## Health Research Authority NatCOL

**‘Section 251’ Support – Annual Review**

It is a standard condition of support that an annual review is supplied every 12 months, from date of the final support letter, for the duration of the support to process confidential patient information without consent. Applicants should submit this 4 weeks in advance of their annual review due date. The annual review due date is specified under the ‘Next Review Date’ field for each application entry in the [Register of Approved Applications.](https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/confidentiality-advisory-group-registers/) Please ensure all sections are fully completed to avoid invalidation.

Notification of changes through this Annual Review submission are not permitted and will not be processed nor receive support; changes are managed via a formal separate amendment process.

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| **PIAG/ECC/CAG reference number:** |  |
| **Full application title:** |  |
| **Application type: research or non-research** |  |
| **Date annual review was due:**(If the annual review has been submitted after its due date, please include an explanation) |  |

**Information sharing:**

Applicants should be aware that data controllers, such as NHS Digital, may wish to check whether an applicant has provided an annual review to the CAG, to ensure the applicant support to process information without consent remains active before the controller can process a request for data access. We will share confirmation with data controllers whether an annual review has been submitted or not, and whether it is valid, in order to facilitate local disclosure decisions.

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| 1. **Security arrangements**

All applicants processing confidential patient information under the Regulations are required to provide evidence of suitable security arrangements via agreed routes. This must be in place before any support can come into effect, must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS Digital at each annual review. Security assurance is required in relation to ALL organisations involved in processing confidential patient information. Please carefully assess where the processing is taking place, and provide security assurance based upon the jurisdiction and organisation where the information is being processed. Applicants may need to provide more than one security assurance depending on the jurisdiction information is processed, or if processing of identifiable information is taking place in more than one organisation.

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| **Processing takes place in:** | **England** | **Wales** | **Scotland** |
| **Security assurance provided by:** | Data Security and Protection Toolkit (DSPT) – by organisation or specific function | Caldicott Principles into Practice (CPiP) report – by organisation | Review by the Public Benefit and Privacy Panel for Health & Social Care |
| **Applicant should contact:** | Exeter.Helpdesk@nhs.net | Darren.Lloyd@wales.nhs.uk  | Public Benefit and Privacy Panel (PBPP) for Health & Social Care |
| **How assurance is provided to CAG** | 1. Organisational self-assessed completion of relevant DSPT.
2. Applicant contacts Exeter Helpdesk to request NHS Digital to review the relevant DSPT self-assessed submissions
3. NHS Digital review the DSPT submission and confirm to CAG when ‘Standards Met’
 | Relevant CPIP out-turn report provided directly by NWIS to CAG | An approval letter from PBPP, where processing is taking place in Scotland, is accepted as evidence of adequate security assurance. |

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| **For applicant completion:**Please list all organisations physically processing relevant information without consent for which security assurance is required. Security assurance is provided through NHs Digital reviewing the self-assessed submission. Please ensure you have contacted NHS Digital and asked them to review your submission. The annual review will not be valid until NHS Digital has reviewed the submission and confirmed its status as ‘standards met’.If confidential patient information is being processed by NHS Digital, please select this box: **[ ]** Security assurance has already been provided for NHS Digital so please do not complete any details below for NHS Digital.

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| **Organisation (Full name)** | **ODS Code** | **Date self-assessment submitted to NHS Digital** | **Date NHS Digital confirmed assessment reached ‘Standards Met** |
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Is any processing of identifiable information taking place in Wales? Is there any processing of identifiable information taking place in Scotland?If processing of confidential patient information is taking place in Wales or Scotland, please contact the Confidentiality Advice Team for advice on next steps.  |

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| **2. Study progress**  |
| 1. **Conditions of support** (if applicable)

Supported applications often have specific conditions of support, in addition to standard conditions of support. Applicants are expected to comply with all standard conditions of support by default to ensure the support remains active. Please set out how you have met the conditions of support (expand box as required). This should include any difficulties experienced and mitigating action taken. Specific conditions of support are located in your conditional or final outcome letter Please answer the following three questions and ensure you check the correct boxes for each question (double click on each box and select ‘checked’ where relevant).   |
| 1. **[ ]**  **The application has no assigned specific conditions of support.**

Please note that if there are specific conditions of support (as per the outcome letters) that have not been reported against, this will ­invalidate the annual review and a new annual review will need to be submitted; this may jeopardise the status of support for those relying upon this lawful basis. 1. **[ ]**  **The following provides an update against existing specific conditions of support.**

List each specific condition (expand as necessary) and explain how it has been metCondition 1: Condition 2:Condition 3: 1. **[ ]**  I can confirm the application adheres to all the standard conditions of support.
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| 1. **Steps taken to anonymise the information or obtain consent from individuals**

What steps have been taken to reduce the identifiability of the information or seek consent from the patients? If this has not been done yet, please confirm at what stage you intend to or the reasons why you are not going to. |
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| 1. **Projected end date**

What is the expected end date for your study; **this is the date by which all confidential patient information is no longer identifiable and support is no longer required**.  |
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| 1. **Project changes**

Please provide a summary of any formal amendments made to the CAG that have been supported. It is important to note that only those details specified in the original application (and any formal amendments) have been supported. For applications supported over 5 years ago, or where the application detail no longer reflects current activity, a new application may be required.   |
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| **3. Justification for ongoing support** |
| 1. **Practicable alternatives/exit strategy**

It is a requirement of the Regulations that applicants review the requirement to continue processing confidential patient information without consent on an annual basis. Please provide an overview of alternatives being considered or taken to remove the need for ongoing support, such as the receipt of anonymised data only or the movement towards a pseudonymised approach. |
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| 1. **Patient and public feedback**
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| Please provide details of any complaints, queries or objections that you have received from patients (which specifically relate to this application to process confidential patient information without consent) and the steps you have taken to resolve them. Have any patients requested that their data is not processed and how has it been ensured that this has been respected? |
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| 1. **Public benefits**

To support the need for continued support, applicants should set out what public benefits have arisen since support has been in place, and from time of last annual review. Support to process confidential patient information without consent is based upon there being a public interest in the activity proceeding so applicants should consider this section carefully. Applicants should set out what public benefit has been achieved, or whether a public benefit is still anticipated.  |
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| **5. Confirmation of contact details**Please confirm contact details for the publicly available register of approved applications.  |
| **[ ]**  The contact details below are the same as those currently published in the Register of Approved Applications. **[ ]**  The contact details below are NOT the same as those in the Register of Approved Applications. In order for this change to be processed the reason for this change must be specified here. The reason for the change to contact details is as follows: Name of controller for application:Contact Name and role: Full address: Telephone: Email:  |

Named applicant Name:

Signed: Date:

Please return this completed form to cag@hra.nhs.uk. Questions over completion should be directed to cag@hra.nhs.uk or contact the CAG general advice line on 0207 972 2557 between 9-5.

Please note this document will be assessed by the Confidentiality Advice Team in the first instance. Depending upon the content, the team might request further information, arrange a subsequent meeting to discuss the content of the annual review, or escalate to the Chair or to CAG.