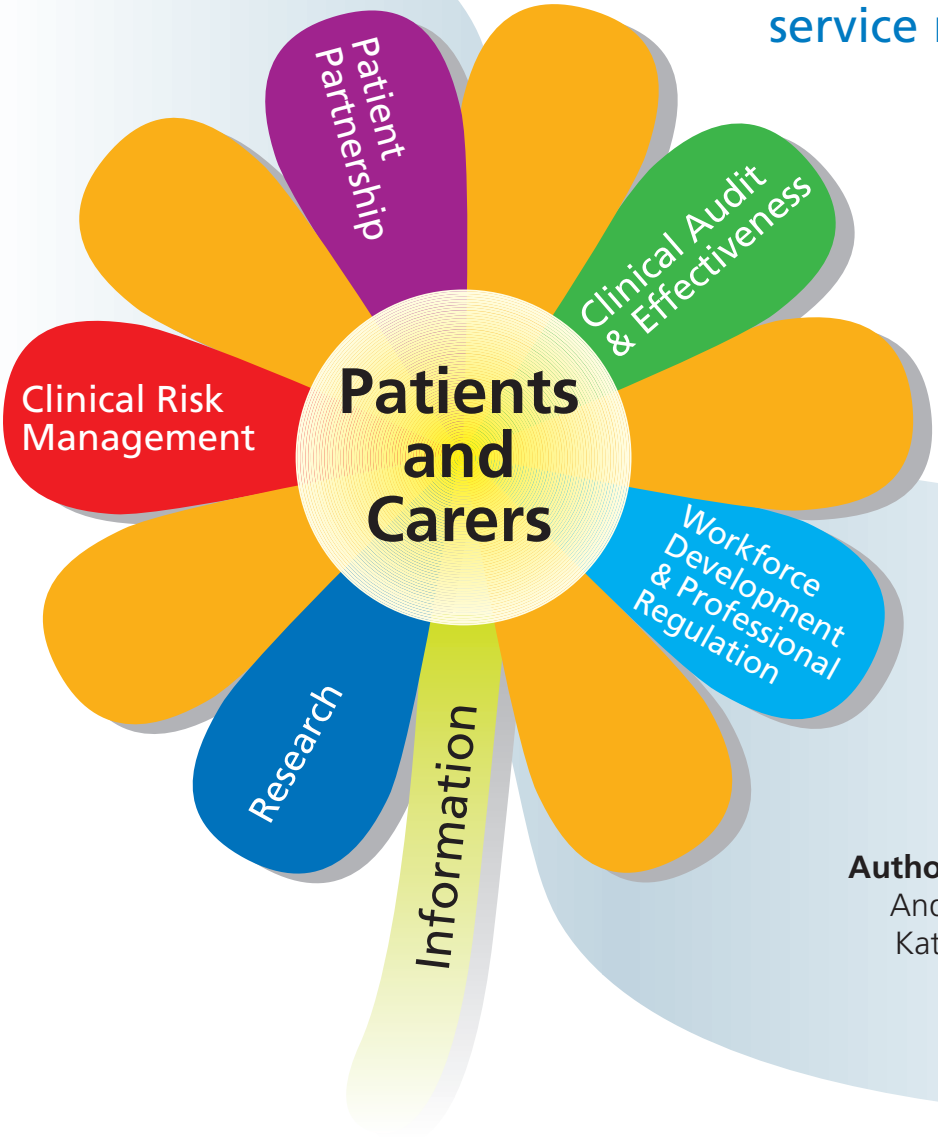
Sheffield Teaching Hospitals NHS
NHS Foundation Trust

The Simple Rules Toolkit

An educational tool designed to help staff differentiate between clinical audit, research and service review activities



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To order a copy of this document:

STHFT staff need to contact the Supplies Department quoting reference number PD3680

Non STHFT staff can place an order for the Toolkit on-line at www.nhs-ennovations.com at a cost of £14.99.

In addition an educational workshop about The Simple Rules Toolkit is available. To book places on this workshop they would need to contact Stephanie Bridgford at Medipex Limited (quoting the Simple Rules Toolkit workshop) Helpline Tel No: 0113 392 6459 Direct Line Tel: 0113 392 6494

STHFT staff need to contact the Clinical Audit and Effectiveness Unit for workshop information.

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APPENDICES

SECTION 1: KEY POINTS ABOUT THE BOOKLET

Why create it?

The Toolkit provides guidance to help staff follow established clinical governance practices and links in respect of data collection activities. Please refer to Diagram 1 on page 6 for an overview.

What will it do?

This Toolkit will help STHFT staff differentiate between clinical audit, research and service review and therefore enable the proposed data collection activity to be correctly categorised most of the time i.e. accepting that no toolkit can be 100% comprehensive.

Consideration must always be given to the risks of applying an incorrect method of data collection e.g. contravening research governance, the risk of harm to patients, the organisation or staff.

Who is it aimed at?

Staff with a responsibility to lead projects involving data collection as well as those wishing to learn more about such activities.

How to use it

In the first instance, use:

- The flowchart on page 6 to gain an overview.
- Use the 'Simple Rules' on page 7 to get a reasonable indication of your project type i.e. is it clinical audit, research or service review?
- To confirm your project type use the 'Rule in Questions' on pages 8-13.
- As a final check to ensure your proposed project is not research – please answer the Research questions in Table 3, page 9.

For grey area projects where the Toolkit does not provide you with a clear categorisation between these activities, staff are advised to seek advice from one of the Trust Departments listed in Appendix B, page 28. Trust policies exist within these departments to deal with service review grey area projects as well as advise on the steps to achieve ethical consideration for these activities (also outlined on pages 14-18 of this document).

Application of this process allows the Trust to issue a letter that will enable STHFT staff to provide evidence for prospective publishers or any other relevant parties that the project has been classified as service review and that ethical review has been achieved. See Appendix D, page 31.

Changing practice following Service Review activities

Any proposed changes in practice arising from these activities must be safe, clinically effective, legal and ethical. In general, all proposed changes to practice must consider the clinical impact of the proposed changes and must be set in the context of risk to patients. The final decision to change clinical practice rests with the lead clinician and their team. For additional guidance, please refer to Table 6 on page 16 for the Ethical Principles Applicable to Service Review.

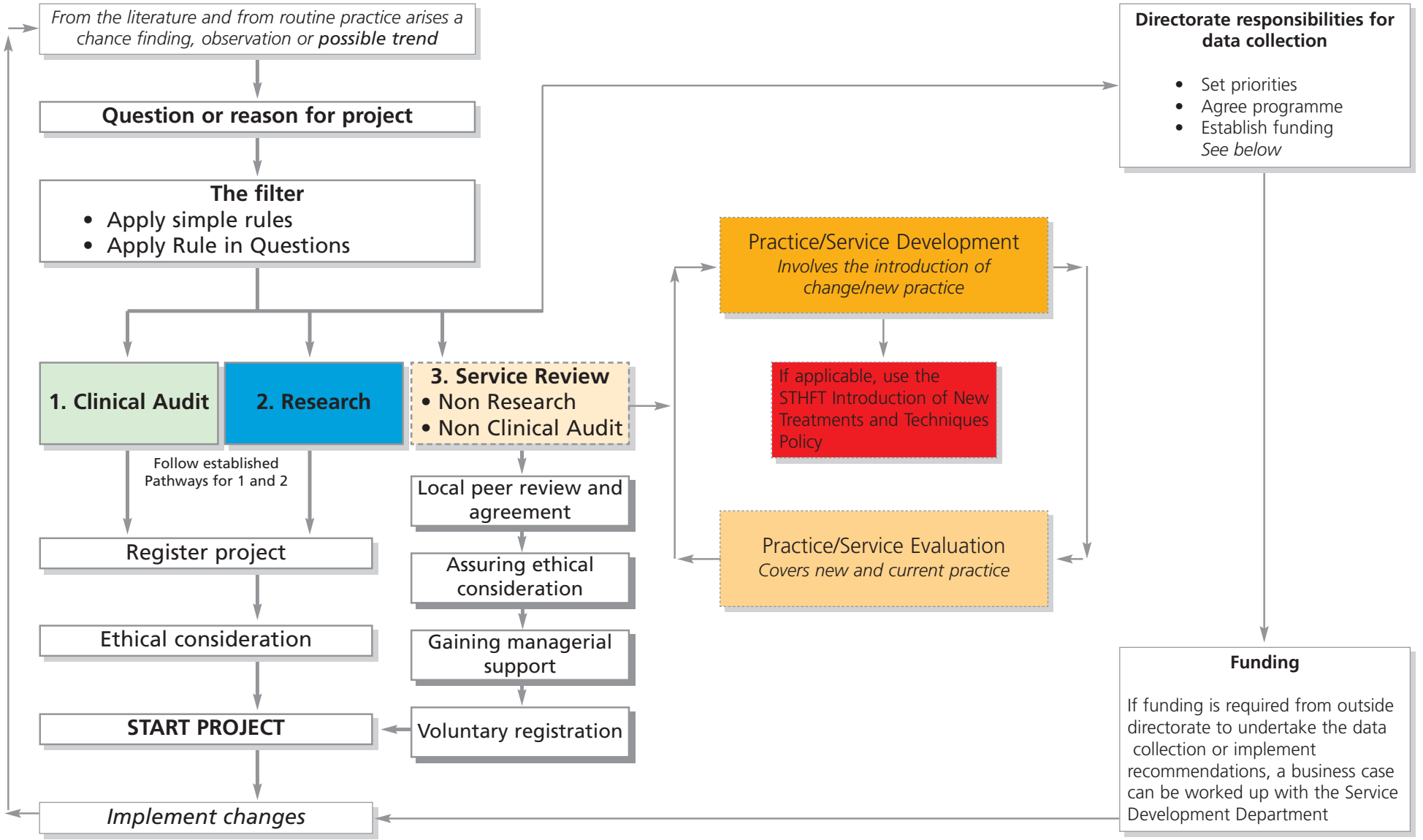
The STHFT Introduction of New Treatments and Techniques Policy must be used as appropriate. Guidance is contained throughout the document.

A flow diagram providing an overview of this policy can be found in Appendix E, page 33. To read the full policy follow this hyperlink:
http://sthnet/STHcontDocs/STH_Pol/IntroOfNewTechniquesAndTreatments.doc

Feedback your views and experiences of the Toolkit

To develop the Toolkit further we need to capture comments and suggestions from those using the Toolkit. To feedback, please use the Feedback Form on the Clinical Audit & Effectiveness Unit Website or contact the Clinical Audit and Effectiveness Unit to speak with the project lead or submit feedback via email to: CAEU@sth.nhs.uk

Diagram 1:
Overview of established clinical governance practices and links in respect of data collection activities



SECTION 2: THE SIMPLE RULES

By applying the simple rules below you will get a reasonable indication of the type of data collection activity you want to embark on and whether you need to use the STHFT Introduction of New Treatments and Techniques Policy.

TABLE 1: THE SIMPLE RULES

Note. All the words in **bold** and ***italics*** are defined in Section 5: Glossary of Terms (see page 19)

Activity		Simple Rule
Clinical audit	1	Measures existing practice against ***evidence-based clinical standards***
	2	All clinical audit must comply with the ***clinical audit governance requirements***
Research	1	Generates new knowledge where there is **no or limited research evidence** available and which has the potential to be ***generalisable*** or ***transferable***
	2	All research must comply with research governance requirements
Service review	1	Incorporates both **service/practice development** and **service/practice evaluation**
	2	**Service/practice development** – introduces a change in service delivery or practice for which there is ***evidence*** derived from research or from other health/social care settings that have already introduced and evaluated the change. New developments should always be evaluated
	3	**Service/practice evaluation** evaluates the ***effectiveness*** or ***efficiency*** of an existing or new service/practice that is **evidence based**, with the intention of generating information to inform local decision-making. This type of activity has sometimes been referred to as a clinical effectiveness study, base-line audit, activity analysis, organisational audit and ***benchmarking***.
	4	All service review activity should comply with clinical governance requirements and follow the ethical principles within Table 6 on page 15
	5	Service/practice development which is concerned with introducing a new treatment or technique must follow the STHFT Policy on Introduction of New Treatments and Techniques as summarised below.
STHFT Policy on Introduction of New Treatments and Techniques		This policy applies to the introduction of: • A treatment or technique which is understood to be safe and effective but new to STHFT • A treatment or technique that is an interventional procedure (as defined by NICE) and has not been used in the NHS before • An existing treatment or technique that is to be adapted for new purposes. • A medicine not on the STHFT formulary or a new indication for an existing formulary medicine.

SECTION 3: THE RULE IN QUESTIONS

TABLE 2: RULE IN QUESTION FOR CLINICAL AUDIT

Note. All the words in **bold** and ***italics*** are defined in Section 5: Glossary of Terms (see page 19)

	QUESTION	YES	NO	DON'T KNOW
2.1	Do you want to measure current practice against ***evidence based clinical standards?*** This will typically involve measuring both process and outcomes at the same time.			

If you have answered **YES** to question 2.1 then your proposed project is clinical audit. Please follow the established STHFT ***clinical audit governance requirements.*** This begins with the submission of a clinical audit registration form to the Clinical Audit and Effectiveness Unit (click here or go to http://sthweb/CAE_nhs/)

If you have answered **DON'T KNOW,** seek further advice before proceeding. For advice, please refer to your local Clinical Audit Lead or the Clinical Audit and Effectiveness Unit (see Section Three of the Clinical Audit Strategy and Supporting Policy Documents http://sthweb/CAE_nhs/Strategies/Clinical Audit Strategy.htm) If required, the STHFT Clinical Audit and Effectiveness Unit Manager will be the final arbiter in deciding if a project is clinical audit.

If you have answered **NO** to this question, your proposed project **IS NOT** clinical audit. Proceed to either the research (Table 3) or service review questions (Tables 4 and 5).

TABLE 3: RULE IN QUESTIONS FOR RESEARCH

Note. All the words in **bold** and ***italics*** are defined in Section 5: Glossary of Terms (see page 19)

	QUESTION	YES	NO	DON'T KNOW
3.1	Do you want to ***investigate*** the ***effects*** of a ***new*** treatment or technique on patients/ carers?			
3.2	Do you want to ***investigate*** the ***effects*** of an existing treatment or technique on a new patient/ carer group or pathology?			
3.3	Do you want to ***investigate*** the ***correlation*** between two treatments/techniques or characteristics?			
3.4	Do you want to **test** a ***new*** technology or ***new*** medicine on a patient or their carer?			
3.5	Do you want to **develop** a new technology using NHS staff or facilities?			
3.6	Is the new knowledge you are providing ***generalisable or transferable*** to other patients or NHS settings?			
3.7	Do you want to ***investigate*** a cognitive, physiological, physical/functional, psychological or social phenomenon of staff, patients or carers where **current evidence** or **knowledge** is lacking?			
3.8	Are you using **human tissue** from patients/staff in your investigation? (You must comply with the Human Tissue Act 2004. Please contact Research Department). Also under certain conditions human tissue can be used in service evaluation - see question 5.8 on page 12.			

If you have answered **YES** to <u>any</u> of these questions, your proposed project is research. Please follow the established STHFT Research Governance pathway. *http://www.sth-research.group.shef.ac.uk/.*

If you have answered **DON'T KNOW** to any of these questions, seek further advice before proceeding. For advice please refer to the Research and Development Department. If required, the STHFT Director of Research will be the final arbiter in deciding if a project is research.

If you have answered **NO** to <u>all</u> of these questions then your proposed project **IS NOT** research. Proceed to either the clinical audit (Table 2) or service review questions (Tables 4 and 5).

TABLE 4: RULE IN QUESTIONS FOR SERVICE REVIEW-PRACTICE / SERVICE DEVELOPMENTS

Note. All the words in **bold** and ***italics*** are defined in Section 5: Glossary of Terms (see page 19)

	QUESTION	YES	NO	DON'T KNOW
4.1	Do you want to **introduce** and evaluate a new practice(s) based on **evidence published in a *peer-reviewed publication***?			
4.2	Do you want to **introduce** and evaluate a new practice(s) based on evidence of implementation and evaluation in another NHS Trust or Health/Social care setting?			
4.3	Do you want to **introduce** and evaluate a new practice(s) for which there is limited evidence but for which you have completed an **assessment** of **need** and **risk**?			
4.4	Do you want to **introduce** and evaluate a new outcome measure or assessment tool **published in *a peer reviewed publication?***			
4.5	Do you want to **introduce** and evaluate a new type of equipment currently licensed in the UK?			

If you have answered **YES** to any of these questions then your proposed project is practice/service development.

But as a final check to ensure your proposed project is **not research** – please answer the research questions in Table 3.

To comply with local clinical governance requirements you will need to:

- Register your project (refer to Appendix A - Registration Process, page 27)
- Follow Ethical Principles (refer to Section 4 Ethical Principles Applicable to Service Review, page 14)
- Where appropriate involve **service users** in your practice/service developments.
- If yes to Q4.5, contact your Directorate Medical Equipment Manager who will advise on the steps you will need to follow to comply with the STHFT Medical Equipment Management Manual.

If yes to Q4.1 to Q4.3 – Please use the **STHFT Introduction of New Treatments and Techniques Policy** if your proposed Service/Practice Development relates to the introduction of:

- A treatment or technique that is understood to be safe and effective, but new to STHFT
- A treatment or technique that is an interventional procedure (as defined by NICE) and has not been used in the NHS before
- An existing treatment or technique that is to be adapted for new purposes
- A medicine not on the STHFT Formulary or a new indication for an existing formulary medicine

Please seek advice from your local Clinical Governance Lead.
http://sthnet/STHcontDocs/STH_Pol/IntroOfNewTechniquesAndTreatments.doc

If you have answered **DON'T KNOW** seek further advice before proceeding. You could contact one of the key Trust departments responsible for supporting clinical effectiveness activities (Appendix B page 28).

There is no single final arbiter for service review work. The default is that if the proposed project is ruled out as either clinical audit or research, then it must be service review.

If you have answered **NO** to all these questions, your proposed project **IS NOT** a practice/service development. Proceed to either the clinical audit (Table 2), research (Table 3) or service evaluation (Tables 5) questions.

TABLE 5: RULE IN QUESTIONS FOR SERVICE REVIEW-PRACTICE / SERVICE EVALUATION

Note. All the words in **bold** and ***italics*** are defined in Section 5: Glossary of Terms (see page 19)

	QUESTION	YES	NO	DON'T KNOW
5.1	Do you want to ***evaluate*** the ***effectiveness*** and or ***efficiency*** of your ***current practice*** or service?			
5.2	Do you want to ***evaluate*** the ***effectiveness*** and or ***efficiency*** of an educational programme?			
5.3	Do you want to ***compare*** the ***effectiveness*** or ***efficiency*** of a ***new*** practice (consistent with new practice as described in Table 4 Q4.1-Q4.3) with your ***current practice*** or service?			
5.4	Do you want to ***compare*** your ***effectiveness*** or ***efficiency*** against another current area of practice within your Trust?			
5.5	Do you want to collect and analyse patient/ staff/carers data to ***evaluate*** patterns of activity?			
5.6	Will your ***evaluation*** provide information of local relevance to inform local decision-making?			
5.7	Will your ***evaluation*** provide information for making clinical decisions about the care or management of your patient?			
5.8	Are you using **human tissue** from patients/staff in your project? You must comply with the Human Tissue Act 2004. Please contact Research Dept.			

If you have answered **YES** to any of these questions then your proposed project is practice/service evaluation.

To comply with local clinical governance requirements you will need to:

- Register your project (refer to Appendix A Registration Process, page 27)
- Follow Ethical Principles (refer to Section 4 Ethical Principles Applicable to Service Review, page 14)
- Where appropriate involve **service users** in your practice/service evaluation.

If yes to Q5.3 – Please use the **STHFT Introduction of New Treatments and Techniques Policy** if your proposed Service/Practice Development relates to the introduction of:

- A treatment or technique that is understood to be safe and effective, but is new to STHFT
- A treatment or technique that is an interventional procedure (as defined by NICE) and has not been used in the NHS before
- An existing treatment/technique that is to be adapted for new purposes
- A medicine not on the STHFT Formulary or a new indication for an existing formulary medicine

Please seek advice from your local Clinical Governance Lead.
http://sthnet/STHcontDocs/STH_Pol/IntroOfNewTechniquesAndTreatments.doc

If you have answered **DON'T KNOW** seek further advice before proceeding. You could contact one of the key Trust departments responsible for supporting clinical effectiveness activities (Appendix B, page 28).

There is no single final arbiter for service review work. The default is that if the proposed project is ruled out as either clinical audit or research, then it must be service review.

If you have answered **NO** to all these questions, your proposed project **IS NOT** a practice/service evaluation. Proceed to either the clinical audit (Table 2), research (Table 3) or service development (Table 4) questions.

SECTION 4: ETHICAL PRINCIPLES APPLICABLE TO SERVICE REVIEW

Introduction

All staff planning to undertake service review should ensure ethical consideration of their project at the appropriate level. Refer to pages 17-18 for a full explanation. The set of ethical principles in this document have been developed to assist with this process. Each project will need individual consideration as to which principles are relevant.

Clinical Directorates should have ownership and control of service review projects involving their patients, data, staff, equipment or facilities. They should therefore be responsible for considering any ethical implications and for ensuring each project complies with STHFT policy and relevant NHS guidance e.g. confidentiality, consent, etc.

STHFT expects that individual staff members proposing or planning a service review project will conduct an initial self-assessment of the project proposal based on their own personal values and with reference to their professional code of practice. The proposal should then be discussed with the Directorate Clinical Governance lead, who, following a local peer review process, may be in a position to authorise further planning or possibly initiation of the project. Some Directorates may require authorisation from the appropriate executive body within the Directorate. Whatever process or route is followed within each Directorate, it is important that staff gain management support for their proposals before proceeding and committing resources. Skills training for staff involved in the project may be obtained from the providers listed in Appendix B page 28.

At any stage throughout the planning and authorisation process, help and advice may be sought from the relevant Trust departments as outlined in Appendix B of this toolkit. Should any matters of a complex or sensitive ethical nature remain unresolved following such discussion and consultation, then the Clinical Director may seek an opinion from the STHFT Clinical Ethics Group (CEG).

When appropriate authorisation has been obtained, consideration should be given to voluntarily registering the proposal on the Trust database (Appendix A page 27). In this way other staff and Directorates will learn about each new project, and they may benefit from knowing the findings and eventual outcome.

Staff wishing to undertake research should register the project with the Research Office according to research governance requirements and follow the necessary procedures to gain approval from a research ethics committee.

Staff undertaking a clinical audit project should follow the ethical guidelines produced by the Clinical Audit and Effectiveness Unit.

The ethical principles

Along with the rest of this Toolkit, the principles on page 14 have been developed to guide STHFT staff in planning and undertaking any type of service review project. The format follows a similar list from the findings of a research study published by public health staff from ScHARR. The views of many STHFT colleagues, along with work in the fields of clinical and research ethics has informed the final list. The principles address the design and conduct of the project; the welfare of participants; and the rights of participants who become involved.

The ethical principles for service review are congruent with the ethical principles that inform professional practice. Therefore in the same way that a practitioner obtains the consent of a patient before undertaking a clinical procedure, consideration should be given to the consent of participants in service review. Similarly, a clinician will weigh up the risks involved in deciding whether or not to use a particular intervention. In service review activity, it is equally important to consider how to minimise any untoward effects, and to identify what could possibly go wrong and what to do if it does. For example if patients are to be interviewed about their experiences of a particular service, it is important to ensure that questions are phrased in an appropriate manner, and how to respond if any patients become distressed with the line of questioning.

Consideration of these ethical issues should begin at the same time as the project plan is forming – they cannot be addressed separately or at a later stage in the design of the project. Not all the principles outlined overleaf will apply to every project, but each one should be considered in turn as appropriate. The suggested indicators have been developed to provide guidance and are not meant to be seen as requirements for every project.

TABLE 6: ETHICAL PRINCIPLES APPLICABLE TO SERVICE REVIEW

	Principle	Suggested Indicators
1	The aim of the project is justified and compatible with the priorities and requirements of the professional group/ Directorate/ Trust, and Directorate support exists.	• A clear written protocol exists • Evidence of Directorate support • Clinical governance lead aware of project • Directorate-based peer review outcome
2	The ethical requirements regarding the identification and recruitment of participants are met. • Contact • Right of equal access • Right to refuse • Right to withdraw • Consent/ agreement In some situations e.g. quality assurance of laboratory medicine analyses or equipment calibration, it may not be necessary to obtain explicit consent.	Processes should be in place (and described in the protocol) to address the following issues: • First contact with the potential participant • Consideration of vulnerability • Right to refuse • Right to withdraw • Consent/ agreement • Justification for not seeking consent with reference to relevant policy or guidance
3	The roles and responsibilities of any participants (patients/ relatives/ staff) are agreed between the project lead and relevant participants.	The protocol outlines the roles and responsibilities of the participants
4	The participant's privacy should be respected and confidentiality should be maintained.	The peer review process should address compliance with NHS Code of Confidentiality, and an opinion from the Trust's Data Protection Officer and/or Caldicott Guardian should be obtained in sensitive or complex situations.
5	A risk assessment should be conducted to pre-empt what could go wrong and what to do if it does, for example what to do if the following occurs: • Patients reveal information that would indicate clinical need or intervention • Malpractice is identified • The project disrupts normal care or routines	• The peer review process should address risks and make recommendations. • Evidence of Directorate agreement
6	A risk-benefit evaluation should be undertaken to assess the potential burden of harm to participants.	The peer review process should address the likelihood of harm and/or distress.
7	Findings are disseminated and shared to areas of the organisation that will learn from them.	• Entry in STHFT project database • Completed projects listed in Directorate Clinical Governance annual report • Project abstracts in STHFT newsletters, etc
8	Participant involvement is accurately presented in reports and shared in a way easily understood.	Evidence of Directorate Patient and Public Involvement (PPI) lead input into reports (if relevant).
9	Where appropriate, due consideration has been given to the legal requirements associated with the use of human tissue.	The peer review process should address compliance with the Human Tissue Act 2004. Advice should be sought from the Trust's Data Protection Officer where appropriate.
10	Staff should be skilled and competent to undertake project tasks, and should be in receipt of appropriate clinical and/or academic supervision. Necessary skills might include data collection, data analysis, project management, time management, communication, etc.	• Project staff CVs • Training records • Competency assessment records • Supervisor's statement
11	Resources (including time and money) required to complete the project are available and supported by managers/ supervisors.	• The peer review process should address resource utilisation • Evidence of management support

How to assure yourself or your team that ethical consideration for your service review project has been achieved

It is the responsibility of each Directorate Clinical Governance Lead to establish local systems for ensuring ethical consideration of all service review projects takes place.

In the absence of any formal national guidance/policy framework to govern service review work, STHFT has produced the following practical advice for Directorates to help frontline staff achieve ethical consideration for their service review projects.

The three levels of sign off are described below and can be used for the following purposes:

1. To complete the relevant section on the voluntary service review registration form. Please follow the hyperlink http://sthweb/CAE_nhs/ to access a copy of the form.

2. To provide prospective publishers, if required, with evidence that ethical review has been achieved. Please refer to page 31, Appendix D for a copy of this proforma letter. This letter can also be used to provide evidence that a particular project has been classified as service review.

Level 1 assurance - lead clinician/project stakeholder group

The lead clinician and/or the project stakeholder group need to assure themselves their proposed project method is consistent with:

- the ethical principles contained within the Toolkit
- their codes of professional conduct
- local Directorate governance systems

You may find it helpful to discuss your proposal with a colleague who has appropriate expertise in the field and/or your line manager. This level of ethical consideration should be sufficient in many cases.

If unable to confidently sign off for Level 1 assurance, you would then need to proceed to the next level.

Level 2 assurance – local governance review

Use local Directorate governance systems to reach a final resolution. In some Directorates there are established peer review groups that staff can take a proposed project to for ethical consideration. For example, Critical Care, Anaesthesia and Operating Services have established a Peer Review Forum which meets regularly to review service review projects and maintains a database of all such activity undertaken in the Directorate. The Professional Services Directorate has identified a system whereby named individuals with expertise provide advice and review proposals. Please contact the Clinical Governance leads in these Directorates for more information.

In other Directorates, there may not be any formally established peer review groups. In these situations the next best thing would be to link with individuals such as the Clinical Governance Lead or the Clinical Director.

If unable to confidently sign off for Level 2 assurance, you would then need to proceed to the next level.

Level 3 assurance – STHFT Clinical Ethics Group

In the occasional case, where a favourable ethical opinion cannot be reached within the above two levels, the STHFT Clinical Ethics Group can provide advice to Directorates.

The referral to the Clinical Ethics Group must come via your Directorate Clinical Governance Lead.

SECTION 5: GLOSSARY OF TERMS

Adequate	Where there is sufficient evidence to enable the clinician to make a recommendation about current best practice. Classifications for the quality and quantity of evidence can be found in the NICE Guideline Development Manual. http://www.nice.org.uk/pdf/GDM_Chapter11.pdf
Benchmarking	The benchmarking process helps practitioners to take a structured approach to sharing and comparing practice, enabling them to identify the best and to develop action plans to remedy poor practice. http://www.dh.gov.uk
Clinical audit governance requirements	These requirements are contained in the STHFT Clinical Audit Strategy and Supporting Policy and Information Documents. (http://sthweb/CAE_nhs/).
Compare	To examine in order to observe a resemblance or difference between results or outcomes.
Correlation	To establish a relationship between variables i.e. to ***investigate*** the ***correlation*** is where a researcher seeks to provide evidence of a relationship between variables.
Current practice	Is an activity occurring in the Trust, which is 'happening now, belonging to the present time', or equipment that is in use now (Oxford Senior Dictionary, 1982). Current practice can be based on either formal or informal knowledge. **Formal knowledge (external evidence, empirical knowledge)** is knowledge that has been validated by independent scientific scrutiny. For example textbooks and peer reviewed publications. **Informal knowledge:** is knowledge that has not been validated by independent scientific scrutiny. For example, unpublished research reports, unpublished reports, conference papers, unpublished but shared experiences (Le Roux, 2003.), and consensus expert opinions.
Decision making	Action or change based on observed and documented evidence of benefit.
Effect	To establish a causal link between variables. i.e. to ***investigate*** the ***effect*** is where a researcher seeks to provide evidence of a causal link between variables.
Effective	Is the capability of producing a result or outcome such as the achievement of a patient's potential for improvement or the prevention of the patient's deterioration.
Effectiveness	The ability of the health care practitioner, multidisciplinary team or organisation to produce results or outcome, i.e. extent to which the recovery potential is achieved.
Efficiency	The ability of the health care practitioner, multidisciplinary team or organisation to achieve results or outcome with the minimum use of resources.
Evaluation (Evaluate)	To ascertain the amount or value or to judge or assess the worth of an existing technology, medicine, practice or intervention.
Evidence	" …data on which to base proof or to establish truth or falsehood" (The New Collins Concise Dictionary, 1985). Within the health and social care environment this involves the provision of data (i.e. the systematic recording of clinically significant observations of change) on which to base

	proof of clinical effectiveness. Evidence can be formal or informal. See current practice definition.
Evidence based clinical standards	Define precisely the service/practice we are seeking to provide. The standards can be based on the hierarchy of evidence. Please refer to FAQ 6.8 on page 23. Also please follow this link and see leaflets 5 and 6. http://sthweb/CAE_nhs/Information/Leaflet%20folder/Leaflets.htm
Generalisable	The ability to infer the findings of a study to a wider population. This can theoretically only occur when the study population is randomised from the wider population. Please refer to FAQ 6.15 on page 25 for additional information.
Investigate	To provide evidence about the existence of a variable or phenomenon i.e. a medical investigation seeks to provide evidence of pathology.
Model	A description of practice adequately representing the real thing, which is regarded as excellent and worthy of reproduction.
New	Is defined as being where no current evidence has been published in peer reviewed publications.
Outcome measure	Is a tool that quantifies change in one or more patient characteristic over time. 'Measurement transforms certain attributes of the world into numbers, which can be summarised, organised and analysed by statistical procedures' (Stein & Cutler, 1996).
Peer reviewed publication	A publication that has been scrutinised by independent, invited experts to establish the credibility of the evidence. However, reviewers may not have full knowledge of the area therefore their judgement may be invalid, Health care practitioners may therefore need to use their own clinical judgement.
Quantifying Evidence	The amount of evidence needs to be quantified a) to be able to judge whether the effect is real or a chance (random) occurrence using probability statistics. b) to be able to establish the internal and external validity of the findings (NICE, 2004).
Transferable	The ability to infer similar findings in another comparable population setting rather than in the wider population from which the study population was drawn. Please refer to FAQ 6.15 on page 25 for additional information.

SECTION 6: FREQUENTLY ASKED QUESTIONS ABOUT THE TOOLKIT

6.1 Does the Toolkit cover university students?

Yes. Your university supervisor will need to use this Toolkit with you to ensure the correct Trust governance systems are adhered to. Also, it is important to note that all student projects must have an STHFT employee as the lead/collaborator and should follow the key steps as outlined in Diagram 1 on page 6.

6.2 Is the confirmation accuracy of the toolkit 100%?

Absolutely not.

However, by applying the Simple Rules and Rule in Questions to a likely clinical audit project, this should confirm it as clinical audit in the vast majority of cases.

But, given the accepted complexity in differentiating between research and service review in particular, there will always be grey area cases where the Toolkit will not be able to provide a clear categorisation between these activities. In these instances if staff are worried that they may inadvertently be undertaking research, advice must be sought from the Research Department or from one of the other Trust departments listed in Appendix B, page 28.

Please note, this is a guidance only document. Also, in the absence of a mandatory registration and approval system for service review activities within the Trust, the final decisions to undertake service review activities rest with the individual professional.

6.3 How do we deal with grey area cases?

We accept there will be the purists view that certain service review projects are in fact grey area research and should therefore be conducted as research. Whereas the pragmatists accept there will always be grey area cases (evidenced by the continuing global debate on this subject) and therefore believe we cannot conduct everything as research as innovation would grind to a halt.

Therefore, a balance is required between these two viewpoints and final decisions must take account of the following points:

- Accept that this Toolkit will enable staff to correctly categorise their data collection activity most of the time i.e. accept that no toolkit can be 100% accurate.
- In grey area cases proceed with caution and be sure any proposed changes in practice are safe, legal and ethical. Consider the risks of applying an incorrect method to their data collection i.e. contravening research governance, is there a risk of harm to patients, the organisation or staff?
- The risk of getting it wrong can be minimised by peer review, advice from LREC, applying the Section 4 Ethical Principles, informed conversations with colleagues and ensuring work is part of Directorate programmes/plans.

6.4 What is the difference between research and the service evaluation described in Q5.3 page 12?

Research is about establishing new knowledge, whereas, Q5.3 is about finding out whether local outcomes replicate the research evidence (please refer to 6.8 below). If they do, then clinicians may want to adopt the new practice, if they don't then the clinicians may want to reject that practice.

6.5 If I compare two evidence based treatments is this research or service review?

Imagine you want to compare two current treatments A and B (both evidence based). If you want to establish the 'effectiveness' or 'efficiency' of the treatments this is a service review activity. In this situation you are looking at the individual's response to treatment in a real clinical situation. You cannot attribute causality in this situation.

If you want to establish the 'effect' of each treatment on the patients this will require randomisation from the patient population, as effect is a term used to describe where there is a causal link between treatments A or B and the patient's outcome. This will then be a research activity where you are investigating the effect of the treatment on a group of patients by testing a hypothesis mathematically to establish the probability of the change being a random event.

If the research project demonstrates that treatment A has a greater effect than treatment B and that this is statistically significant i.e. not a random event but attributable to the treatment given, you would change your practice. To establish this you use inferential statistics to confirm or reject your hypothesis.

6.6 If your service review demonstrates that treatment A is more effective and efficient than treatment B, can you change your practice?

Yes, because the aim of the health care practitioner/medical practitioner and the aim of the organisation is to provide the best patient outcomes with the minimum use of resources. To establish the effectiveness and efficiency of the treatment you would use descriptive statistics. You are providing informal evidence of the most efficient and effective evidence based treatment.

6.7 Can I change practice (e.g. set new standards of care) through service review, clinical audit or as a result of using adequate evidence from elsewhere?

Yes, if the methods used were rigorous and the data collected robust, it is then safe to make such decisions. From a clinical governance perspective, consideration must be given to the clinical impact of the proposed changes and must be set in the context of risk to patients.

The key concerns about making changes to clinical practice focus on whether the proposed change is safe, clinically effective, clinically efficient and all concerned are properly trained, competent and supported, and that the change is properly resourced.

The final decision to change clinical practice rests with the lead clinician and their team i.e. professional accountability.

6.8 Which hierarchy of evidence is STHFT working to?

STHFT has adopted the hierarchy below as published by NICE (2004)

Ia	Evidence obtained from systematic review or meta-analysis of Randomised Controlled Trials (RCT's)
Ib	Evidence obtained from at least one RCT
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/ or clinical experiences of respected authorities

6.9 In the absence of higher levels of evidence, can service review data be used as part of the discussions needed to set local level IV standards as per hierarchy of evidence in 6.8 above?

Yes. The ideal scenario would be that:

- The current practice is within a centre of excellence,
- The standards must be set via local consensus,
- Robust service review methodologies are applied to the data collection. Please note, the practical reality is that poor methodologies are often applied leading to the use of unreliable data.

6.10 Can you explain what evidence means at STHFT?

Evidence can be regarded as ". …data *on which to base proof or to establish truth or falsehood*". (The New Collins Concise Dictionary, 1985).

In the health and social care environment this can be translated into the provision of data (i.e. the systematic recording of clinically significant observations of change) on which to base proof of clinical effectiveness. The amount of evidence needs to be quantified in order to be able to judge whether the effect is real or a chance (random) occurrence. In a peer reviewed article of a quantitative research project the criteria used to establish this is based on probability. This increases the confidence the reader can have about new knowledge of treatment efficiency or disease prognosis. The quality of the study also needs to be established through critical appraisal, as a poorly designed project may produce statistically significant results that have limited clinical value. The use of evidence to inform clinical decision-making and clinical practice is based on the synthesis of informal and formal knowledge (see Current Practice explanation in Glossary of Terms on page 19).

There has been considerable debate over the last decade around the small proportion of medical treatments that are based on sound scientific evidence (Smith, 1991, Grayson, 1997) and about the wisdom of basing clinical decisions and practice solely on the findings of quantitative research (Mant 1999, Rolf, 1999).

" *… external clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external (formal) evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decisions.*" (Sackett et al., 1996)

6.11 What is service review?

Service review is defined as an activity undertaken within the organisation that involves service providers, service users or facilities, the purpose of which is to ensure the provision of high quality, effective and efficient care. It incorporates the development and evaluation of practice and services and mostly relies on the use of data contained in current hospital information systems e.g. patient notes, databases, surveys. It may involve collecting new data.

Service review in the health service can enhance the local knowledge base and improve the quality of local decision-making by critically evaluating service delivery using a number of quality improvement tools.

Service Review incorporates both **service/practice development** and **service/practice evaluation**.

6.12 What is the difference between service/practice evaluation and evaluation research?

There is considerable debate as to whether evaluation of initiatives in health care is a separate activity from research or a particular kind of applied research. The Toolkit takes the position that some evaluation activities in health care settings constitute research whereas others fall outside the remit of research and are referred to as service/practice evaluation. Evaluation research and service evaluation both require a well thought out design and the collection, analysis and interpretation of data; it can therefore be very difficult to differentiate between these activities. In terms of the Toolkit, it is suggested that the two activities may differ in terms of purpose and outcome. ***Evaluation research*** involves the use of systematic rigorous methods with the aim to describe and explain the effects of a new innovation in service delivery and to make generalisations about its worth. As with other forms of research the intention is to generate new knowledge that has applicability beyond the setting in which the evaluation is undertaken. ***Service evaluation*** also uses systemic rigorous methods to describe and investigate the efficiency of an established service or clinical intervention with the purpose of generating information that is of local significance. The aim of service evaluation is to generate information that can be used to inform local decision-making.

6.12a Why are both words service and practice used in conjunction with development and evaluation?

The reason both terms are included is as follows:

- Different professional groups are familiar with different terms
- Interchangeable terms
- Important to highlight practice development as a support service within the Trust

6.13 What is the difference between service/practice development and action research?

Action research and service/practice development have in common a concern with developing practice through the implementation of change. Both may use similar systematic processes and methods and it can therefore be difficult to differentiate between these two activities. In terms of the Toolkit, it is suggested that the two activities may differ in terms of purpose and outcome. In facilitating change, action research seeks to develop knowledge about the change process and outcomes of the change introduced which may have wider application beyond the particular setting where the research took place (Hart and Bond 1996). Thus, an important outcome of action research is the contribution to new knowledge. The purpose of practice/service development is to implement change at local level rather than generate knowledge that has wider applicability. Practice development is generally context specific and so it cannot be assumed that practice development initiatives are directly transferable to other

settings. Rather, it is important to consider the context into which a successful practice development initiative is being implemented in a new setting.

6.14 Why would I need to use the 'New Techniques and Treatments Policy'?

The purpose of this policy is to guide you through the clinical and financial governance considerations you will need to take into account prior to a new service development (remember this should involve an element of service evaluation). You can access the New Techniques and Treatments Policy at: http://sthnet/STHcontDocs/STH_Pol/IntroOfNewTechniquesAndTreatments.doc

6.15 Why is the word transferable used in the Toolkit definition of research?

The DoH definition of research uses the words 'new knowledge that is generalisable'. The term generalisable describes the ability to infer findings to the population from which the research subjects were randomised i.e. if another sample were randomly selected from the population the findings would be the same. (see glossary) This term is used when an experimental design has been implemented. In health care research within the NHS there are many other research designs that would provide valuable findings about processes, interventions, attitudes involving patients, carers, staff or technologies. The term used to describe how the findings from these types of research are used is transferable (see glossary). We have therefore developed the DoH definition in order to encompass all forms of health care research.

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Appendix A: REGISTRATION PROCESS

Clinical Audit

Steps to register a clinical audit project on the STHFT database.

Step 1:
Complete the Clinical Audit Project Registration Form (click here or go to http://sthweb/CAE_nhs/)

Step 2:
The Form must be signed off by the senior clinician leading on the project.

It is fully appreciated that another member of staff may have filled out the form and may well be doing the vast majority of the audit work.

For advice on who would be an appropriate senior member of staff, please ask your Directorate Clinical Audit Lead or contact a member of the Clinical Audit & Effectiveness Unit staff (CAEU).

However, by having one of the signatories as a senior member of staff should reduce the risk of audits being inadvertently abandoned and/or recommendations not being implemented e.g. this could happen when a non-permanent member of staff has done the majority of the audit work but moves on.

Step 3:
Once verified as clinical audit, the relevant CAEU member of staff who looks after that particular directorate/speciality area will also sign the form.

Step 4:
Once we have the correct signatures, only then can it be entered onto the database. This ensures that all projects entered onto the database, whether they are supported or unsupported by the CAEU, are clinical audit. At this point the project can commence.

Research

Please follow the research governance pathway established and administered by the Research Office. This will ensure appropriate authorisation is achieved.
http://www.sth-research.group.shef.ac.uk/

Service Review (Development/Evaluation)

Registration for 'service review' projects is not mandatory. However, as best practice, we would strongly recommend that staff should use the existing STHFT databases to register their projects. Projects can be voluntarily registered on the Practice Development Database (http://sthweb/PracDev_nhs/Projects.htm) or the service review section of the STHFT Clinical Audit Database. Please note, in addition some Directorates may have their own registration processes/databases.

However, the CAEU will always register service evaluation work (a specific form of service review) on the STHFT Clinical Audit Database if the CAEU Service Evaluation Manager is formally supporting the work.

Appendix B: Where to go for help

The Trust Departments individuals can go to for advice and support to do the work, gain an ethical opinion where necessary, register their work where applicable and if appropriate be referred to specialist staff working within STHFT but outside these Trust Departments.
The level of advice and support will be subject to pre-existing workloads.

	Clinical Audit Support	Research Support	Service Review Support
Clinical Audit and Effectiveness Unit *(Supports all professional groups)*	In relation to any clinical audit work, staff within the Clinical Audit and Effectiveness Unit will offer advice and may be able to offer support ***Main Office(s)*** *Ext 15115/13477*		Please contact Clinical Audit and Effectiveness Unit to establish the range of work supported ***Main Office(s)*** *Ext 15115/13477*
Research Department *(Supports all professional groups)*		In relation to any research work, staff in the Research Department will offer advice and may be able to offer support ***Main Office*** *Ext 13740*	
Service Improvement Team *(Supports all professional groups)*			Please contact the Service Improvement Team to establish the range of work supported ***Main Office*** *Ext 66051*
Centre for Professional and Practice Development *(Supports nursing, midwifery and allied health professionals)*			Please contact the Centre for Professional and Practice Development to establish the range of work supported ***Main Office*** *Ext 15334*
Patient Partnership Department *(Supports all professional groups)*			Please contact the Patient Partnership Department to establish the range of work supported ***Main Office*** *Ext 13463*
Clinical Risk Management Office *(Supports all professional groups)*			Please contact the Clinical Risk Management Office to establish the range of work supported ***Main Office*** *Ext 15488*

Appendix C: STHFT STAFF INVOLVED IN TOOLKIT DEVELOPMENT

- **Membership of the Core Toolkit Development Group**
  Janet Brain, Clinical Audit & Effectiveness Manager
  Samantha Debbage, Practice Development Manager
  Kate Gerrish, Academic Research Lead, Central Nursing
  Sue Mawson, Academic Research Lead, Professional Services
  Jean Schofield, Clinical Audit Development Manager
  Andre Somers (Chair), Clinical Effectiveness Development Manager

  And subsequent members being:
  Philippa Collins, Research Manager
  Irene Mabbott, Practice Development Co-ordinator (Evidence Based Practice)

- **Membership of the initial CAEU working group**
  Charlie Gilbert, Clinical Audit & Effectiveness Facilitator
  Paul Griffiths, Interface Project Co-ordinator
  Meline Hayward-Lovett, Clinical Audit & Effectiveness Facilitator
  Andre Somers, Clinical Effectiveness Development Manager

- **Membership of Toolkit Working Parties**
  Core Toolkit Development Group as above
  Initial CAEU working group as above
  Steve Baker, Director of Prescribing
  Beverly Bond, Information Co-ordinator (CAEU)
  Sue Cross, Clinical Audit & Effectiveness Facilitator
  Rosalie Havik, Education Advisor (CAEU)
  Vicky Patel, Education Advisor (CAEU)
  Janet Turner, Service Evaluation Manager
  Enid Wadsworth, Clinical Audit & Effectiveness Facilitator
  Brenda Zinober, Senior Research Manager

- **Trustwide Consultees**
  Richard Eastell, Former R&D Director
  Chris Welsh, Medical Director
  Angela Tod, Research Fellow

- **Workshop Consultation**
  Andrew Ash (Cytology), Biomedical Scientist
  David Barber (Medical Physics),Clinical Scientist
  Kevin Channer (Cardiology), Consultant
  Colleen Cherry (Occupational Therapy), Deputy Clinical Lead
  Alison Clarke (Physiotherapy), Senior 1 Physiotherapist (Neuromedicine)
  Annie Cooper (Metabolic Bone), Consultant
  Rachel Cottam (Radiology), Radiographer
  Ben Dorward (Pharmacy), Neurosciences Pharmacist
  Allison Edis (Medicine), Matron, Dermatology/Rheumatology
  Liz Elfleet (Radiology), Senior Radiographer I
  Alison Ford (Histology), Biomedical Scientist
  Julie Foster (Obstetrics and Gynaecology), Research & Audit Nurse
  Robin Freeman (Anaesthetics), Consultant

Dermot Gleeson (Gastroentology), Consultant
David Levy (Oncology), Consultant
Alan Lobo (Gastroenterology), Consultant
Helen Marsden (Physiotherapy), Senior Physiotherapist
Sue Mason (Accident & Emergency), Consultant
Jonathan Michaels (Vascular Surgery), Consultant
Steve Morley (Clinical Chemistry), Consultant
Alan Murray (Immunology), Operations Manager
Angela Nicholls (Orthopaedics), Deputy Directorate Manager
Sandra Orr (Restorative Dentistry), Consultant
Helen Parry (Medical Physics), Research Nurse
Dina Patel (Immunology), Biomedical Scientist
Jeanette Roberts (Orthopaedics), Sister
Chris Rudd (Dietetics), Dietetic Lead Clinician
Ann Sheppard (Operating Services), Research and CG Lead
Elizabeth Smith (Radiology), Radiographer
Karen Sneddon (Urology), Clinical Educator
Chris Stubbs (Renal), Matron
Graeme Wild (Immunology), Clinical Scientist
Mark Yardley (ENT), Consultant

- Acknowledgements

Nicky Faulkner, Office Manager (CAEU)
Laura Palmer, Office Manager (CAEU)
Hannah Treasure, Administration Support Officer (CAEU)

- Acknowledgements/External Consultees

Dr Robert Dixon, Manager, Sheffield Health and Social Research Consortium
Amanda Hunn, OREC Manager Yorkshire & The Humber

- Approval by Trust Management Groups

Toolkit Development Group
Clinical Governance Group

Appendix D: STHFT SIGN OFF LETTER FOR SERVICE REVIEW WORK

To whomever this may concern

This letter will help STHFT staff provide evidence to prospective publishers or any other relevant parties that the stated project has been classified as service review and that ethical review has been achieved.

Title of project: _____

Signature of project lead clinician: _____

Date: _____ / _____ / _____

Part 1: Evidence this project has been signed off as service review

Please complete the table below.

	Please tick one box	Please print name, sign and date
1a. Self declared by project lead clinician as service review		
1b. Signed off by the Research Department		
1c. Signed off by the CAEU		
1d. Signed off by the Practice Development Team		

Where the sign off is 1b to 1d, if the project materially changes from the original project description represented to the above signatory, it is the responsibility of the project lead clinician to re-present the project for further consideration. This includes self review in the case of 1a above. Any failure to do this is the responsibility of the lead clinician.

Part 2: Evidence that ethical review has been achieved for this project

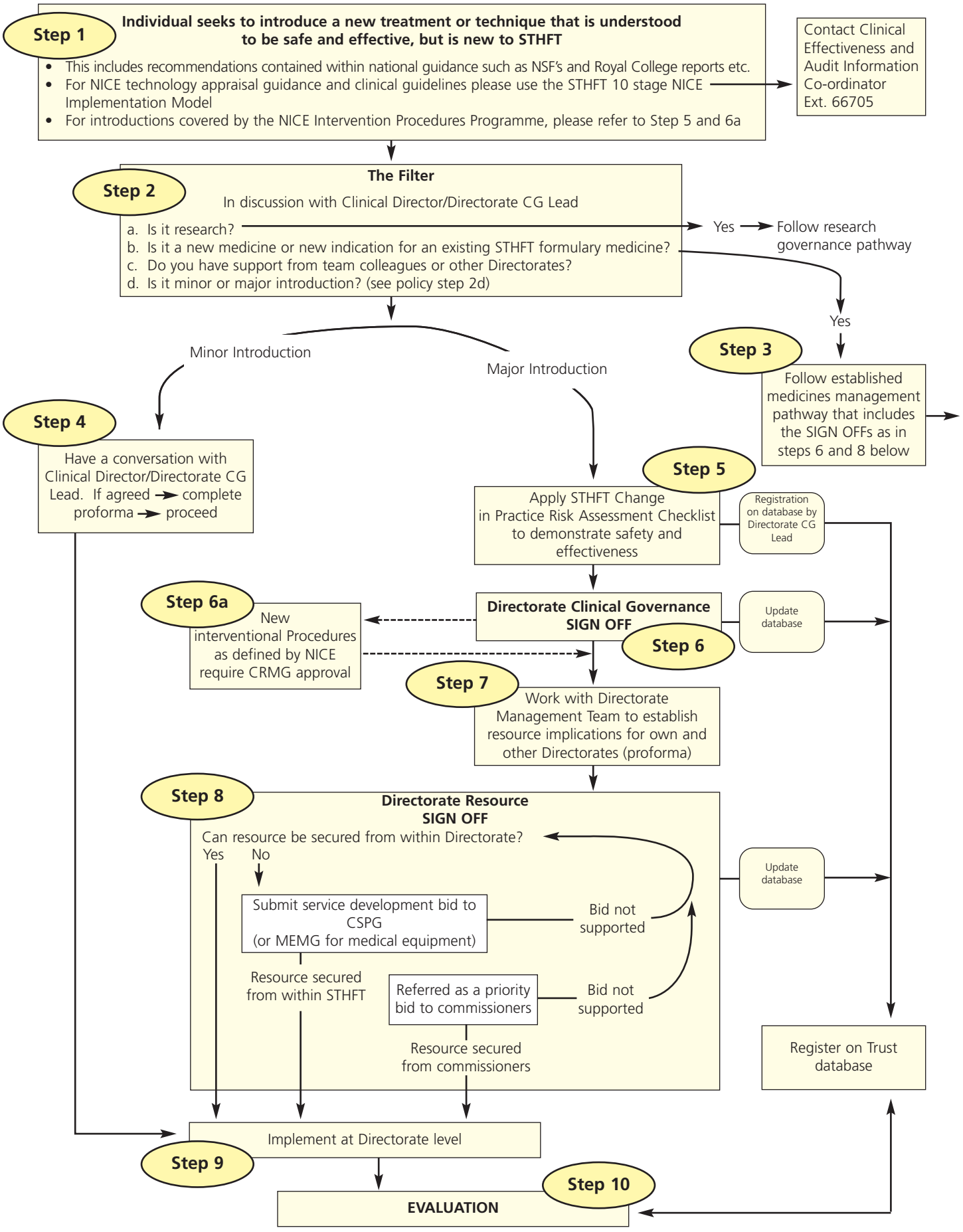
Please complete the table below.

	Please tick box	Please sign and print name
Level 1 assurance - lead clinician/ project stakeholder group		
Level 2 assurance – local governance review		Signatory could be Chair of relevant directorate peer review group or the Clinical Governance Lead or the Clinical Director.
Level 3 assurance – STHFT Clinical Ethics Group		Signatory would be Chair of STHFT Clinical Ethics Group or their Deputy

For any of the above sign offs, if the project materially changes from the original project description represented to the above signatory, it is the responsibility of the lead clinician to re-present the project for further consideration. Any failure to this is the responsibility of the lead clinician.

Appendix E: FLOW DIAGRAM PROVIDING AN OVERVIEW OF THE STHFT INTRODUCTION OF NEW TREATMENTS AND TECHNIQUES POLICY

Overview of the model for introducing new treatments and procedures



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