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28 September 2021

Dr Marisa Mason
National Confidential Enquiry into Patient Outcome and Deaths (NCEPOD)
Ground Floor, Abbey House
74-76 St John Street
London
EC1M 4DZ

Dear Dr Mason,

Study title: National Confidentiality Enquiry into Patient Outcome and Death
CAG reference: PIAG 4-08(b)/2003

Thank you for your amendment request to the above non-research application, submitted for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Supported applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

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 an application should be supported, and if so, any relevant conditions.

Secretary of State for Health and Social Care support 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:

1. The amendment, to include the first case note review of 2021, investigating Crohn's disease, is supported, subject to compliance with the standard conditions of support.

Amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the first of the reviews due to take place in 2021, which will investigate the care of patients with Crohn's disease.

The review has been commissioned as there is believed to be room for improvement in the quality of acute and long-term care provided to patients with Crohn's disease.

The applicants aim to publish the results of the review in January 2023.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair agreed that the amendment request was a very important activity, very much in the public interest, that has resulted in considerable improvements in care over the years. The Vice-Chair was assured that the method will be in line with NCEPOD support. The Vice-Chair noted there is adequate patient notification described in the amendment form and commendable patient consultation described in the protocol. On the basis of usual practice, and a wish not to delay such important work, The Vice-Chair recommended support for this amendment.

However, due to the application being submitted many years ago, the Vice-Chair proposed a re-submission of the application, in order for CAG to have a more detailed review of data flows and how the anonymisation of patient records for review is carried out. This is in line with the plans of the applicant, who has already been planning to re-submit the application for CAG review.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

1. 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: **Confirmed – The NHS Digital 2020/21 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (by check of the NHS Digital DSPT Tracker on 23 September 2021).**

Reviewed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
NCEPOD Amendment form_PiAG 4-08(b) 2003_Crohn's.		26 August 2021
Crohn's disease study protocol FINAL 20210826		26 August 2021

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.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

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

Email: cag@hra.nhs.uk

Enclosures: Standard conditions of support

Standard conditions of support

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

The applicant and those processing the information 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.
6. Activities remain consistent with the General Data Protection Regulation and 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 supported 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.