

## RESEARCH AND DEVELOPMENT POLICY

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Applies to:	Clinical Research Team Staff and others undertaking research/evaluation within the Trust Other staff – for Information Only

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## DOCUMENT CONTROL

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## 1. INTRODUCTION

- 1.1 The *Research Governance Framework for Health and Social Care* (RGF) (Department of Health, second edition, 2005) requires all NHS organisations to ensure that all research projects comply with the RGF in respect of:
- Ethics
  - Scientific quality
  - Data protection and information governance
  - Financial probity
  - Exploitation of intellectual property
  - Health and safety (including safety reporting)
- 1.2 Research activity may include clinical trials, research projects and development projects, which may be externally funded or undertaken within existing resources. A range of methodologies and tools may be employed in the design of these projects, including surveys, structured interviews, focus groups and data collection and analysis. Not all projects that use these methodologies would be regarded as “research”, but this policy sets out the registration, governance and approval arrangements to ensure that all projects that collect data from staff or patients of the Trust are conducted ethically and safely. See **Appendix A** for the differences between research, service evaluation and clinical audit. The registration and conducting of Clinical Audit projects is covered by a separate policy: [Clinical Audit Policy](#).
- 1.3 A core standard for all health care organisations is that they have systems to ensure the principles and requirements of the RGF are constantly applied. The RGF seeks to promote improvements in research quality across the board, provides a context for the encouragement of creative and innovative research and aims to forestall poor performance, adverse incidents, research misconduct and fraud, and to ensure that lessons are learnt and shared when poor practice is identified.

## 2. PURPOSE AND RATIONALE

- 2.1 The purpose of this document is to set out the Trust’s policy in relation to Research and Development (R&D) and describe how R&D is implemented in the Trust. The policy ensures all research studies, clinical trials, patient and staff surveys, service evaluations are conducted safely and ethically and with due regard to data protection and confidentiality.
- 2.2 This policy applies to any member of staff undertaking or involved in research\evaluation who works for the Trust or with the Trust; this includes all staff with honorary or substantive contracts of employment within the Trust. Where applicable it requires all staff to follow the RGF and the Trust supports staff in this aim.
- 2.3 This policy also applies to R&D being undertaken for undergraduate and postgraduate qualifications. ***It is the responsibility of the student or their supervisor to contact the R&D Office to discuss any proposal to undertake research within the Trust.***

### 3. POLICY STATEMENT

- 3.1 Somerset Partnership NHS Foundation Trust aims to carry out good quality, relevant research safely, ethically and with due regard to data protection and confidentiality in line with the requirements of the RGF. The Trust recognises the contribution R&D makes to providing reliable evidence to inform key areas of clinical policy and practice and to the delivery of a high quality, cost effective health service that ultimately improves patient care.

### 4. DEFINITIONS

- **RGF** - Research Governance Framework for Health and Social Care
- **Research** - the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. The findings should be reported so that they are open to critical examination and accessible to all that could benefit from them.
- **Service evaluation** - measures current service or new service development without reference to a standard. Does not involve randomisation of patients to different interventions.
- **Clinical audit** - measures current service against specific pre-determined standards of care/treatment.
- **R&D** – Research and Development
- **ICH** - International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
- **GCP** – Good Clinical Practice
- **Portfolio Study** – a study which is adopted by the National Institute for Health Research and thereby eligible for Clinical Research Network (CRN) support. To be eligible, the study must be attempting to derive generalisable (i.e. of value to others in a similar situation) new knowledge by addressing clearly defined questions with systematic and rigorous methods; have full research funding; to have been subject to high quality peer review.
- **Own account study** – a study that has not been adopted by the NIHR as a portfolio study or has no commercial funding. Costs are met by the study sponsor or the individual completing the research. These are generally internal Trust studies where the Investigator is an employee of the Trust, or a student on placement with the Trust.
- **Multi-centre study** – a study that takes place in more than one Trust, institute or centre of research.
- **Single-centre study** – a study that only takes place in one Trust, institute or centre of research.
- **Multi-site study** – a study that takes place at multiple sites within a Trust.
- **Single site study** – a study that only takes place at one site within one Trust.
- **IMP** - Investigational Medicinal Product. A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial.
- **CTIMP** – Clinical Trial of an Investigational Medicinal Product

- **Medical Device** - defined in Directive (93/42/EEC) as any instrument, apparatus, appliance, material or other article (used alone or in combination) for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception.
- **NIHR** – National Institute for Health Research. The national institute that supports research within the NHS.
- **LCRN** – Local Clinical Research Network. The primary vehicle for providing infrastructure to support study involvement at local NHS Trusts. Somerset Partnership is a member of the South West Peninsula Clinical Research Network (CRN: SWP)
- **CLARHC** - Collaboration for Leadership in Applied Health Research and Care; part of the NIHR focused on applying health research on the needs of patients and supporting the translation of research evidence into practice in the NHS. Somerset Partnership is a member of the South West Peninsula Collaboration for Leadership in Applied Health Research and Care (PenCLAHRC)
- **PPIE** – Public and patient involvement and engagement
- **SOP** – Standard Operating Procedure

## 5. DUTIES AND RESPONSIBILITIES

- 5.1 It is the responsibility of organisations providing health and social care in England to be aware of all research undertaken in their organisation, or involving participants, organs, tissue or data obtained through the organisation. Health care organisations have a duty of care to provide robust research governance procedures.
- 5.2 The Trust ensures that patients, service users, carers and their care professionals are provided with information (which they are able to easily understand) regarding any research which may have a direct impact on their care, their experience of care or their work in the organisation.
- 5.3 The Trust ensures that all research activities are conducted in accordance with the Research Governance Framework (RGF), which recognises and takes account of the diverse needs, customs and the effect of the research on the individuals and communities impacted by the research.
- 5.4 The Trust has a structure in place to facilitate the strategic management of Research and Development (R&D).
- 5.5 The Trust ensures that no health or social care research with human participants, their organs, tissue or data may begin before:
- An identified Chief Investigator, Principal Investigator or Local collaborator has accepted responsibility for that research;
  - The study has received full ethical approval by the relevant Ethics Committee;
  - Delegation of responsibilities is agreed and documented.

- 5.6 **The Trust Board:** has overall responsibility for ensuring all research activities are conducted in accordance with the RGF.
- 5.7 **Chief Executive:** is accountable for the Trust's compliance with the RGF. The Chief Executive delegates responsibility as follows:
- 5.8 **Medical Director:** has delegated responsibility for R&D and reports to the Trust Board on all research activity.
- 5.9 **Data Protection Officer:** has delegated responsibility for data protection and Information Governance, and delegates the checking of data protection/information governance arrangements for research studies to the Head of Research and Clinical Effectiveness.
- 5.10 **Head of Research and Clinical Effectiveness:** reports to the Medical Director on all matters relating to R&D in the Trust. The Head of Research & Clinical Effectiveness coordinates the approval of all research projects in the Trust and strategically manages the R&D office.
- 5.11 **R&D Office:** facilitate and coordinate the approval and implementation of R&D activity within the Trust, and support the conducting of research within the Trust as appropriate.  
Duties include:
- For studies defined as “research” within the NHS, ensuring that the relevant approvals have been provided by the Health Research Authority before any research is undertaken within the Trust
  - Ensuring all research agreed by the Trust complies with the standards for each project as set out in the study protocol
  - Providing advice to researchers on matters relating to research governance and approval; including making researchers aware of the Research Governance Framework, Data Protection Act, Health and Safety or any other guidance relating to research
  - Providing advice and support for the setting up and administration of externally funded research (commercial and non-commercial)
  - Encouraging the uptake of research and identifying Principal Investigators/Local Collaborators for multi-site studies of interest to the Trust
  - Providing advice to potential researchers on research methodology, funding opportunities and grant applications
  - Facilitating and supporting NIHR portfolio studies taking place in the Trust
  - Supporting non-NIHR portfolio studies taking place in the Trust as resources allow
  - Financial management of the R&D budget
  - Liaising with the Pharmacy team if the study involves the use of Investigational Medicinal Products (IMPs)
  - Ensuring anyone conducting research within the Trust is suitably qualified and hold appropriate contracts
  - Ensuring any research conducted within the Trust receives senior management approval

- Ensuring all adverse events relating to research are reported to the Chief Investigator of the appropriate study.

5.12 **Chief Investigator (CI):** the senior individual responsible for the conduct of the research who is accountable to their employer, and through them to the sponsor of the research. The CI is also directly accountable to the care organisation(s) where the research is taking place (or through which the data team has access to participants, their organs, tissue or data). If the research is at more than one site, the CI takes on personal responsibility for the design, management and reporting of the study, co-ordinating the Principal Investigators or Local Collaborators who take the lead at each site. CI's and sponsors of research studies are encouraged to make contact with the R&D Office of the Trust at an early stage if the Trust's participation and support in the research study is desired.

- The CI is responsible for ensuring that the research is ethically approved and that an application is complete and submitted to the HRA via the Integrated Research Application System (IRAS).
- The CI will have completed Good Clinical Practice (GCP) training if requested by the HRA or R&D Team. GCP training is mandatory for clinical trials involving investigational medicinal products.

5.13 **Principal Investigator (PI):** the senior individual responsible for the local arrangements of a research study within the Trust; this could be at either a single site or multiple sites within the Trust. The PI is directly accountable to the care organisation(s) where the research is taking place (or through which the data team has access to participants, their organs, tissue or data). If the research is at more than one site within the Trust, the PI takes on personal responsibility for the co-ordination of any Local Collaborators who may be taking the lead at individual sites.

- The PI takes responsibility for the Trust's involvement in the research project with guidance and support from the R&D Office. The PI assists the R&D Office in facilitating the local management of the study, protecting the Trusts best interests, and ensuring the research protocol is followed. This includes ensuring that all adverse events relating to the research project are reported back to the R&D office and correctly documented in accordance with Trust policy.
- The R&D Office is responsible for ensuring an appropriate PI (or LC) is identified for a multi-site research project initiated outside the Trust. This individual must hold a contract with the Trust and must be agreed with the CI and/or sponsor.

5.14 **Local Collaborator (LC):** the individual responsible for the local arrangements of a portfolio study within the Trust, at an individual site. The LC is directly accountable to the care organisation(s) where the research is taking place.



- The LC takes responsibility for the Trust's involvement in the research project with guidance and support from the R&D Office.
- The LC assists the R&D Office in facilitating the local management of the study, protecting the Trust's best interests, and ensuring the research protocol is followed. This includes ensuring that all adverse events relating to the research project are reported to the R&D office and correctly documented in accordance with Trust policy.
- The R&D Office is responsible for ensuring an appropriate LC (or PI) is identified for a multi-site research project initiated outside the Trust. This individual must hold a contract with the Trust and must be agreed with the CI and/or sponsor.

5.15 **Clinical Research Group:** is responsible for monitoring research activity within the Trust and reports to the Medical Managers Meeting.

5.16 **Head of Medicines Management:** scrutinises all research studies that involve Investigational Medicinal Products (IMPs) and provides advice prior to the Trust confirming its capacity and capability to deliver a research study within the organisation. (The Trust has a service level agreement with Yeovil District Hospital to provide research pharmacy services).

5.17 **Health Research Authority (HRA):** is responsible for approving the conducting of clinical research within the NHS (including a favourable ethical opinion [www.hra.nhs.uk/](http://www.hra.nhs.uk/))

## 6. RESEARCH AND DEVELOPMENT CULTURE

6.1 The Trust is committed to developing first class research and development capabilities that brings about benefits for the patient and ultimately improves the way services are delivered.

6.2 The raising of R&D profile and culture is achieved through:

- Facilitation of Trust/University collaborative research
- Participation in, and encouraging the hosting of, high quality national multi-centre research
- Development of well-established research programmes and themes
- Encouraging opportunities for R&D training.

6.3 The Trust contributes to the research programmes of the National Institute for Health Research (NIHR), via the South West Peninsula Clinical Research Network (CRN: SWP) and reports as required on NIHR adopted research activity within the Trust.

6.4 The Trust is a member of CRN and actively supports any research study adopted onto the NIHR portfolio where invited to do so. This may include research programmes originating from academic institutions, clinical organisations, charitable bodies or commercial organisations.

- 6.5 The Trust will consider supporting research not adopted onto the NIHR portfolio. This may include projects sponsored by the Trust (for employees of the Trust), another NHS organisation, charitable bodies, academic institutions (including student projects) and commercial organisations. Support for research projects undertaken by non-employees is conditional on the following:
- There is no cost implication or financial impact
  - It is directly beneficial to patients and/or staff
  - There is substantial specialist interest within the Trust
- 6.6 The sponsor of a research study takes responsibility for initiation, management and funding of a study. There must be a sponsor for any research that takes place within the NHS or social care services in England. Normally, the sponsor is one of the organisations taking the lead for particular aspects of the arrangements for the study. This may be:
- The Chief Investigator's employing organisation;
  - The lead organisation providing health or social care
  - The funder

The Trust will usually respond positively to any request to sponsor research initiated by an employee of the Trust, subject to senior management approval and satisfactory funding arrangements. The sponsorship of any research is determined on a case by case basis. The Trust expects any sponsored research to be fully funded from an external source; that is not from operational budgets, and to be subject to scientific review.

## 7. PROJECT APPROVAL

- 7.1 Anyone wishing to undertake a project which involves the structured collection and analysis of data must contact the R&D Office in order to seek advice on the classification of the project (research, evaluation or audit) and approval/registration procedures. A range of methodologies and tools may be employed in the design of these projects, including surveys, structured interviews, focus groups and data collection and analysis. See **Appendix A** for the differences between research, service evaluation and clinical audit.
- 7.2 Anyone **not** employed by the Trust, but planning to complete a project involving staff or patients of the Trust (or their data) must have a sponsor for the project and identify a supervisor from within the Trust.
- 7.3 Anyone undertaking a project involving staff or patients of the Trust (or their data) must have a contractual relationship with the Trust (eg. contract of employment, honorary contract, letter of access, student placement contract etc.). The R&D office can advise on the most appropriate arrangements in each case.

## Research

7.4 Approval for “research” to be conducted within the NHS is given by the HRA, which includes a favourable ethical opinion from an independent ethics committee if the research involves patients or their carers. Where necessary, individual NHS organisations must confirm their capacity and capability to deliver the research within their organisation. Application is made through the Integrated Research Application System (IRAS): [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk).

7.5 Advice and guidance, templates and forms to complete are available on the Trust intranet: [Research](#).

## Service evaluation

7.6 Approval for a service evaluation (which includes the evaluation of a service through patient survey) is given by the Head of Research & Clinical Effectiveness. The proposal form at **Appendix B** should be completed and emailed to the Head of Research & Clinical Effectiveness.

7.7 Advice and guidance, templates and forms to complete are available on the Trust intranet: [Service evaluation](#).

## Clinical Audit

7.8 Approval for a clinical audit project is given by the Clinical Audit Manager on behalf of the Head of Research & Clinical Effectiveness. The approval process is detailed in the [Clinical Audit Policy](#).

7.9 Advice and guidance, templates and forms to complete are available on the Trust intranet: [Clinical audit](#).

## Medical Device evaluation

7.10 The trialling of a medical device that has been certified by the European Union (i.e. awarded a CE mark) but is NOT on the NHS Electronic Drug Tariff (compiled of behalf of the Department of Health by the NHS Business Services Authority) [www.drugtariff.nhsbsa.nhs.uk/](http://www.drugtariff.nhsbsa.nhs.uk/) (bandages etc) or on the Trust approved medical devices list (instruments, apparatus, appliances), shall follow the procedure outlined in Appendix C.

7.11 The trialling of a medical device that has not been certified by the European Union (i.e. awarded a CE mark) shall be regarded as **research** (see 6.4 above)

## 8. CONDUCTING RESEARCH

### Patient and public involvement in research

8.1 Involving patients and public in research is an important part of NHS R&D and is indeed a key requirement of research governance. Department of

Health policy over recent years has emphasised the importance of involving patients and the public in all aspects of their health care, including research.

- 8.2 Involvement means those who use the Trust's services are active partners in the research process rather than the subjects of research. Involvement can occur during any or all of the processes involved in R&D including; setting the research agenda, commissioning research, undertaking research, interpreting research, disseminating the results of research and getting findings put into practice.
- 8.3 The Trust actively supports and encourages the inclusion of patients, and their carers in line with the NIHR guidance on Patient and Public Involvement (PPI). This involves encouraging and training Trust staff to involve patients/carers in all stages of R&D ensuring robust consent and confidentiality arrangements are in place.

### **Standard Operating Procedures (SOPs)**

- 8.4 The Trust complies with the NIHR Research Support Services Framework, including the creation of SOPs and delegation logs for the delivery, record management and functional responsibilities for each research project.
- 8.5 The Trust ensures that for any CTIMP, a SOP is developed to cover all the delegated responsibilities within the specific project.
- 8.6 The Trust ensures that an Adverse Event Reporting section is included in the SOP for each project.

### **Record Management**

- 8.7 The Trust ensures that the records of all involved in research projects conducted by the Trust are securely stored and archived in accordance with Trust policy, protecting the integrity and confidentiality of patient, service user, carer and staff information and data generated by research.
- 8.8 Project documents and source data for projects will be stored electronically on a secure Trust server rather than stored in paper files. Any signed documents (such as consent forms) should be scanned in .pdf format, filed electronically and the original confidentially destroyed. In exceptional circumstances, the research sponsor may require original documents containing 'wet' signatures to be retained, in which case a paper file will be created and stored securely in accordance with the Trust's Record Keeping and Records Management Policy.
- 8.9 Details of all ongoing research projects within the Trust are made available on the Trust Intranet, and public website where appropriate.
- 8.10 The Trust expects to receive the results of any research project conducted within the Trust in the form of a report and will publish this on the Trust Intranet (and public web site where appropriate). In addition, the Chief Investigator must make the results widely available in an accessible form to all those with the potential to derive benefit including patients, carers and

health professionals. This could include publication in a peer-reviewed journal and/or presentations at appropriate national and international meetings. The Chief Investigator is also responsible for making the results known to the participants in the research.

### **Health and Safety**

- 8.11 Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants and of research and other staff is given priority at all times, and health and safety regulations must be observed.

## **9. MONITORING COMPLIANCE AND EFFECTIVENESS**

- 9.1 The Medical Managers Meeting is responsible for monitoring overall compliance with this policy, receiving assurance from the Clinical Research Group in the form of quarterly reports.
- 9.2 This policy will be regularly reviewed and maintained by the Clinical Research Group. Review of the policy will occur at least once every three years or sooner if required due to changes in local or national guidance.
- 9.3 Adherence to this policy will be monitored by internal audit and external audit from the NIHR.
- 9.4 Research Governance is monitored by the Clinical Research Group and by the NIHR CRN: SWP annual review.
- 9.5 Internal and external audit results are presented to the Clinical Research Group for consideration, identifying good practice, any shortfalls, action points and lessons learnt. This Group are responsible for ensuring improvements, where necessary, are implemented.

## **10. TRAINING AND COMPETENCY REQUIREMENTS**

- 10.1 The R&D Office staff receive appropriate training on research governance, research management, data protection, information governance, health and safety, ICH GCP (Good Clinical Practice), in accordance with the RGF.
- 10.2 All staff working within or wishing to carry out research receive appropriate training, including ICH GCP and any training specific to the study in accordance with the RGF.
- 10.3 ICH GCP is a mandatory requirement for those engaged in research that involves an investigational medicinal product or if the study sponsor specifies it as a requirement. The Trust actively encourages all staff involved in research to undertake GCP training.

## 11. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

Department of Health, Research Governance Framework for Health and Social Care (2<sup>nd</sup> edition), 2005

National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2009

ICH-GCP Guidelines (CPMP/ICH/135/95)

The Medicines for Human Use (Clinical Trials) Regulations, 2004

National Institute for Health Research Support Services Framework – Streamlining the Management and Governance of R&D Studies in the NHS (version 1), 2010

Health Research Authority (including NRES) [www.hra.nhs.uk](http://www.hra.nhs.uk)

Integrated Research Application System (IRAS):

[www.myresearchproject.org.uk](http://www.myresearchproject.org.uk)

National Institute for Health Research (NIHR): [www.nihr.ac.uk](http://www.nihr.ac.uk)

NIHR Clinical Research Network: South West Peninsula (CRN: SWP):

[www.nihr.ac.uk/nihr-in-your-area/south-west-peninsula](http://www.nihr.ac.uk/nihr-in-your-area/south-west-peninsula)

### Cross reference to other procedural documents

[Equality and Diversity Policy](#)

[Clinical Audit Policy](#)

[Health and Safety Policy](#)

[Record Keeping and Records Management Policy](#)

[Risk Management Policy](#)

[Untoward Events Reporting Policy](#)

Standard Operating Procedures in Research

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

## 12. APPENDICES

12.1 For the avoidance of any doubt the appendices in this policy are to constitute part of the body of this policy and shall be treated as such.

Appendix A How Research, Clinical Audit and Service Evaluation differ

Appendix B Survey/Evaluation Proposal Form

Appendix C Evaluation of Medical Devices Procedure

## APPENDIX A

### How Research, Clinical Audit and Service Evaluation differ

#### Research

The deriving of new, generalisable knowledge by addressing defined questions with systematic & rigorous methods. Often involves comparing those receiving a new intervention with those receiving normal care (the control group).

#### Clinical Audit

The comparison of actual practice against agreed, documented, evidence-based standards with the intention of improving patient care. (See [Clinical Audit Policy](#))

#### Service Evaluation

The judging of a service's effectiveness/efficiency through the systematic assessment of purpose, activities, outcomes and/or costs. It is undertaken to evaluate the service and identify areas that could be improved. It will often involve asking the views of the users/customers of a service, or the staff who provide a service and sometimes includes the “benchmarking” of one service compared with others.

RESEARCH	AUDIT	SERV. EVAL
Designed to test hypotheses, or identify/explore themes following certain methods.	Designed to answer; ‘does this service reach a predetermined standard?’	Designed to answer; ‘what standard does this service achieve?’
Addresses clearly defined questions, aims & objectives.	Measures against certain standards.	Measures current service without reference to a standard.
May involve evaluating, comparing or studying interventions (particularly new ones).	Only involves an intervention currently in use by a service.	Only involves an intervention currently in use by a service.
Normally involves collecting data that is additional to routine care. May involve treatments, samples or investigations.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of interview or questionnaire.
May involve allocating patients to intervention groups.	No allocation to intervention groups.	No allocation to intervention groups.
May involve randomisation of patients to receive different interventions.	Does not involve randomisation.	Does not involve randomisation.
Must be approved by an Ethics Committee.	Does not require approval by an Ethics Committee, BUT does require ethical consideration.	Does not require approval by an Ethics Committee, BUT does require ethical consideration.

Service Evaluation/Survey Proposal Form

PROPOSER:		DIRECTORATE/SERVICE/ TEAM:	
SUPERVISOR:		Relationship to Proposer:	

TITLE:	
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SURVEY/EVALUATION OBJECTIVE(S)

ETHICS SCREENING – Does the survey/evaluation <i>(delete whichever does not apply)</i> :			
1. <i>Infringe any patient's rights or risk breaching any patient's or carer's confidentiality or privacy?</i>	Yes/No	6. <i>Allocate any interventions differently among groups of patients or staff?</i>	Yes/No
2. <i>Pose any risk for or burden on a patient beyond those of his or her routine care?</i>	Yes/No	7. <i>Is there anyone involved with the survey who does not normally have access to patient's records or information?</i>	Yes/No
3. <i>Involve any clinically significant departure from usual clinical care?</i>	Yes/No	8. <i>Collect data directly from any patient or carer?</i>	Yes/No
4. <i>Gather any information about a patient or carer beyond that collected in routine patient care?</i>	Yes/No	8b. <i>If Yes, could the study subject a patient or carer to more than minimal burdens or risks if it is time consuming or requests sensitive information?</i>	Yes/No
5. <i>Report any data that could be used to identify any patient or practitioner?</i>	Yes/No		



### WORK PLAN

	<i>Planned date:</i>		<i>Planned date:</i>
<b>1. Start by:</b>		<b>3. Data analysed by:</b>	
<b>2. Data collected by:</b>		<b>4. Report completed by:</b>	
<b>5. Report to be submitted to:</b>			

### HELP NEEDED

<b>Is help or support from any other department or service needed to complete the evaluation?</b>	<b>Yes/No</b>
<b>If yes, describe whose help is needed and the nature of the help:</b>	

**PLANNED METHODOLOGY** (eg. No. of clients, cases, episodes, instances and/or time period to evaluate. Attach any proposed questionnaires)

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## Evaluation of Medical Devices Procedure

### C.1 Definitions/Context

C.1.1 A **Medical Device** means: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means. (*Directive 2007/47/EC*)

C.1.2 For a number of products it is not clear if they are medical devices or not. There are a number of examples of products that may or may not be medical devices depending on the Intended Purpose for Use, assigned by the manufacturer to the products. The following Toiletry and Cosmetics Products can also be Medical Devices if a medical claim is being made by the manufacturer for the device, although these products are usually not Medical Devices:

- tooth brushes, dental sticks, dental floss, dental chewing gums;
- baby nappies, hygiene tampons, mattress protectors;
- contact lenses intended to provide colour to the eyes;
- instruments for tattooing;
- deodorants for use with devices;
- wigs.

C.1.3 Medical devices fall into the following classes:

**Class I:** (with sub-divisions **Im** – devices that include measurement, and **Is** – devices that are sterile) devices that are not intended to help support or sustain life or be substantially important in preventing impairment to human health, and may not present an unreasonable risk of illness or injury. Examples include: elastic bandages, examination gloves, and hand-held surgical instruments.

**Class II:** devices that require mandatory performance standards and postmarket surveillance so that they perform as indicated without causing injury or harm to patient or user. Examples include acupuncture needles, powered wheelchairs, infusion pumps, air purifiers, and surgical drapes.

**Class III:** devices that need premarket approval, a scientific review to ensure the device's safety and effectiveness because they support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Examples include

implantable pacemaker, pulse generators, HIV diagnostic tests, automated external defibrillators, and endosseous implants.

#### C.1.4 Non-invasive devices which come into contact with injured skin:

**Class I** if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates, absorbent pads, island dressings, cotton wool, wound strips, adhesive bandages (sticking plasters, band-aid) and gauze dressings which act as a barrier, maintain wound position or absorb exudates from the wound.

**Class IIb** if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent such as - dressings for chronic extensive ulcerated wounds; dressings for severe burns having breached the dermis and covering an extensive area; dressings for severe decubitus wounds; dressings incorporating means of augmenting tissue and providing a temporary skin substitute.

**Class IIa** all other cases, including devices principally intended to manage the micro-environment of a wound such as those having specific properties intended to assist the healing process by regulating the environment (humidity, temperature, oxygen levels, other gases, pH values); adhesives for topical use; Polymer film dressings; Hydrogel dressings; Non-medicated impregnated gauze dressings.

## C.2 Class I Procedure

C.2.1 New products may be evaluated without explicit written patient consent, although a report identifying the clinical and cost benefits of recommending a new product at the end of the evaluation period is recommended.

## C.3 Class II Procedure

C.3.1 For products **not** included on the NHSBSA Electronic Drug Tariff, the patient's written informed consent must be obtained prior to using the product under evaluation.

C.3.2 At the conclusion of the evaluation a report outlining both the clinical and cost benefits of a new product should be written and submitted to the Somerset Wound Formulary Group with the recommendation to add/not add the product to the Somerset-wide formulary.

## C.4 Class III Procedure

C.4.1 In the unlikely event of the Trust being involved in evaluating class III devices, each case will be discussed and agreed at the Medical Devices Group and the decision ratified at the Clinical Governance Group.