CALDICOTT APPROVAL FORM
FOR USE OF PATIENT IDENTIFIABLE DATA
for Health Research, Audit purposes or Service Improvement
NHS Highland data only

Please return this form to:
Christine Robinson, Public Health

Email: christine.robinson7@nhs.net
Typewritten applications only please

Public Health, Assynt House, Beechwood Park, Inverness IV2 3BW

Project, Programme or Study Title

Does remote monitoring of cardiac implanted electronic devices reduce time to clinical decision and incidence of inappropriate shocks: A study in a remote and rural community

Name of Applicant: Kara Shuttleworth

Address: Cardio-respiratory, Kerr Suite, Raigmore Hospital

Tel No 01463704249

Email address: kara.shuttleworth@nhs.net

Name of organisation receiving data: NHS Highland

and their Data Protection Registration Number: z5634253

What patient identifiable information are you looking to use? Please tick all those which apply

CHI Number	√
Forename	
Surname	
Initials	
Date of Birth	
Address	
Postcode	
Age	√
Gender	√
Other: (Please detail)	

General Description of the Study
Please provide a brief description of the study, including aims, objectives, methods and envisaged benefits to patients or the wider public. In particular, it should be clear whether the study relates to audit and service improvement or research**.**
(Principle 1)

AIM: to investigate the ability of remote monitoring to reduce time from a clinical event to clinical decision. Secondary aim is to study the ability of remote monitoring to reduce the number of inappropriate shocks.
Data will be retrospective data of devices implanted 01/05/200-31/04/2012.
Once the data is collected it will be compared to national and international data to evaluate the efficiency of our service.

Requirement to use identifiable data (Principle 2)
Please request only the minimum detail required to meet the purpose of the study

CHI, Age, Gender:
CHI will only be present in initial research to identify patients and recor of care. This data will then be annonimised before further research or publication.

Why is each data field required? (Principle 3)

CHI: So that relevant patient notes can be obtained and details about care. Data will then be annonimised.

Age and Gender: So that demographics of patient groups can be compared to each other, to ensure groups have similar age and gender mix.

Please justify the request for using patient identifiable data in your research study or audit. (Principle 4)

Age and Gender are required in order to compare patient groups with each other and with already published studies.

Please provide details of how the data is to be transferred during its storage and destruction. (Principle 5)

Data will be stored on a database on a NHS Highland computer

Describe the measures in place to protect and use the data securely and confidentially.

Database will be on a NHS password protected computer. Only accessible on an NHS Highland computer

Please outline your organisational compliance with legal requirements (Principle 6)

Legal requirements are governed by NHS Highland. All compliance will be in line with this.

Please provide details on the type of information to be shared, why and with whom, and also how it will be shared. (Principle 7)

Age and gender of patients will be shared when the project is written up. If published age and gender of study patients will be included. CHI numbers will not be included.

Will the data be transferred outside the European Economic Area at any time?

Yes ☐ **No** √ ☐

If yes please give reason for transfer out with the EEA.

Please can you give details of the privacy and security measures that are in place (that you are accepting as 'adequate measures' to protect the data by those receiving it (whether in the UK, EU or outside of the EEA).

Data will only be initially received and reviewed by myself. With all work being carried out on NHS Highland password protected computers. Age and gender will be grouped when releasing final results. So no individual patients will be identified.

What are your arrangements for dealing with the data at the end of the study?

If proved beneficial to patient care data base will continue in use. As the data base collected will have details about care it will be kept securely on the NHS Highland system, before being securely destroyed

What have you done to establish whether anyone else has the data you require?

There is a local database of patient details with ICD's. However this does not include patient treatment, therefore further information is needed.

Please note: Copies of completed Approval Forms will be forwarded to NHS Highland's Area Information Security Manager and, if the project falls into non-research category, the Clinical Effectiveness Manager for comments.

Applicant: Kara Shuttleworth

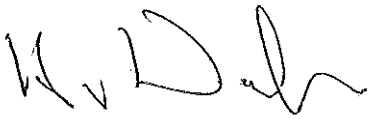
Job Title: Trainee cardiac Physiologist

Professional Registration Details eg GMC/GDC

Signature: **Kara Shuttleworth** **Date: 10/02/16**

Authorisation Granted **Yes** [x] **No** [ ]

Comments:



Signature ……
…… **Date: …19 Feb 2016…**

Caldicott Guardian: Dr Hugo van Woerden, Director of Public Health, NHS Highland

Caldicott Principles

Principle 1 – Justify the purpose(s)
Every proposed use or transfer of patient-identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.

Principle 2 – Don't use patient-identifiable information unless it is absolutely necessary
Patient-identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).

Principle 3 – Use the minimum necessary patient-identifiable information
Where use of patient-identifiable information is considered to be essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out.

Principle 4 – Access to patient-identifiable information should be on a strict need-to-know basis
Only those individuals who need access to patient-identifiable information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.

Principle 5 – Everyone with access to patient-identifiable information should be aware of their responsibilities.
Action should be taken to ensure that those handling patient-identifiable information – both clinical and non-clinical staff – are made fully aware of their responsibilities and obligations to respect patient confidentiality.

Principle 6 – Understand and comply with the law
Every use of patient-identifiable information must be lawful. Someone in each organisation handling patient information should be responsible for ensuring that the organisation complies with legal requirements.

Principle 7 – The duty to share information can be as important as the duty to protect patient confidentiality
Health and social care professionals should have the confidence to share information in the best interest of their patients within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

FOR OFFICE USE ONLY

	YES	NO	DATE
Data Protection Issues Clarified			_____
Applicant Notified			_____

Application Number …… (for office use only)