



Medical
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Council



COP1 Notices 2020

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*Support and guidance
for those conducting research
with human participants,
their tissues or data*

COPI and COVID Data

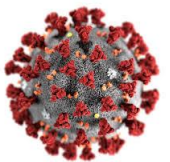
- Overview of the COPI Notices
- Status Quo
- What happens when the Notices are withdrawn



COPi Notices

On March 20th 2020, the Secretary of State for Health and Social Care issued a Notice under Regulation 3(4) of the Health Service Control of Patient Information Regulations 2002 (COPi). This allows CPI to be processed for COVID research, subject to conditions. The main conditions are:

- Processing is limited to permitted persons and organisations: (a) the Public Health Laboratory Service; (b) persons employed or engaged for the purposes of the health service; (c) other persons employed or engaged by a Government Department or other public authority
- Processing under the Notice is allowed until 31st March 2021
- The Notice applies to England / Wales only
- The Notice does not apply to NHS Digital, NHS England & Improvement or UK Biobank, which are subject to separate COPi Notices

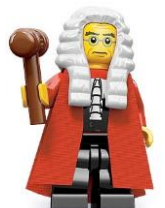


What Happened?

The COPI Notice has accelerated health research by:

- providing a legal avenue allowing COVID CPI to flow into research projects
- bypassing the need for, and time involved with, the usual legal avenues (consent, CAG approval)
- establishing a NHSX process (approx. 60 projects)
- removing the need to apply the National Data Opt-Out

The Notice is temporary and, even if an extension is granted, there will come a date when the Notice can no longer be used as a legal avenue for processing CPI



What Happens When The COPI Notice Lapses?

Need to make arrangements for processing CPI once the COPI Notice lapses.
The main risks are:

- Researchers lose legal avenues and cannot conduct current or future research
- Organisations require researchers to delete data collected under the COPI Notice
- Researchers are unclear about what approvals they need to continue their research
- Data providers / research approvers are overwhelmed with applications for approvals / amendments
- The National Data Opt-Out is applied
- CPI is used unlawfully

BAD THINGS

Options?

Two options once the COPI Notice lapses:

- 1) stop processing CPI
- 2) find a legal avenue for processing CPI



Stop Processing CPI?

- Anonymise the data (utility?!)
- Pseudonymise via a TRE?



Legal Avenues For Processing CPI

Consent

Section 251 (Confidentiality Advisory Group)



Section 251 Support

- All applications were looked at informally by a member of CAG
- Most applications had questions to answer
- Will need full CAG applications under Regulation 5 (research)



Confidentiality Advisory Group

- Appointed dedicated staff for transitioning to CAG approval
- Will have precedent set criteria for 'standard projects'
- Are running a pilot project
- Will contact the projects that they are aware of

Issues?

- Volume of CAG applications / other amendments
- Need Patient / Public Involvement (PPI), takes time
- Objections apply, data quality

National Data Opt-Out

- National Data Opt-Out will apply post-COPI Notice
- Currently 2.75%
- Applies to all NHS and Adult Social Care information
- Was in the process of rolling out when COPI Notices went live

OPT-OUT ☒

OPT-IN ☐

Advice

- Apply for Section 251 support as soon as possible
- Only active once the COPI Notice is withdrawn
- Start PPI and objections



Summary

- Establish if data is still needed
- Think about a CAG application. Start PPI / objections
- Think of implications for other approvals
- Get in touch with CAG



Questions?

