PICANet

Customised Data Collections: Policy on requests, development and data use

Version 1.5 October 2015

Document History

Version	Author	Date	Comments
1.1	Phil McShane	11/09/2013	First outline
1.2	Sarah Fleming	23/09/2014	First draft
1.3	Roger Parslow	02/03/2015	Edited draft for comment at CAG
1.4	Jodie Singh	13/07/2015	Edits post CAG
1.5	Caroline Lamming	06/10/2015	Edits post Team Meeting

1 Introduction

1.1 PICANet collects a core audit dataset on referrals, transport and admissions to paediatric intensive care units in the UK and Ireland and provides aggregated analysis of this data in yearly reports and via a web interface that allows users to obtain local reports on a large number of different variables. Data from the audit are used for benchmarking and to monitor trends at a local, regional and national level.

1.2 PICANet has a remit to support local audit. Using the PICANet Web data collection tool we are able to develop Customised Data Collections in a single PICU or across any number of PICUs.

1.3 This document outlines the procedures for requesting a custom audit, the approval process, practical issues about data collection and analysis as well as ethics and governance.

1.4 The custom audit facility is not funded to develop data collection for research purposes or for the collection of data related to clinical trials. For these functions, separate funding must be negotiated with PICANet and appropriate governance including ethics approvals obtained.

1.5 Note: These procedures relate to custom audit fields that will collect new data on patients. Customised Data Collection fields required for administrative purposes only e.g. to record data has been checked by a second data entry clerk, do not need to go through this process and can be implemented by PICANet directly.

2 Information governance

2.1 Customised Data Collections can be collected under the approvals held by PICANet. New data to be collected for research or clinical trials can only be included with the appropriate ethics approval.

2.2 PICANet will manage all data collected through Customised Data Collections.

2.3 Patient identifiers will not normally be released to a third party but in rare circumstances this may be justified. Any proposal to release identifiers to a third party would require explicit agreement from the HRA Confidentiality Advisory Group and NHS Research Ethics approval where appropriate. It is unlikely that processing of personal identifiers by a third party will be necessary as in most cases such processing would be carried out by PICANet.

2.4 RELEASE OF PATIENT IDENTIFIERS WILL ALSO REQUIRE EXPLICIT PERMISSION FROM THE HEALTHCARE QUALITY IMPROVEMENT PARTNERSHIP (HQIP) USING THEIR DATA ACCESS REQUEST FORM. THE TERMS AND CONDITIONS OF RELEASE OF DATA ARE SET OUT IN THE HQIP DATA SHARING AGREEMENT.

3 Customised Data Collection request procedures

Figure 1 below describes the process of applying to carry out a Customised data collection through PICANet.

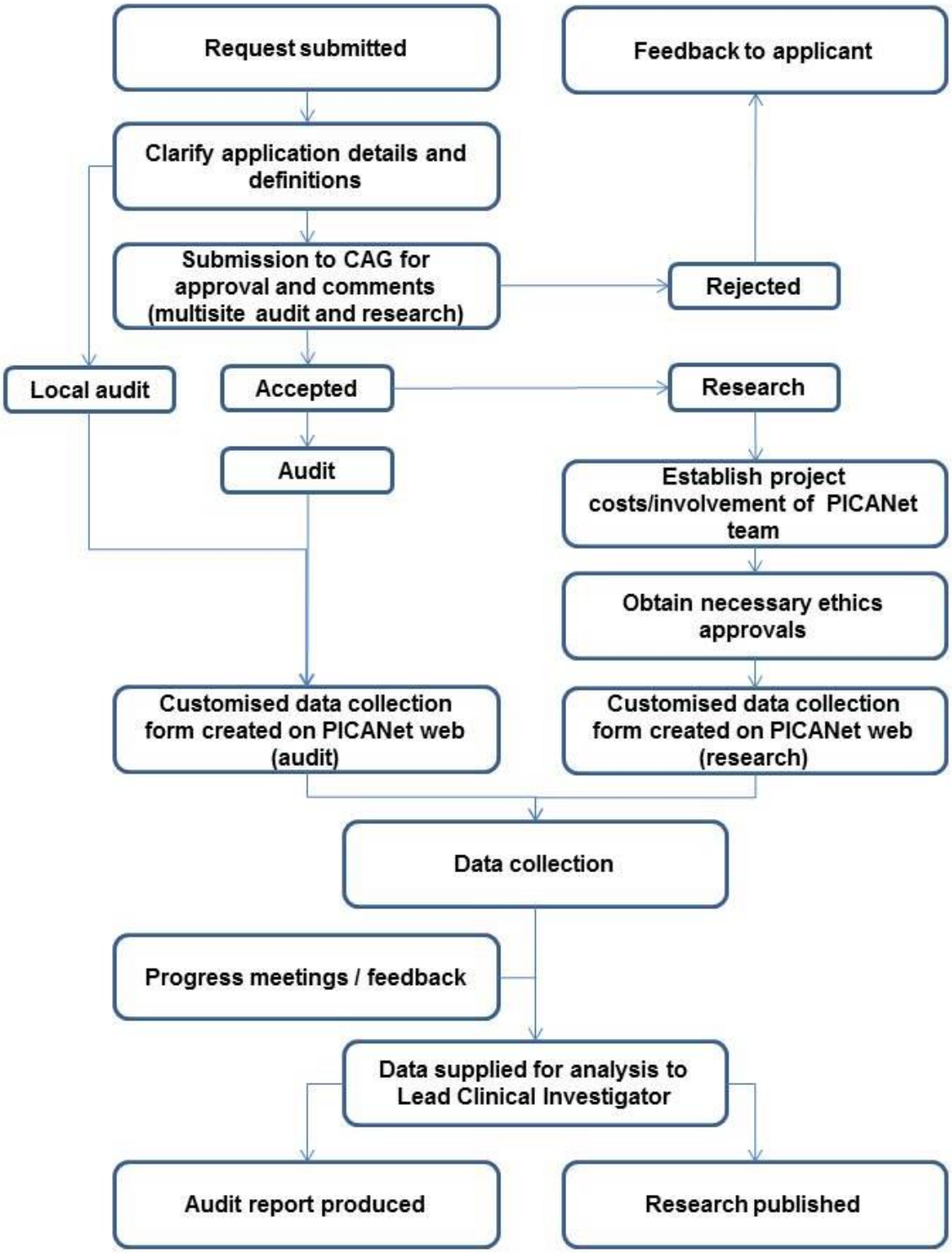

Figure 1. PICANet Customised data collection application and approvals procedure

3.1 All Customised Data Collection requests (audit and research) must have a Lead Clinical Investigator who will work with PICANet on the audit or research project.

3.2 The Lead Clinical Investigator must be available to respond to queries from the PICANet team to allow the development and execution of the audit to be completed without unnecessary delay.

3.3 All Customised Data Collection requests must be sent to the PICANet team email (picanet@leeds.ac.uk) using the appropriate form. These are available at www.picanet.org.uk and the form is reproduced in Appendix 1.

3.4 Requests to carry out a Customised Data Collection will be considered for approval on an individual basis by the PICANet team and PICANet Clinical Advisory Group.

3.5 The decision to proceed with a Customised Data Collection will be based on clinical relevance and PICANet priorities and objectives, feasibility and cost (including data collection burden on participating units).

3.6 Requests should specify the following information:

- The objectives of the proposed audit/research.
- The data to be collected, together with any validation checks needed providing a copy of any data collection form/questionnaire if available.
- Additional data required from the PICANet dataset.
- Selection criteria, including clinical factors, dates, geographical scope.

3.7 An estimate of costs (based development and data analysis) and any potential or actual sources of funding should be provided.

3.8 Note that funding of Customised Data Collections may be required to cover additional core staff time for development of data collection tools within PICANet Web and administration of data collection.

3.9 Commercial organisations requesting the creation of a Customised Data Collection will be charged for this service. The level of fee will be determined by the complexity of the request in addition to a flat rate charge. Further governance arrangements may need to be put in place.

3.10 As a Customised Data Collection is being developed, the PICANet team will provide updates on progress at regular intervals to the applicant, time to completion will depend on the complexity of the audit and the PICANet team workload.

3.11 All Customised Data Collection requests will be displayed on the PICANet website.

3.12 The Lead Clinical Investigator for each Customised Data Collection including local audits must report their findings to PICANet and provide details of their analytical techniques and any further data adjustment/manipulation

3.13 Any outliers identified in the process of the audit must be notified to PICANet who will follow the standard procedure for dealing with outliers in collaboration with the Lead Clinical Investigator.

3.14 All individuals or organisations requesting custom audit data must confirm their agreement to the terms and conditions detailed in this document.

3.15 All data collected by Customised Data Collection will be covered by the PICANet data and information requests policy (available at http://www.picanet.org.uk/Documentation/Policies/) and any data collected will be covered by the same terms and conditions as the core data-set.

3.16 The Clinical Advisory Group will review outputs of all Customised Data Collections within 5 years of data collection. The process for regular reporting of outputs is to be defined before collection begins.

4 Data collection

4.1 Development of Customised Data Collection tools: Data collection will be carried out online as part of PICANet Web, through additional forms added to the core data collection tool. Once permission for the Customised Data Collection has been granted data definitions and validation rules will need to be developed with clear inclusion/exclusion criteria, in conjunction with the PICANet team.

4.2 Supporting documentation: The Lead Clinical Investigator will need to provide clear supporting documentation (as detailed in 4.1) to be supplied to the units to aid in the identification of eligible patients and to clarify the procedures for data collection e.g. clear instructions on the completion of any data collection items. This will need to be of the same standard as the definitions provided in the data manual for core PICANet data items (http://www.picanet.org.uk/Documentation/Guidance/).

4.3 Queries about data collection and definitions: If there are queries relating to the ways specific sections of the custom audit are to be completed or whether particular patients are eligible for inclusion PICANet will be the main contact whilst the Customised Data Collection is underway. PICANet will require a response from the Lead Clinical Investigator which they will then pass on to the units through PICANet Web. The Lead Clinical Investigator must provide a contact email address/telephone number in case individual queries arise relating to data definitions or eligibility so a swift response can be provided.

4.4 Progress reporting: Before data collection the Lead Clinical Investigator will need to provide a description of the type of progress report required during study implementation, this may be a custom report provided by the PICANet team giving a breakdown of responders e.g. by unit, age and sex or an individual data download. Progress will be reported on an appropriate timescale, in most cases this will be monthly but for audits where the inclusion criteria will only identify a small number of children it may be longer.

4.5 Availability of data: Customised Data Collection data linked to the main PICANet dataset will be held by PICANet. Anonymised extracts of the data will be made available to the Lead Investigator by arrangement with the PICANet team.

4.6 Data ownership: The data collected through Customised Data Collections will be owned by PICANet.

5 Variation to the terms and conditions set out in this document

The terms and conditions in this document have been agreed by the Principal Investigators of PICANet, the PICANet Steering Group and the PICANet Clinical Advisory Group but are subject to change at any time in accordance with changes in UK legislation.

6 Appendix 1: Customised Data Collection request form (web form headings)

Title

Name

Position

Lead Investigator

Organisation

Address

Telephone number

Email Address

Title of Customised Data Collection

What is the aim of the audit/research?

What additional data items are needed? [Where applicable, include the following: Units to be included, definition of patient group, number of cases expected, data to be collected (where possible provide copies of questions or web links to relevant articles)]

Proposed audit time period

dd/mm/yyyy to dd/mm/yyyy

Do you have any funding for data collection?

Yes/No

If Yes, what is the source?

N/A Own organisation NIHR HQIP Other (please state)

Will you require other PICANet data?

Yes No N/A

What other data will you require?

What will you use the data for?

Internal audit National/Regional audit Research

How will you disseminate the findings of your audit?

Internal report/presentation External report/presentation Peer-reviewed Publication Other (please specify)

Who else will be involved?

If this is research has ethical approval been granted?

Yes No N/A

If this is research is it compliant with research governance?

Yes No N/A

Any other relevant information…

☐ I have read the PICANet Policy on Customised Data Collection requests and agree to the stated terms and conditions

7 Appendix 2: Customised Data Collection Response Form

If you are willing to participate in the [INSERT TITLE OF CUSTOMISED DATA COLLECTION], please complete the following information and email to picanet@leeds.ac.uk with a copy to [INSERT EMAIL ADDRESS OF CLINICAL INVESTIGATOR]

Name of organisation: . . . . . .

Lead organisation contact: . . . . . .

Email address: . . . . . .

Date: . . . . . .

I/we are willing to participate in [INSERT TITLE OF CUSTOMISED DATA COLLECTION]. We have discussed the customised data collection with all staff involved and can confirm that we have the capacity to partake in [INSERT TITLE OF CUSTOMISED DATA COLLECTION].