NHS
West Lancashire
Clinical Commissioning Group

Commercial Sponsorship and Joint Working Policy

With you.
For you.

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Contents

1. Introduction

The changing nature of the NHS in response to Government policies and the ever-increasing demands by the public will create new opportunities for more joint working between the pharmaceutical companies and the NHS, to deliver better health outcomes for patients. This policy has been developed to ensure that all parties carefully consider any proposal for joint working.

The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of the patients, one or more pharmaceutical companies and the NHS pool skills, experience and or resources for the joint development and implementation of patient centered projects and share a commitment to successful delivery.

2. Scope

This policy provides a framework to assist the organisation and NHS staff in determining when a joint working agreement or commercial sponsorship is appropriate. Specifically, it aims to assist NHS staff maintain appropriate ethical standards in the conduct of NHS business.

The aim of this policy is to describe the approach of joint working and commercial sponsorship for West Lancashire Clinical Commissioning Group (CCG) in relation to potential pharmaceutical industry and other sponsoring organisations partners. It is designed to enable the CCG to create useful relationships with the pharmaceutical sector which:

- Benefit the local population by improving and maintaining the quality of healthcare provided;
- Develop education, training and service opportunities for local healthcare workers;
- Are transparent, open to public scrutiny and challenge and fulfil the highest standards of financial, professional and ethical probity.

Definitions
For the purpose of this policy, **commercial sponsorship** is defined as including NHS funding from an external source, including funding of all or part of the costs of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, and hospitality, hotel and transport costs (including trips abroad), provision of free services (speakers), buildings or premises.

Joint working is defined as situations where, for the benefit of the patients, organisations pool skills, experience and or resource for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner. Joint working is different to sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.

2.1 Consultation and Communication
The policy is a revision of a previous policy document published by Central Lancashire PCT, updated in accordance with further guidance issued by the Department of Health on the joint working between the NHS and commercial organisations (Department of Health, 2008)

2.2 Principles and Values underpinning joint working with the pharmaceutical Industry

The following values should underpin joint working and all parties involved are asked to confirm and adhere to these:

- Mutual trust, honesty and respect;
- Openness and transparency;
- Recognizing and valuing the contribution of all partners;
- Access and sharing of information pertaining to the project;
- Consensus, collaboration and inclusion as the “best way” in decision making;
- Acknowledgement of the interdependent relationship between the NHS and the pharmaceutical industry;
- Commitment to the framework

2.3 Principles for working with the Pharmaceutical Industry and other sponsoring organisations

- The CCG will use available resources to generate the greatest benefit for the population for West Lancashire through the promotion of high quality effective healthcare;
- The CCG recognises that the pharmaceutical industry and other sponsoring organisations have a role to play, alongside the NHS, in promoting and maintaining the health of the local population;
- The CCG wishes to work in partnership with the pharmaceutical industry and other sponsoring organisations on issues where there is a shared common aim and where the benefits of working together meet the guidelines for partnerships outlined;
- The CCG wishes to encourage the pharmaceutical industry and other sponsoring organisations to develop high quality effective liaison with the NHS that is aligned to the needs of NHS patients;
- Partnership activities will be directed towards collaborative action aimed at providing high quality effective healthcare throughout West Lancashire;
- All joint working between the pharmaceutical industry and the NHS must be for the benefit of patients;
- The interests of individual patients must be protected;
- Clinical aspects of care, including the development of guidelines and protocols, should be under local/national NHS control;
- All patient identifiers should be removed from any data shared with the pharmaceutical industry to respect and preserve patient confidentiality in line with the Data Protection Act;
- Reports or information pertaining to the project/agreement should not be used or published without explicit permission given by all partners entering the agreement;
- Joint working should not be seen as an endorsement or promotion of a specific medicine or technology;
- Joint working should not undermine or conflict with the ethical requirements of any healthcare professional, including the duty of the clinicians to provide whatever treatment they consider clinically appropriate;
- Pharmaceutical companies must comply with the ABPI Code of Practice for the Pharmaceutical Industry at all times;
- All NHS staff must comply with the NHS (and relevant professional bodies) codes of conduct at all times;

- If joint working involves research, then best research practice should be applied and consultation with the NHS Research Ethics Committee – Central Booking Service should be sought.

These principles reflect a move away from the traditional relationship between the NHS and the pharmaceutical industry, which relied predominantly on “good will” and product related sponsorship activity. In the future, relationships will be supportive of strategic education, training, professional and service developments.

2.3 Accountability

- A contract of responsibilities and expectations should be drawn up between the CCG and pharmaceutical company.
- The NHS parties should be accountable for any agreement and agreements should include arrangements for monitoring and evaluation.
- An assessment of the costs and benefits in relation to alternative options (where applicable) should be made to ensure that the decision-making process is transparent and defensible.
- Schemes should be agreed at a corporate rather than an individual level.
- Ensure joint working agreement has break clauses built in to enable the CCG to terminate the agreement if it becomes clear that it is not providing expected value for money or clinical outcomes.
- Advice should be sought from the Head of Medicines Optimisation to assess the benefits of the offer of sponsorship or joint working.

Joint working toolkit

The Department of Health and the Association of the British Pharmaceutical Industry have developed a joint working toolkit (May 2012) the purpose of the toolkit is to:

- Encourage NHS organisations and staff to consider joint working as a realistic option for the delivery of high quality healthcare.
- Provide the necessary information and have easy access to the tools which help to enter into joint working

The toolkit should be utilised when considering joint working arrangements with the pharmaceutical industry or other commercial organisations

Department of Health and the Association of British Pharmaceutical Industry joint working toolkit

2.4 Roles and responsibilities

Employers should:

- Make all staff aware of NHS guidance and relevant codes of conduct;
- Take responsibility for ensuring that codes are observed;
- Ensure that all sponsorship arrangements are documented;
- Make it a matter of policy that offers that could possibly breach the ABPI code of conduct are reported to the governing body ;
- Ensure that all staff declare and record, in line with Standing Financial Instructions, any financial interest in organisations which have implications for funding e.g. they hold contracts with the NHS, and;
- Review existing contracts and corporate governance policies to ensure that they meet the ethical standards required.

3. IMPLEMENTATION

3.1 Guidelines for Partnerships

The common aim of both organisations (CCG and pharmaceutical company) will be to promote high quality effective
healthcare for a specific priority area. The following criteria must be explicitly addressed in any proposals for partnership:

- How it benefits the health of the local population, especially in terms of quality of healthcare delivered and evidence based clinical practice;
- How it links to the CCG's priority objectives;
- How it links to local and national strategic priorities;
- How it links to the sponsoring companies corporate objectives.

3.2 Product and Company Names

Any proposal will need to state explicitly the quantity and/or nature of any advertising and promotion of individual products and pharmaceutical or other companies.

The CCG will not endorse or support proposals where there is excessive promotion of individual products, services or companies.

The CCG will evaluate proposals in terms of measurable improvement in the quality of care providing in line with evidence-based practice.

The CCG will actively encourage the pharmaceutical industry and other companies to reduce resources currently invested in goodwill activity and brand promotion and reinvest in appropriate partnership activity.

3.3 Publicity

Before the commencement of any proposal, the pharmaceutical company or other third party should undertake not to publicise its involvement with the CCG without the prior knowledge and agreement of the CCG.

3.4 Contact Policy

Individual Independent Contractors:

Individual independent contractors continue to be able to engage with the pharmaceutical industry and other sponsoring organisations. They should, however, ensure that this conforms to the standards expected by existing legislation, professional guidelines and takes account of clinical governance needs and patient confidentiality.

Where the activity involves a single practice or GP, and where this involves a co-ordinating educationally based activity for themselves or on behalf of a small group, the practice or GP can continue to make direct arrangements with the company involved.

The CCG encourages Independent Contractors to apply the core principles and guidelines outlined in this policy and the attached checklist (Appendix A).
The contact point for clarification is the Head of Medicines Optimisation.

When a company is targeting initiatives at local Independent Contractors, the
CCG should wish to be informed by contacting the Head of Medicines Optimisation prior to commencement of the arrangement.

CCG Staff:
Any pharmaceutical or other company should inform the CCG through the Head of Medicines Optimisation or appropriate service manager before contact is made with CCG staff. This will ensure that the most appropriate member of staff or contact can be identified and that staff time and resources are maximised rather than duplicated for both parties. Staff who are approached should redirect the approach to the appropriate service manager.

Verbal contact must be supported by written notification.

CCG wide initiatives:
Initiatives, which include

- Involving more than a single practice, GP or other healthcare professional;
- Proposals to support service developments;
- Involving the statutory post graduate educational infrastructure;
- The roll out of evidence based practice across the CCG;
- A research element;

should be taken through the process described below.

1. Written/phoned request for meeting should be directed initially to the Head of Medicines Optimisation.

2. Outline the proposed area for collaboration/partnership prepared in advance, preferably written with due consideration of the principles and guidelines contained in the policy.

3. The CCG Head of Medicines Optimisation or Director will direct the contact to the most appropriate individual for further action. It is envisaged that this will normally include the following lead representatives:

    - Chief Officer ;
    - Lead Clinicians for the specific priority area within the proposal;
    - Chief Finance Officer.

The process below should then be followed:

- Hold a face-to-face meeting regarding the proposal. A meeting summary will be produced for the benefit of the company and the CCG and a copy kept on file by the Chief Finance Officer ;
- The sponsoring company should produce a written proposal outlining the initiative in detail and submit this to the CCG;
- The written proposal, after discussion with relevant clinicians and managers including the Chief Finance Officer, should be sent to the CCG Executive Committee or its delegated committees for a decision. Prescribing related proposals should be copied to the Medicine Management Committee;
- If supported, the proposal will be taken forward by a nominated lead from the CCG.

This has been developed to ensure a single point of contact for the pharmaceutical industry and other sponsoring organisations and a robust and transparent decision-making system for the CCG.

The pharmaceutical industry and other sponsoring organisations are strongly discouraged

from cold-calling members of CCG staff, Executive Committee members, or CCG Governing Body Members to discuss promotional events.

4. CCG led initiatives

Where the CCG has identified projects that could be taken forward in collaboration with the pharmaceutical Industry or other sponsoring organisations, the appropriate senior manager or clinical lead should be informed. The system to develop a proposal and contact the pharmaceutical sector or other appropriate sponsor should be agreed and noted in writing between the individual proposer, the nominated lead and the Head of Medicines Optimisation. See appendix C sponsorship checklist and appendix D commercial sponsorship and joint working agreement.

The developed proposal must be taken to the CCG Executive Committee for final decision regarding implementation and management.

Approaches the CCG will consider for initiative development

- Funding or (rarely) personnel on short term secondment to develop policies to address specific issues;
- Funding to facilitate training and educational initiatives that are aimed at improving the management of a condition;
- Funding or (rarely) personnel on short term secondment to implement the delivery of agreed policies at practice level;
- Use of industry educational or management resources to augment existing CCG resources for specific projects.

Approaches the CCG will not support

- Nursing support for setting up clinics. An organised approach addressing the whole pathway of care would be more appropriate than pump priming.
- Company representatives seeing several members of the CCG or practice (with the associated opportunity costs) to deliver the same message;
- Activity where there is no explicit benefit other than that of promoting good will, a product or company;
- Sponsorship of practice based events other than those outlined above and in line with the guidelines contained in this policy;
- Initiatives that duplicate or conflict with existing practices;
- Any partnership specifically linked to the purchase of particular products or to supply from particular source, unless they result from a transparent tender for defined goods and services.

4.1 Direct Product Promotion

The CCG Head of Medicines Optimisation wishes to receive from the pharmaceutical industry and other sponsoring organisations, for information purposes, copies of any promotional mailings that are sent to GPs, Non-Medical Prescribers and Health Care Teams within West Lancashire CCG.

4.2 Sponsorship for Meetings and locally arranged education sessions

Representatives organising meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs that may have been incurred. For example, if the refreshments have been organised and paid for by a medical practice the cost may be reimbursed as long as it is reasonable in relation to what was provided and the refreshments themselves were appropriate for the occasion. Donations in lieu of hospitality are unacceptable as they are inducements for the purpose of holding a meeting. If hospitality is not required at a meeting there is no obligation or right to provide some benefit of an

equivalent value. Donations to charities in return for representatives gaining interviews are prohibited.

The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves or that which could be reciprocated by the NHS. It should not extend beyond those whose role makes it appropriate for them to attend the meeting.

Where meetings are sponsored by external companies, that fact must be disclosed in the papers relating to the meeting and in any published proceedings.

The provision of hospitality includes the payment of reasonable, actual travel costs, which a company may provide to sponsor a delegate to attend a meeting. The payment of travel expenses and the like for persons accompanying the delegate is not permitted. The payment of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, for speakers, is permissible. If the honoraria relates to a meeting attended in CCG work time then it should be made payable to the CCG.

Pharmaceutical companies may appropriately sponsor a wide range of meetings and locally arranged education sessions. These range from small lunchtime audio-visual presentations in a group practice, hospital meetings and meetings at postgraduate education centres, launch meetings for new products, management training courses, meetings of clinical trialists, patient support group meetings, satellite symposia through to large international meetings organised by independent bodies with sponsorship from pharmaceutical companies. See appendix E for sponsorship for meetings and locally arranged education sessions application form.

In summary, therefore, with any meeting, certain basic principles apply:

- The meeting must have a clear educational content;
- The hospitality associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion and:
- Any hospitality provided must not extend to a spouse or other such person unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant at the meeting in their own right;
- Spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany;
- Administrative staff may be invited to meetings where appropriate. For example, receptionists might be invited to a meeting in a general practice when the subject matter related to practice administration.

Meetings organised for groups of doctors, other health professionals and/or for administrative staff, which are wholly or mainly, of a social or sporting nature are unacceptable.

Meetings organised by pharmaceutical companies, which involve UK health professionals at venues outside the UK, are not necessarily unacceptable. There have, however, to be valid and cogent reasons for holding meetings at such venues. As with meetings held in the UK, in determining whether such a meeting is acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, hospitality provided and the like. As with any meeting it should be the programme that attracts delegates and not the associated hospitality or venue.

The provisions of all relevant clauses in the ABPI Code of Practice apply equally to meetings and courses organised or sponsored by pharmaceutical companies, which are continuing

professional development (CPD) approved. The fact that a meeting or course has CPD approval does not mean that the arrangements are automatically acceptable under the Code. The relevant provisions of the ABPI Code of Practice and, in particular, those relating to hospitality, must be observed.

4.3 Acceptance of Commercial Sponsorship for attendance at Conferences and Courses

Acceptance by West Lancashire CCG of commercial sponsorship for attendance at relevant conferences and courses is acceptable, but only where the employee seeks permission in advance and the CCG is satisfied that acceptance will not compromise purchasing decisions in any way. Fees should be paid by the CCG and reimbursed by the sponsors. Acceptance of commercial sponsorship for attendance at conferences and courses needs to be recorded in line with West Lancashire CCG's conflict of interest policy.

4.4 Provision of Information to Commercial Sponsors

Patient information attracts a legal duty of confidence and is treated as particularly sensitive under Data Protection legislation. Professional codes of conduct also include clear confidentiality requirements. It is extremely important therefore that NHS bodies assure themselves, taking advice when necessary, that sponsorship arrangements are both lawful and meet appropriate ethical standards. A principal component of such assurance will be compliance with the principles of the Caldicott report (summarised in Appendix B).

The Data Protection Act 1998 requires that each database should have a data controller responsible for the satisfactory administration of the data and its conformance with the DPA. The Chief Officer of the CCG and a partner of each GP practice are such named persons. Data controllers have a duty to ensure that legal and ethical restrictions on the disclosure of confidential patient information, or data derived from such information are complied with. Additionally, disclosure for research purposes should not take place without the approval of the appropriate research ethics committee.

Recent case law has suggested that disclosure of anonymised patient information does not constitute a breach of confidentiality. However, there is a breach of confidence if information is disclosed in any form by which the patient can be identified. West Lancashire CCG will not, therefore, under any circumstances, allow information to be given to commercial sponsors by the CCG's officers that will identify either individual patients, staff, contractors or premises without their informed consent.

Where a sponsorship arrangement permitting access to patient information appears to be legally and ethically sound (e.g. where the sponsor is to carry out or support NHS functions, where patients have explicitly consented), a contract should be drawn up which:

- Draws attention to obligations of confidentiality;
- Specifies security standards that should be applied;
- Limits use of the information to purposes specified in the contract; and
- Makes it clear that the contract will be terminated if the conditions are not met.

All information generated as a result of commercial sponsorship activity or research and subsequent publications shall remain the property and copyright of the CCG.

Disclosure of patient information to commercial healthcare organisations is generally a point of major concern with patients and it has not been established in any detail as to what forms of disclosure might be acceptable. Consistent with current standards of best practice, West Lancashire CCG would carefully vet any such exchanges at the highest level, and information

should only be shared where it is in the overall best interests of patients or the public at large.

4.5 Information – 'Commercial in Confidence'
Staff should be particularly careful of using, or making public, internal information of a 'commercial-in-confidence' nature, particularly if its disclosure would prejudice the principle of a purchasing system based on fair competition. This principle applies whether private competitors or other NHS providers are concerned, and whether or not disclosure is prompted by the expectation of personal gain.

However, the CCG should be careful about adopting a too restrictive view on this matter. It should certainly not be a cause of excessive secrecy on matters that are not strictly commercial per se. For example, the term 'commercial in confidence' should not be taken to include information about service delivery and activity levels, which should be publicly available. Nor should it inhibit the free exchange of data for medical audit purposes, for example, subject to the normal rules governing patient confidentiality and data protection. In all circumstances the overriding consideration must be the best interests of the patients.

4.6 Commercial Sponsorship of Posts – 'Linked Deals'
West Lancashire CCG should not enter into such agreements unless it has been made abundantly clear to the company involved that the sponsorship will have no effect on the purchasing decisions of the CCG. Where such sponsorship is accepted, the CCG will arrange for monitoring systems to be established to ensure that purchasing decisions are not being influenced by the sponsorship agreement.

The CCG should under no circumstances agree to 'linked deals' whereby sponsorship is linked to the purchase of particular products or to supply from particular sources.

4.7 Sponsored Travel
On occasions where West Lancashire CCG consider it necessary for staff advising on the purchase of equipment to inspect such equipment in operation in other parts of the country (or, exceptionally, overseas), the CCG should meet the cost, so as to avoid putting in jeopardy the integrity of future purchasing decisions.

4.8 Income from Sponsorship
Where the major incentive for the CCG in entering into a sponsorship arrangement is the generation of income rather than other benefits, then the scheme should be properly governed by income generation principles rather than sponsorship arrangements. Such schemes should be managed in accordance with income generation requirements, i.e. they must not interfere with the duties or obligations of the CCG. A memorandum trading account should be kept for all income generation schemes.

4.9 Monitoring Arrangements
In order to demonstrate openness and transparency the CCG will ensure that:

- All sponsorship is reported to the Clinical Executive Committee;
- All prescribing related projects will be reported to the Medicines Management Committee and to the Clinical Executive Committee through quarterly reports;
- Details of sponsored projects and research initiatives will be recorded in a clear and open manner in the CCG's Annual Report;
- All staff (employed by the CCG and associated with the CCG) should record any financial interest in organisations (e.g. company shares or research grant), which impact upon funding, whether through contracts, sales or other arrangements that they

may make with non-NHS organisations in the CCG's Register of Members and Staff's Interests. The Register is regularly reviewed by the Audit Committee who report to the CCG Governing Body. The register is reviewed quarterly by the Governing Body. ;

- All staff (employed by or associated with the CCG) involved in setting up and implementing joint projects must take note of and comply with the Codes of Conduct of the NHS and the relevant professional bodies such as the GMC and NMC.
- Any issues relating to implementation or further development of this policy should be directed to the Head of Medicines Optimisation.
- Offers that could possibly breach codes of conduct must be reported to the CCG Governing Body at the next available meeting.

4.10 Research and Development

Exceptionally, in the case of non-commercial research and development (R&D) originated or hosted by NHS providers, commercial sponsorship may be linked to the purchase of particular products, or to supply from particular sources. This should be in accordance with the guidance at paragraph 28 of HSG (97) 32 Responsibilities for meeting Patient Care Costs Associated with Research and Development in the NHS.

Paragraph 28 of HSG (97) 32 states:

"At present, industry frequently contributes to the costs of pharmaceuticals (and other products), which are the subject of non-commercial R&D in the NHS. Although, by definition, such items constitute Treatment Costs, the NHS will continue, under the Partnership Arrangements, to look to researchers and non-commercial research funders to secure such contributions before approaching the NHS for support." Where there is industry collaboration in such studies, companies may alternatively make a contribution towards the study's costs, rather than supply of product.

Any funding for research purposes should be transparent. There should be no incentive to prescribe more of any particular treatment or product other than in accordance with the peer reviewed and mutually agreed protocol for the specific research intended. When considering a research proposal, whether funded in whole or part by industry, the CCG will wish to consider how the continuing costs of any pharmaceutical or other treatment initiated during the research will be managed once the study has ended and as such should be submitted to the Medicines Management Committee for discussion of the impact of the research.

Where R&D is primarily for commercial purposes, NHS providers are expected to recover the full cost from the commercial company on whose behalf it is carried out. (HSG (97) 32, paragraph 7). An industry-sponsored trial should not commence until an indemnity agreement is in place; see the guidelines in HSC (96) 48 NHS Indemnity, Arrangements for Clinical Negligence Claims in the NHS. A standard form of indemnity agreement, agreed with ABPI, can be found at Annex B of that guidance.

The NHS should benefit from commercial exploitation of intellectual property derived from R&D that the NHS has funded, or for which it has been funded, even where people outside the NHS own the intellectual property itself. The CCG will ensure that an agreement to this effect is included in any contracts concerning R&D. The guidelines in HSC 1998/106 *Policy Framework for the* Management of Intellectual Property within the NHS from R&D should be followed.

References Documents

Commercial Sponsorship – Ethical Standards for the NHS (Department of Health November 2000)

Code of Practice for the Pharmaceutical Industry Clause (ABPI: 2006)

Department of Health v Source Informatics (1999)

NHS Lifehouse Project: Data Protection Work Team Report on Data Usage, Consent, Ethical Approvals, and Research Controls (Cambridge Health Informatics Ltd/NHS Executive LRO: December 2001)

Standards of Business Conduct for NHS Staff HSG (93)5

The New NHS: Modern and Dependable

Data Protection Act 1998

Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS HSG (97) 32`

NHS Indemnity Arrangements for Clinical Negligence Claims in the NHS HSC (96)48

Policy Framework for the Management of Intellectual Property within the NHS from Research and Development HSC 1998/106.

Department of Health (2008) Best practice guidance on joint working between the NHS and Pharmaceutical Industry and other relevant commercial organizations

APPENDIX A

DEPARTMENT OF HEALTH CODE OF CONDUCT

The following code of conduct is extracted from the Department of Health's policy *Commercial Sponsorship – Ethical standards for the NHS.*

Staff and independent contractors working in the NHS should follow existing codes of conduct. Staff who are not covered by such a code are expected to:

- Act impartially in all their work;

- Refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgment or integrity, and to avoid seeking to exert influence to obtain preferential consideration. All such gifts should be returned and hospitality refused.

- Declare and register gifts, benefits, or sponsorship of any kind, in accordance with time limits agreed locally, (provided that they are worth at least £25), whether refused or accepted. In addition gifts should be declared if several small gifts worth a total of over £100 are received from the same or closely related source in a 12-month period.

- Declare and record financial or personal interest (e.g. company shares, research grant) in any organisation with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgment is not influenced by such considerations.

- Make it a matter of policy that offers of sponsorship that could possibly breach the Code be reported to their Board.

- Not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others.

- Ensure professional registration (if applicable) and/or status are not used in the promotion of commercial products or services.

- Beware of bias generated through sponsorship, where this might impinge on professional judgement and impartiality.

Neither agrees to practice under any conditions that compromise professional independence or judgment, nor impose such conditions on other professionals.

APPENDIX B

CALDICOTT PRINCIPLES

The Caldicott Report envisaged that organisational Guardians should be responsible for agreeing, monitoring and reviewing protocols governing access to patient-identifiable information by staff within their own organisations wherever there is scope for local flexibility. The Guardian should also be responsible for agreeing, monitoring and reviewing protocols governing the exchange of such information across organisational boundaries. The six basic Caldicott principles can be summarised as follows:

Principle 1 - Justify the purpose(s)

Every proposed use or transfer of person-identifiable information within or from an organization should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.

Principle 2 - Don't use person-identifiable information unless it is absolutely necessary

Person-identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).

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

Principle 4 - Access to person-identifiable information should be on a strict need-to-know basis

Only those individuals who need access to person-identifiable information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.

Principle 5 - Everyone with access to person-identifiable information should be aware of their responsibilities

Action should be taken to ensure that those handling person-identifiable information - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect confidentiality.

Principle 6 - Understand and comply with the law

Every use of person-identifiable information must be lawful. Someone in each organisation handling confidential information should be responsible for ensuring that the organisation complies with legal requirements.

Appendix C

Sponsorship Checklist

	Y	N	Comments
Does the service on offer align with current views on evidence-based clinical practice?			
Is the service on offer consistent with the CCG priorities and policies			
Are you satisfied that the service is independent of purchasing and prescribing decision?			
Is this or a similar service already available from another source local? Can they be compared with each other?			
Can the NHS individuals involved confirm that there is no current or potential future conflict of interest			
Have all stakeholders discussed the proposed service are all willing for their patients to take part (where relevant) and are they willing to sign any service agreements			
Will you be provided with a fully documented service agreement that covers: • Aims and objectives of the service • An accountability framework within which the provider will operate, including a confidentially agreement • The protocols to be used in the service and named personnel involved • The procedure to be followed in the event of any adverse incidents • The professional indemnity and liability arrangements the service has in place • The option to modify or suspend the service in the light of any assessments, evaluations or adverse effects • The option for either party to withdraw, with agreed and clearly defined notice periods on both sides.			
Are the skills, competencies, professional status and qualifications of the named individuals who will be providing the service of sufficient level to ensure the service will be safe, effective, efficient and reliable?			
Are the lines of accountability (clinical, professional and managerial) of these individuals clearly documented and appropriate?			
If the service requires direct access to patients or patient information, are you satisfied that both it and the service provider can meet the requirements outlined in the following section on data and confidentiality?			

Assessment of Data and Confidentiality Issues

	Satisfied	
	Y	N
If practice / unit or patient data is being used, there must be a clear statement included in the service agreement regarding: • Who will have access to that data and in what form (eg aggregation and anonymised). • How, where and by whom that data will be manipulated. • To what purpose that data will be put.		
Each GP principal involved should give written consent if their patients are to be involved or their patients' data used in any way.		
In maintaining confidentiality, if direct contact with patients is required: • It is the responsibility of the practice / unit to identify and inform patients who may be eligible to participate. • Any invitation should indicate that the patient is under no responsibility to take part. • Prior to patient involvement in the programme, individual informed consent must be obtained.		
If data is stored electronically, e.g. laptop computer, then: • Any patient-identifiable information must be retained for use solely within the practice / unit except with prior express written agreement. • Data must be password protected. • There must be a clearly defined protocol for satisfactory data encryption. This should be at practice / unit level with patient codes held within the practice (similar to a clinical trial). Encryption must not rely on identifiers such as patient name, NHS or practice number, addresses or postcodes. • Use of patient-identifiable data must be consistent with caldicott principles and information governance requirements. If in doubt, seek advice from the CCG caldicott guardian or SIRO		
If data is to be aggregated (either within or between practices or units), then: • Practice / unit must have a clear understanding of what purpose such data is to be used for. • There must be a clearly defined protocol for data management, which includes information on the nature and ownership of the aggregated data and protocols to govern requests for access to that data. • No practice / unit-level should be identified from the aggregated data set. • The practice / unit should have the option not to share their data as part of the aggregated data set if they wish		

Post Approval checklist

Before any service is implemented, the following issues will need to be addressed:
All GP principals and other key staff must be aware of, and have agreed to participate as appropriate, with the proposed service:

- Agree clearly who is responsible for supervising and reporting on the service to the primary health care team and other relevant healthcare professionals as appropriate.
- Be satisfied that any information or material to support the proposed service are valid, evidenced based, contemporaneous and non-promotional.

Practices / units should make arrangements to involve or make patients aware of the service if appropriate, as early as practically possible.
Practices / units should agree a process for reviewing the service at appropriate intervals and assessing the service in terms of achieving its stated objectives. It may be beneficial to involve patients in the process.

Appendix D

Commercial Sponsorship / joint working agreement

This proposal form should be signed by all parties and submitted for consideration with the attached documents and a copy of the service level agreement

Name of Project:

Proposal submitted by:

……..Name of lead proposer

……...Job Title

Representing……..

1. Agreement between……..(commercial organisation) and

   ……. (Department/director) for provision of commercial sponsorship for: (title of project/event)

   ……

2. …….(name) has completed the sponsorship checklist in appendix C (copy to be submitted with this form)

3. Brief details of the proposed initiative

[Type a quote from the document or the summary of an interesting point. You can position the text box anywhere in the document. Use the Drawing Tools tab to change the formatting of the pull quote text box.]

4. Description of work and people involved

[Type a quote from the document or the summary of an interesting point. You can position the text box anywhere in the document. Use the Drawing Tools tab to change the formatting of the pull quote text box.]

5. Action plan

[Type a quote from the document or the summary of an interesting point. You can position the text box anywhere in the document. Use the Drawing Tools tab to change the formatting of the pull quote text box.]

6. Details of support provided (financial, staffing, services)

[Type a quote from the document or the summary of an interesting point. You can position the text box anywhere in the document. Use the Drawing Tools tab to change the formatting of the pull quote text box.]

7. Brief detail of benefit to – patients, and/or CCG

[Type a quote from the document or the summary of an interesting point. You can position the text box anywhere in the document. Use the Drawing Tools tab to change the formatting of the pull quote text box.]

8. Brief detail of benefit to the sponsor

> [Type a quote from the document or the summary of an interesting point. You can position the text box anywhere in the document. Use the Drawing Tools tab to change the formatting of the pull quote text box.]

9. …….. (Commercial organisation) may only be involved to the extent defined in this agreement, consistent with the commercial sponsorship – Ethical standards for the NHS, 2002.

10. Such reports will be used for the purpose described above …….. (Commercial organisation) cannot use the report or information from this work without explicit permission from the CCG.

CCG Approval

Proposal agreed by the Director of Finance on behalf of the CCG (obligatory for CCG related projects)

Name Signature Date

Proposal agreed by representative from…….(commercial organisation)

Name Signature Date

Copies of the form should be forwarded to the executive assistant to the board for recording in the CCG hospitality / sponsorship register

Appendix E

Sponsorship for meetings and locally arranged education sessions

To…….

of (state company)…….

Thank you for agreeing to sponsor the meeting on…….

Entitled……

To the value of £……..

Sponsorship is accepted on the understanding that:-

- The course organiser retains overall control of the training event
- The sponsor does not have the right to present teaching material
- Where the organiser considers additional value may be gained from a presentation by the sponsor, that the content of the material is agreed in advance of the meeting
- The sponsor does not use the CCG contact to promote products outside of the meeting
- Any stand the sponsor uses to promote products is to be outside the main meeting room where practical
- Attendance of the meeting by the sponsor is at the discretion of the course organiser
- Where course material is provided by a pharmaceutical company, that there is no promotion of specific (the name of the company supporting the training event is acceptable)

Please confirm that you accept the terms of the detailed above

Signed…….Date……..

Print name…….

Company……

Signed (on behalf of the CCG)……..Date…….

Copies of this form must be returned to the CCG Chief Finance Officer and the Executive assistant to the Board for recording in the CCG hospitality register