## Health Research Authority NatCOL

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

**PIAG/ECC/CAG reference number:**

**Application title:**

**Research / Non-research:**

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| **1. Security arrangements (UPDATED)**Changes to the [security assurance process](http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-cag-application-advice/) have commenced with immediate effect. All applicants processing confidential patient information under the Regulations are now required to provide evidence of suitable security arrangements via a satisfactory Information Governance Toolkit submission. Existing applicants due to provide an annual review from 01 April 2013 will be required to provide a Toolkit submission. For further information please follow the link above and/or contact exeter.helpdesk@nhs.net. |
| 1. Is there currently an up to date IG Toolkit submission in place to cover the processing of this activity? Yes / No
2. IG Toolkit organisation code:
3. IG Toolkit score (if already in place): %
4. IG Toolkit reference:
5. IG Toolkit version:
6. Date of contact with Exeter Helpdesk:
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| **2. Study progress**  |
| 1. **Conditions of approval** (if applicable)

Please set out how you have met the conditions of approval (expand box as required). This should include any difficulties experienced and mitigating action taken. |
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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 data or seek consent from participants? 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. Will any identifiable information be retained for analysis purposes? Please confirm at what stage you intend to destroy the study and identifiable data. |
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| 1. **Project changes**

Please confirm that there have not been any changes to the data controller, purpose, scope, data flows, data sources or identifiable data items of the project. Please note that if you have any made any alternations to these aspects of the project you must also submit an amendment request. Notification of changes through this Annual Review submission are not permitted. |
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| **3. Justification for ongoing support** |
| 1. **Practicable alternatives/exit strategy**

It is a requirement of the Regulations that data controllers 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 negate the need for ongoing support, such as the receipt of anonymised data only or the movement towards a pseudonymised approach. |
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| **4. Patient/service user feedback** |
| 1. **User involvement**

Please provide an update on any service user involvement you have undertaken in the last year and any amendments that have been made to the study as a result of this. |
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| 1. **Patient feedback and objections**

Please provide details of any complaints, queries or objections that you have received from patients (which specifically relate to your processing 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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| **5. Confirmation of contact details**Please confirm contact details for the purpose of our publicly available register of approved applications. |
| Applying organisation: Contact Name and role: Full address: Telephone: Email:  |

Information Guardian/Chief Investigator Name:

Signed: Date:

Please return this completed form to HRA.CAG@nhs.net. Questions over completion should be directed to HRA.CAG@nhs.net or contact the Office on 0207 972 2557.

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.