	Professor Brendan Delaney, Imperial College London
21/CAG/0159	UK REACH: United Kingdom Research Study into Ethnicity And COVID-19 outcomes in Healthcare workers	Dr Manish Pareek, University of Leicester
21/CAG/0122	PRINCIPLE: Platform Randomised Trial of Treatments in the Community for Epidemic and Pandemic Illnesses	Professor Christopher Butler, University of Oxford
21/CAG/0157	CVD-COVID-UK/ COVID-IMPACT: UK-wide linked routine healthcare data to address the impact of cardiovascular diseases and other health conditions and health-related risk factors on COVID-19 and the impact of COVID-19 on cardiovascular diseases and other health conditions	Professor Cathy Sudlow, British Heart Foundation Data Science Centre (HDR-UK)
21/CAG/0004	Neonatal Complications of Coronavirus Disease (COVID-19) Study	Professor Jenny Kurinczuk, University of Oxford
21/CAG/0156	VIVALDI: COVID-19 in care homes	Professor Laura Shallcross, University College London
21/CAG/0180	National COVID-19 Chest Imaging Database	Dominic Cushnan, NHS England
21/CAG/0125	ISARIC/WHO Clinical Characterisation Protocol Severe Emerging Infection	Professor Calum Semple, University of Liverpool

21/CAG/0044	UK Longitudinal Linkage Collaboration	Dr Andy Boyd, University of Bristol
21/CAG/0117	CCP-Cancer UK: Clinical Characterisation Protocol for Severe Emerging Infections in the UK – a prospective companion study for patients with Cancer and COVID-19	Professor Carlo Palmieri, University of Liverpool
22/CAG/0026	Covid impact on RSV Emergency Presentations: BronchStart	Dr Damian Roland, University Hospitals of Leicester NHS Trust
22/CAG/0082	PANORAMIC: Platform adaptive trial of novel antivirals for early treatment of Covid-19 in the community	Professor Christopher Butler, University of Oxford
21/CAG/0144	GM COVID Cancer: Risk of COVID-19 related hospital admission and death in cancer patients in Greater Manchester	Prof Corinne Faivre-Finn, University of Manchester and The Christie NHS Foundation Trust
22/CAG/0097	AGILE: Seamless Phase I/Iia platform for the evaluation of candidates for COVID-19 treatment	Saye Khoo, Royal Liverpool and Broadgreen University Hospitals NHS Trust

The following 2 applications were supported by CAG early on in the transition process in preparation for expiry of the COPI notice at the end of March 2021 and end of September 2021. **The applicants have since confirmed that processing of CPI has been completed and have not transitioned to Regulation 5 support on 01 July 2022.**

CAG reference	Study title	CI and Organisation
21/CAG/0002	RECOVERY supportive care	Professor Gavin Perkins, University of Warwick
21/CAG/0119	PEACH	Dr Jonathan Sandoe, University of Leeds and Leeds Teaching NHS Trust