# NHS Health Research Authority Logo‘Section 251 Support’ End Closure Report

## Introduction

Support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 (‘Section 251 support’) provides a legal basis for identifiable patient information to be processed without consent to prevent a breach of the common law duty of confidentiality.

It is the responsibility of applicants to inform the Confidentiality Advice Team (CAT) when they are no longer processing identifiable patient information without consent to ensure that the legal basis can be appropriately withdrawn and the public register updated.

As such all applicants should submit the below closure report once they (and all relevant parties named in the application) are no longer processing identifiable patient information without consent**.** It should not be completed when processing of identifiable information without consent continues, including for archiving and holding purposes.

Once this closure report has been acknowledged, ‘Section 251 support’ will no longer be in effect and there will be no lawful basis to process identifiable information without consent. **Applicants are responsible for ensuring they have informed all parties covered under support that the applicant has expired to avoid inadvertent breaches of confidentiality.** It is advised that this is discussed with all parties prior to submitting this form.

This form should be submitted, with relevant supporting documentation, to [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk). Please contact CAT at [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk) if you have any queries.

If you should declare the end of study to other review bodies you can find information on how to do this on the [HRA website](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/#declaring).

## Application References

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| **PIAG/ECC/CAG Reference Number** |  |
| **Application Title** |  |
| **Research or Non-research** |  |
| **Closure date** |  |

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| **Applicant Name** |  |
| **Address** |  |
| **Email** |  |

Please note on receipt of this form the applicant name and declaration will be checked against that recorded on the [public register](https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/confidentiality-advisory-group-registers/). If the applicant does not appear to have a connection to the application, the CAT will ask for further evidence to ensure that the applicant has appropriate authorisation to submit this form.

## Why ‘Section 251 support’ is no longer required.

Please confirm below why ‘Section 251’ support is no longer required by selecting the appropriate option and provide further detail in the space provided.

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|  | **All identifiable patient information held without consent under this support has been pseudonymised**.  *Note: In this context pseudonymisation means information that identifies a patient has been removed and replaced with, for example, a reference number. The identifiable information that the reference number links to is kept separate to, and is not accessible by, the organisation that holds the clinical information.*  In the box below, please:   * Detail the legal entity which holds the clinical information without direct identifiers * Detail the legal entity which holds the direct identifiers and linkage key, and the common law legal basis to enable it to hold direct identifiers. * Provide assurances that appropriate technical and organisational controls are in place so that it is not possible to reidentify the clinical information for those people who do not have an existing legal basis to access identifiable data |
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|  | **All identifiable patient information held without consent under this support has been removed (and is irretrievable), and any information that continues to be held is anonymised**.  *Note: In this context, anonymised means that all information is held in such a manner that individuals are no longer identifiable, and there are no means for the information to be reidentified by any party.*  In the box below, please:   * Detail the methods used to anonymise the information (for example deletion of identifiers). |
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|  | **Only anonymised patient information was extracted/received. Access to source data containing identifiable patient information without consent is now complete.**  Please provide any supporting comments. |
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|  | **All previously unconsented identifiable patient information under this support is now processed with consent.**  Please provide any supporting comments on the consent procedures that have taken place. |
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|  | **Support was in place to cover potential incidental disclosures whilst undertaking observational activities. These activities have now been completed.** |
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|  | **An alternative legal basis is now in place and being relied upon.**  Please set out in full detail the legal basis that is being relied upon to enable this processing to avoid a breach of the common law duty of confidentiality.  Please also provide supporting evidence (for example, an email) that the new legal basis has been considered satisfactory by a person of sufficient authority at the organisation(s) where the breach occurs (for example Data Protection Officer, Head of Information Governance). |
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|  | **The activity did not commence.**  Please provide full details why the activity did not commence. |
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|  | **Any other reason**  Please provide full reasoning on why support is no longer required, including full assurance that processing of confidential patient information without consent is no longer occurring. |
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## Public Benefits

The CAG is keen to understand the public benefits of the activity that has been undertaken under Regulation 5 support. In the box below please provide full details of the public benefits that have arisen from this work (please provide supplementary information as necessary).

This information will also be added to the expired register entry so the public can see the benefits that have arisen from the unconsented use of identifiable patient data.

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## Applicant Declaration

By completing the below you declare:

* All information in this form, to the best of your knowledge, is correct.
* Identifiable patient information is no longer being processed by any parties or organisations named within this application
* All organisations named within this application have been made aware of this submission and any further processing will be a breach in the common law duty of confidentiality.
* Support under Regulation 5 of the NHS (Control of Patient Information) Regulations 2022 for this application reference can be expired

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| **Chief Investigator/Lead Applicant Name** |  |
| **Organisation** |  |
| **Signed** |  |
| **Date** |  |