

Livewell Southwest

**Sponsorship and Working with Industry
Policy**

Version No 3
Review: January 2018

Notice to staff using a paper copy of this guidance

The policies and procedures page of LSW Intranet holds the most recent version of this document and staff must ensure that they are using the most recent guidance.

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Chief Pharmacist**

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Reader Information

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References/Source	<ol style="list-style-type: none"> 1. The New NHS: Modern and Dependable (DoH December 1977) 2. Medicines and Healthcare Regulatory Authority (MHRA): The Blue Guide – Advertising and Promotion of Medicines in the UK, 3rd edition 1st revision September 2014 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376398/Blue_Guide.pdf 3. Devon Partnership NHS Trust: Commercial sponsorship and joint working with the pharmaceutical industry and other relevant commercial organisations v 1.1 April 2010 4. Best practice guidance for joint working between the NHS and the pharmaceutical industry DH 1 February 2008

	5. Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry; Department of Health /Association of British Pharmaceutical Industries (ABPI); 27 August 2010
Associated Documentation	LSW Policy. Acceptance of Gifts/Hospitality Policy (incorporating Declarations of Interest).
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Document review history

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v1:0				New document
v1:1	Updated for publication	10/01/06 to 18/01/06	Paul Manson / Stuart Edmunds	Prepared for publication on web
v1.2	Updated	10/01/08 to 10/01/09	Karen Northcott / Paul Manson	Minor revisions following review
v1.3	Updated	January 2009	Karen Northcott	Minor revisions following review. Changes to comply with new format
v1.4	Updated	January 2011	Karen Northcott	Minor amendments only
V2	Updated	August 2012	Professional Lead LSW	LSW V1.4 adapted to include LSW logo and organizational name change
V2.1	Formal Review	June 2014	Professional Lead	Minor amendments
V2.2 V2.3	Review	August 2015	Chief Pharmacist	Re-format, formulary update and removal of clinical cabinet. Check and amend in line with the "Blue Guide"
V 3.0	Approved	October 2015	Chief Pharmacist	Payments for consultancies and speakers added to sponsorship rules

Contents		Page
1	Introduction	5
2	Purpose	5
3	Duties	5
4	Definitions	7
5	Principles	7
6	Sponsorship less than £500	11
7	Major Sponsorship (greater than £500) or Joint Working	11
8	Monitoring Compliance and Effectiveness	12
Appendix A	Sponsorship Checklist and Approval Form (£25-£500)	14
Appendix B	Major Sponsorship / Partnership Working Agreement (>£500)	15

Sponsorship and Working with Industry Policy

1 Introduction

- 1.1 Commercial Sponsorship from the Pharmaceutical Industry (and others) can provide an additional source of funding for organisations working on behalf of the NHS. There must be appropriate checks and controls in place to ensure that such sponsorship is appropriate.
- 1.2 The Department of Health issued guidance relating to joint working between the NHS and pharmaceutical industry in March 2008 and this policy reflects this guidance.

2 Purpose

- 2.1 This policy sets out the principles and standards which should be applied when Livewell Southwest (LSW) and its employees / officers engage with the Pharmaceutical Industry (and others) around sponsorship. These same principles and standards should apply equally to sponsorship by other profit making organisations and also non-profit-making or charitable organisations.
- 2.2 This Policy covers any sponsorship or joint working where LSW is a major participant (including health community sponsored projects) and sponsored projects where there has been specific LSW approval and endorsement.
- 2.3 This policy will give an opportunity for the organisation to monitor this and ensuring sponsorship is appropriate.

3 Duties

- 3.1 The LSW standard contract of employment includes the following clause:

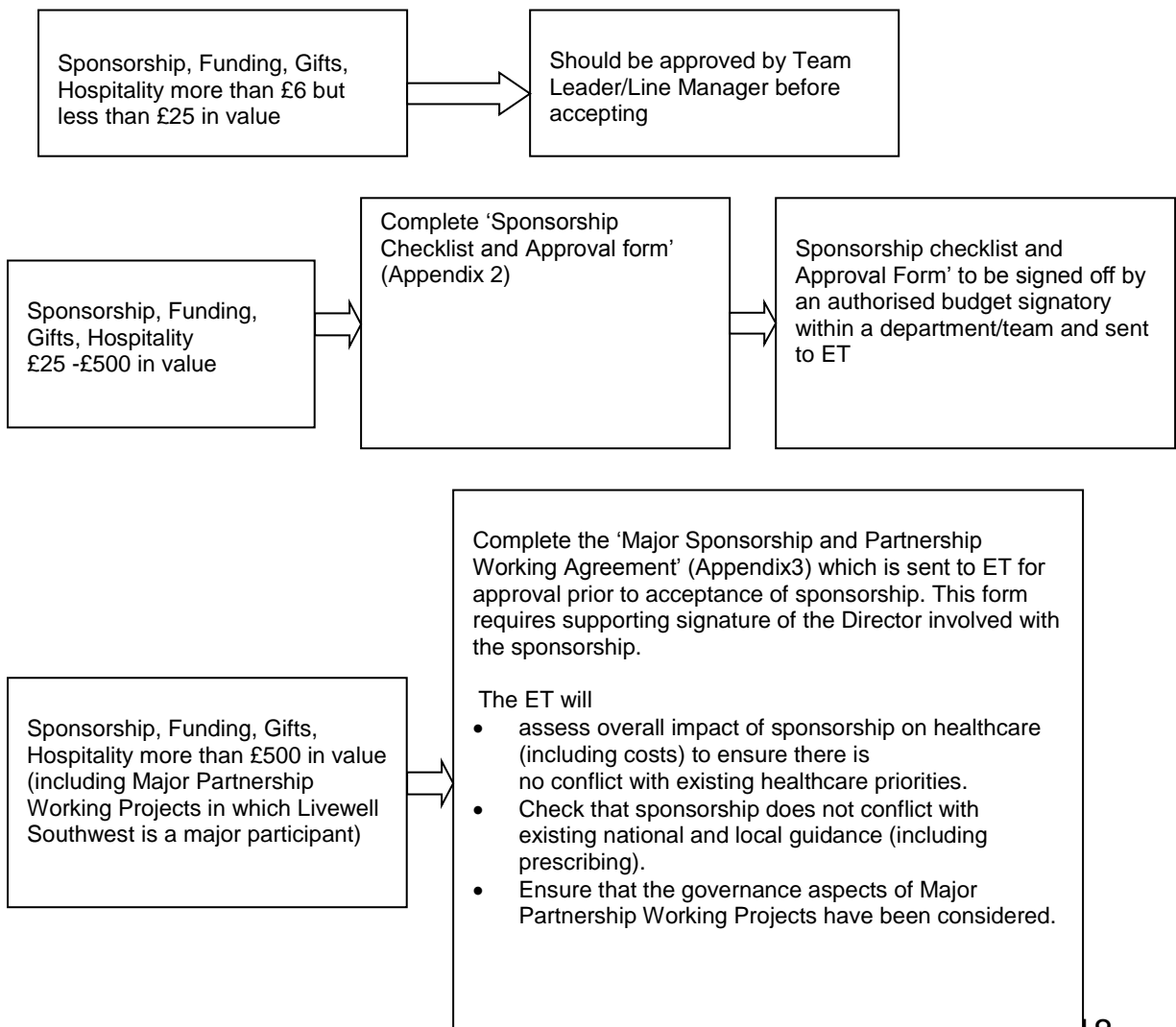
19. ACCEPTANCE OF GIFTS OR HOSPITALITY

The conduct of staff must be scrupulously impartial and honest. The Bribery Act 2010 prohibits staff from soliciting or receiving any gift of any kind from contractors or their agents, or from any organisation, firms or individual with whom they are in contact by reason of their official duties. Trivial articles issued for advertisement are not subject to this rule. You must ensure that you understand and follow the guidance provided in Induction for staff. These are the NHS ME short guide for staff and LSW's explanatory notes for staff. It is a requirement of your appointment that your registration of interests is kept up to date and you must see that any new interests that arise are properly recorded and brought to the attention of your manager. Further guidance is available from your Manager or the Workforce Development Department where appropriate.

- 3.2 All LSW employees are also responsible for ensuring that any sponsorship offered is assessed and approved as laid down in the algorithm below and that the guidance in this policy is followed.

- 3.3 It is the Line Managers responsibility to approve any sponsorship between £6 and £25 (ex VAT) offered to any staff they manage.
- 3.4 Where sponsorship is between £25 and £500, it is the responsibility of the authorised budget signatory to sign off the sponsorship checklist and approval form.
- 3.5 Where sponsorship is greater than £500, the director involved will be required to sign to the 'Major Sponsorship / Partnership Working Agreement Form' to indicate support.
- 3.6 The ET are responsible for ensuring that 'Major Sponsorship / Partnership Working Agreement Forms' are assessed and a response is provided to the LSW Lead in a timely manner.
- 3.7 The LSW Lead involved in any Major Sponsorship / Partnership Working Agreement will be required to provide feedback on outcomes.
- 3.8 The ET will audit outcomes and where appropriate feedback summary information to the board.

Overview of responsibilities:



4 Definitions

- 4.1 Commercial Sponsorship' is defined as including, "Funding for the benefit of NHS patients or for organisations providing NHS services from an external source, including funding of all or part of the cost of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs, provision of free services (including printing costs) and buildings or premises.

Abbreviations:

ABPI - Association of the British Pharmaceutical Industry.

DH – Department of Health.

IT – Information Technology.

LDP – Local Delivery Plan.

MHRA – Medicines and Healthcare Regulatory Authority

NHS – National Health Service.

NICE – National Institute of Health and Clinical Excellence.

LSW – Livewell Southwest.

QIPP – Quality, Innovation, Productivity and Prevention.

SWDF - South West Devon Formulary

5 Principles

- 5.1 The MHRA Blue Guide – Advertising and Promotion of Medicines in the UK, 3rd edition 1st revision September 2014, should be followed at all times.

- 5.2 Gifts, Inducements and other benefits:

The Blue Guide provides that "a person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer or promise to such persons any gift, pecuniary advantage or benefit unless it is- (a) inexpensive; and (b) relevant to the practice of medicine or pharmacy".

a) Inexpensive items are considered to be those which do not cost a company more than £6 (excluding VAT) and represent a similar value to the recipient.

b) The criterion of "relevance" is only met by items which have a clear business use and may include such items as pens, notepads, calculators, computer accessories, diaries, calendars, surgical gloves, tissues and coffee mugs.

A similar approach applies to membership schemes and cumulative points schemes which have the effect of conferring benefits in the form of free or reduced price goods or services. The goods or services must comply with the criteria for relevance and be “inexpensive”.

5.3 Professional samples

Regulation 298 applies to the supply of a free sample of a licensed medicinal product to a person who receives it for the purpose of acquiring experience in dealing with the product. Such a sample may only be supplied to a person qualified to prescribe medicinal products, and on the following conditions:

- (i) they shall be supplied on an exceptional basis only;
- (ii) a limited number only of samples of each product may be supplied in any one year to any one recipient;
- (iii) they should be supplied only in response to a written request, signed and dated, from the recipient (this may be an electronic signature);
- (iv) suppliers shall maintain an adequate system of control and accountability;
- (v) they shall be no larger than the smallest presentation available for sale in the UK;
- (vi) they must be appropriately labelled in line with the requirements of Article 54 of Directive 2001/83/EC and be marked "free medical sample – not for resale" (or similar); and,
- (vii) every sample shall be accompanied by a copy of the SPC.

Samples cannot be supplied under this regulation to persons qualified only to supply medicines.

The supply of samples of medicines containing controlled drugs in schedules 1, 2, 3 or 4 of the Misuse of Drugs Act 1971 (Controlled Drugs) is prohibited within LSW.

Guidance on the interpretation of ‘limited’ in the context of regulation 298 is given in self-regulatory codes of practice. See chapter 10 of the Blue Guide for details.

Department of Health policy is that there is no role for short-term supplies provided by pharmaceutical companies on request to medical practitioners for use in emergency situations, e.g. out-of-hours and in the patient's home (so called "starter packs")³. The MHRA considers these free “starter packs” to be samples for promotional or advertising purposes under the Regulations. Consequently they are required to comply with the requirements above for professional samples.

5.4 Medical sales representatives

Medical sales representatives should adequately trained and, during each visit, give to all persons whom they visit, or have available for them at the time of the visit, the current SPC for each product which they promote at that visit. This is to enable the healthcare professional to check any statements made against the licensed product particulars covering the use of product. The SPC can be provided electronically.

Representatives must also report all information relating to the safety of a product which they receive from healthcare professionals directly to scientific services set up by the licence holder under the Regulations.

- 5.5 Any commercial sponsorship or hospitality received to the value of £25 or greater and anywhere appropriate potential conflicts of interest should be recorded in the LSW 'Register of Interests Document'.
- 5.6 In any dealings with the Pharmaceutical Industry, LSW and patient confidentiality should be respected and protected at all times in line with the LSW policy on confidentiality and data protection.
- 5.7 In any dealings with the Pharmaceutical Industry, clinical decisions should be made in the best interests of patients.
- 5.8 No agreements are permissible which lead to higher costs unless this is associated with an improvement in quality in line with national and local priorities.
- 5.9 Only projects which lead to gain for the LSW on behalf of the NHS overall will be acceptable. No agreements are permissible which reduce the quality of service in other parts of the NHS.
- 5.10 No agreement will be entered into with any sponsor whose products are prejudicial to health or conflict with the principles and objectives of the LSW.
- 5.11 No agreement will be entered into with any organisation whose business or function is ethically unacceptable to the organisation.
- 5.12 All LSW employees who are involved in receiving offers of sponsorship, funding or gifts from outside agencies should comply with their own professional codes of practice (where applicable).
- 5.13 All offers of sponsorship, funding or gifts from pharmaceutical companies must comply with the ABPI Code of Practice.
- 5.14 Where commercial sponsorship is used to fund LSW training events or other training for LSW staff, the promotion or inclusion of medicines and products not included in SWDF is not to be permitted. Formulary products can only be mentioned in the same context as they are included in the SWDF e.g. 1st line, 2nd line etc. Training events, which rely heavily on the use of sponsored materials, should be discouraged unless they promote good practice agreed to by the Organisation.
- 5.15 Where commercial sponsorship is used to fund LSW sponsored guidelines, training or educational materials for staff or patients, commercial products may not be specifically mentioned other than as detailed in Devon SWDF. This includes written materials, recorded materials and information made available to LSW staff and patients for use on a computer or through the Internet. A small acknowledgement to the sponsor is allowed but company logos are not permitted.

- 5.16 Where an offer of sponsorship involves a period of evaluation by the LSW before formally entering into a sponsorship / partnership working arrangement e.g. to allow testing of software, there is no need to complete sponsorship / partnership working forms until the proposed sponsorship or offer of resources is judged to be worthy of further consideration.
- 5.17 Where a sponsored project leads to the development of guidelines or advice, this will be carried out by the appropriate LSW working group independent of the sponsors. While it is recognised that consultation with the industry may be necessary when developing a guideline, the overall decision on what is included should lie with the Organisation.
- 5.18 LSW employees may accept offers of hospitality to attend external professional meetings or events from commercial companies so long as the following criteria are met:
- The level of hospitality is, within reason, appropriate to the event e.g. a working lunch or dinner at the same venue as the event; or travel costs and / or standard accommodation to attend a reputable conference in the UK.
 - The meeting has direct relevance to the professional role of the employee.
 - That line manager approval is obtained for hospitality of value equivalent to £5 - £25.
 - That line manager and director approval is obtained for value equivalent to greater than £25, using Appendix A to assess the request. Exceptions to Q. 2 are possible (see below).
 - That such hospitality must not exceed £500 equivalent value. For hospitality of £100 or greater in value it is recommended that the cost is shared by more than one sponsor for reasons of probity.
 - That such meetings or events can include information on medicines or products not included in the SWDF but only in the context of an overall impartial review of a medical condition and / or its treatment.
 - That all such hospitality is recorded in the Register of Interests.
- 5.19 LSW encourages all mothers to use breastfeeding as the first choice method of feeding infants wherever possible. All education materials provided to mothers should be in line with this guidance, should not promote specific infant formulae and should comply with existing legal restrictions and other codes of practice.
- 5.20 Individuals and organisations within LSW should ensure that contact with the Pharmaceutical Industry is appropriate and proportionate given the nature and scale of the proposal.
- 5.21 No preferential access to the Organisation is to be given to any commercial company unless this is necessary as part of a specific LSW approved project.
- 5.22 LSW staff who in the course of their work regularly meet with industry representatives should have a structured approach for meeting with Industry. An example which is used by the LSW Medicines Management Team is attached at Appendix A.

6 Sponsorship (less than £500) for Events, Meetings, Training, Education Materials, Consultancies, External Speaker payments, Patient Leaflets, Staff Costs and Equipment

- 6.1 The following rules apply to all employees and officers including part-time and seconded staff that have a role in the Organisation.
- 6.2 If an employee is involved in attending wider meetings (e.g. health community wide commissioning groups) on behalf of the LSW, they should comply with the rules and principles of this policy.
- 6.3 Offers of gifts / hospitality / sponsorship in any form to the Organisation or its staff of less than £25 (but more than £5) should be approved by a line manager or department head before accepting.
- 6.4 Offers of sponsorship greater than £25 but less than £500 should be assessed by completing a 'Sponsorship Checklist and Approval Form' (Appendix B). If all answers to the questions are 'Yes', the sponsorship can be approved by an authorised budget signatory within a department/ team who signs at the bottom of the form. The completed form should be sent to the ET, Appendix A).

7 Major Sponsorship (Greater Than £500) and Partnership Working Agreements

- 7.1 Where sponsorship exceeds £500 and/or the sponsorship is part of a major 'Partnership Working' arrangement, a 'Major Sponsorship/Partnership Working Agreement Form' (Appendix C) should be completed by the Professional and signed by the supporting Locality Manager. This must be submitted to the ET for approval before the project proceeds. This will allow a full evaluation of the sponsorship agreement including the governance issues of the project and also for the overall impact of project to be assessed in relation to healthcare priorities.
- 7.2 The ET will evaluate and approve or reject major sponsorship and inform the Professional accordingly. Where the ET considers that a particular sponsorship may not fit in with national or locally agreed health priorities and guidelines (including prescribing), the group will seek advice from the Clinical Commissioning Group (CCG) before making a final decision.
- 7.3 The ET will ensure that the Department of Health document 'Best Practice Guidance on Joint Working between the NHS and Pharmaceutical Industry and Other Relevant Commercial Organisations' is followed as closely as possible.
- 7.4 The written agreement must clearly specify the benefits to the NHS, the Organisation or practice, arising from any sponsorship agreement. The benefits to the sponsor must also be explicit.
- 7.5 Although sponsors may be consulted in relation to the clinical aspects of sponsored projects, the final decisions and overall control lies with the Organisation.

- 7.6 Projects, which involve the use of clinical guidelines or protocols prepared by sponsors, should only be used if agreed by the appropriate service group(s).
- 7.7 Projects which involve the exchange of patient information should seek the advice of the Caldicott Guardian.
- 7.8 All staff involved in the development of a sponsorship agreement must declare any prior interest in terms of previous sponsorship or relationship to any of the individual sponsors in question.
- 7.9 Sponsors should not advertise the participation of LSW in their project or use the information gleaned from the project as an endorsement of their product, packages or company without specific written permission of the Organisation. The Organisation should agree the nature of any endorsement or linked publication.
- 7.10 All agreements must include a 'break' clause enabling the termination of the agreement at reasonable notice given the nature of the agreement.
- 7.11 Sponsors should be informed that any sponsorship arrangement would have no effect on purchasing or commissioning decisions within LSW, other than any effect overtly stated in the agreement.
- 7.12 Sponsorship agreements which involve several sponsors are to be preferred to those which involve a single sponsor.
- 7.13 Payment arrangements should be separately accounted for within the organisations accounts.
- 7.14 All sponsors should be provided with copies of this policy document before draft arrangements are agreed.
- 7.15 Where an employee of LSW is working on a multi-agency project for which the organisation is a major participant, they will be guided by this policy. If any sponsorship for the project appears to be in conflict with the policy, the advice of the ET should be sought.
- 7.16 The ET may attach specific conditions to the approval of major sponsorships. It is the responsibility of the LSW Lead contact involved in the sponsorship to ensure that these conditions are followed. Occasionally the ET may require specific feedback regarding the process of sponsored projects and events.

8 Monitoring Compliance and Effectiveness

The ET will monitor the following:

- Assess adherence to this policy across the Organisation
- Discuss and review the outcomes of all major sponsorship projects
- Review and update the policy accordingly

Approval by Medicines Governance Group (MGG)

Chief Pharmacist (Chair of MGG)

Name: Steve Cooke

Signature:...

Date: 25/11/15

Final Approval by Livewell Southwest

Director of Professional Practice, Safety and Quality

Name: Geoff Baines

Signature.....

Date: 29/12/2015

Appendix A – Sponsorship / payment Checklist and Approval Form (£25- £500)

Instructions for Completion:

This form should be completed for sponsorship between £25 and £500 in value.

- Provided all answers to the questions are 'yes', the sponsorship / payment can be approved by a Locality Manager/ Medical Director to sign off the form. This form should then be sent to the ET for information.

For all sponsorship / payment greater than £500, a more detailed 'Major Sponsorship / Partnership Working Agreement Form' (Appendix B) should be completed and sent to the ET for approval prior to accepting sponsorship.

Summary of Sponsorship offer

Name and Contact Details of LSW lead person liaising with commercial company:	
Name of potential sponsors involved and contact details:	
Details of proposal including benefits to the organisation, patients and potential benefits to the sponsor. What is the money to be spent on?	
Amount of funding and time period involved	

Checklist

Criteria	Yes / No
1. Does the sponsorship offer comply with the rules specified in the LSW policy on 'Working with Industry'?	
2. As part of sponsorship, are all medicines or products, which are promoted or otherwise mentioned in line with SWDF, or other locally agreed prescribing advice? (Including specific context e.g. 1 st line, 2 nd line etc).	
3. Where sponsorship is offered to facilitate the development of Guidelines and protocols etc. will this be carried out by the appropriate LSW working group independent of the sponsors?	
4. Is this sponsorship in line with nationally and locally agreed healthcare priorities?	

Locality manager to sign off where all answers to checklist are 'yes'.

Signature of authorised budget signatory within a department/ team:

..... Date / / 20...

Appendix B - Major Sponsorship / Partnership Working Agreement (> £500)

This form should be used for sponsorship of greater value than £500 including multi-agency projects for which the Organisation is a major participant and the LSW share of sponsorship is greater than £500. The completed form (all three pages) should be submitted to the ET for approval before accepting any sponsorship.

Project Summary:

1. Recipient (include LSW contact details)	
2. Sponsor(s) (including contact details)	
3. Details of Project	
4. Aims and objectives of Project	
5. Benefits to Organisation / NHS (e.g. improvement in services as defined by NICE, NSFs etc)	
6. Benefits to Sponsor	
7. Start Date	
8. Finish Date	
9. Termination arrangements (The agreement should be capable of early termination by the LSW).	

Resources and costs:

1. Overall cost of partnership project?	
2. What are the direct / indirect resource / cost commitments by sponsor(s)?	

3. What are the direct / indirect resource / cost commitments by LSW? (If any)	
4. How will the resources / costs be monitored and recorded? How will payment be made?	
5. Will sponsorship lead to higher costs elsewhere in the NHS?	
6. List valid and relevant information on cost – effectiveness / value for money	

Governance and management arrangements:

1. Who has been consulted in relation to project and how was this done?	
2. How will patients be informed of project?	
3. What is the decision making process of the project?	
4. What are the operational and management arrangements?	
5. How does the project relate to, and mesh with existing systems of care in the primary and secondary care?	
6. Has project been piloted or are there plans to do this? How would this be done?	
7. Has the project been compared with other proposals on offer? Please give details.	
8. Has the sponsor read the LSW	

policy document Sponsorship and Working with Industry' and agree to abide by the rules detailed in this document?	
9. Does the project include the use of protocols and guidelines? Who is responsible for producing these? Please include full details of guidelines.	

Data and patient protection:

1. Does the project involve the sharing of clinical data at patient and/ or Organisational level?	
2. Are there potential conflicts of interest in relation to access to this data? Please give details.	
3. What arrangements have been put in place to ensure patient confidentiality and patient consent are considered?	
4. Where projects include collection of data for research purposes, has this been approved by the Medical Ethics Committee?	
5. Who will have access to data and in what form?	
6. How will the data be used?	
7. For clinical services, what professional indemnity and liability arrangements will be in place?	

LSW lead contact signature:

Date:

LSW Locality Manager Signature:

Date:

Sponsor signature:

Date:

For ET use only

Reference Number:

Outcome: **Approved/Not Approved**

Comments: