

# WORKING WITH THE PRIVATE SECTOR: guidelines for LSHTM staff

June 2001

## Introduction

In the face of increasing public sector collaboration with the private sector, an ad hoc group<sup>1</sup> of London School of Hygiene and Tropical Medicine staff has been considering what principles should guide staff in such collaborations. These guidelines<sup>2</sup> have been drawn up by Gill Walt, Ruairi Brugha and Barbara Judge, in response to the increasing opportunities for LSHTM staff to undertake research in collaboration with the private commercial sector.

While recognising the support and intellectual stimulation that might occur from such partnerships, staff are concerned to avoid arrangements that might compromise the School's intellectual principles, freedom of enquiry and public mission. These draft guidelines lay out some of the issues staff may want to consider before embarking on working with the private sector.

An appendix of experiences of staff provides additional insight into some of the positive aspects of collaborations, as well as some of the concerns.

It would be helpful to get feedback from those who have had some experience with industry collaboration in research, to see how far these guidelines might or might not have been helpful, and what amendments should be considered. Please address comments and suggestions to Gill Walt, Ruairi Brugha or Barbara Judge.

<sup>1</sup> Ruairi Brugha, David Bradley, Steve Bennett, Simon Croft, Liz Corbett, Val Curtis, Alison Grant, Heiner Grosskurth, Andy Haines (the Dean) Kara Hanson, Shabbar Jaffar, Barbara Judge, Jo Lines, Ruth McNerney, Sylvia Meek, John Porter, Peter Smith, Neil Stoker, Gill Walt, Deborah Watson-Jones, Gill Walt, Brendan Wren

<sup>2</sup> These Guidelines are based on information from a number of different sources: *An Approach to Public Health Agency Collaboration with Private Industry* (Marks and the Industry Guidelines Working Group, Centers for Disease Control, Atlanta) 1999; *Research Participation Agreements*, Stanford University (<http://corporate.stanford.edu/research/biotech/rpa.html>) 2001; *Faculty of Medicine statement on Research Sponsored by Industry*, Harvard University, (<http://www/hms.harvard.edu/integrity/industry.html>) 2001; Procedures implementing Board of Regents Policy on Conflicts of Interest in Research or Development; *Guidelines on working with the private sector*, World Health Organisation 2000. A number of universities in the UK were contacted by telephone (Cambridge, Oxford, Nottingham) but none had any formal guidelines.

## **Preamble**

The mission of the School is to contribute to the improvement of health worldwide through the pursuit of excellence in research, postgraduate teaching, advanced training and consultancy in international public health and tropical medicine. In working towards its mission, the School collaborates with many different organisations, and bases its relationships with other organisations on principles which promote sound, and independent science; proper use and stewardship of all funds; and benefits to society that are greater than those to the School alone.

## **Pre-requisites to considering a collaboration**

1. LSHTM should be clear about how the potential collaboration fits within its overall mission and priorities, and consider the following issues:
  - Initiation, whether internal or external, may influence the control and direction of the project. [For example, Stanford University differentiates between collaborations where the intellectual direction of the research comes from the private sector, with the staff member overseeing the project; and collaborations where university staff initiate the partnership].
  - The centrality of the project to LSHTM's research goals and priorities.
  - The advantages (explicit and implicit) to the private sector partner of working with LSHTM.. Are these compatible with LSHTM's mission? Is a collaboration likely to involve reciprocal action by LSHTM that would be incompatible with the School's mission?
  - The use of resources (especially staff time – inputs) and the extent to which they are fully recoverable. Will the likely outputs (quality of the research, publications etc) justify LSHTM's investment?
  
2. LSHTM must be comfortable with the partner's broad mission and public image, and potential public health impact, not just in the area of mutual interest. For controversial issues, multiple collaborators should be sought, to represent a broad spectrum of opinions and interests. In most cases, it is desirable to avoid collaborations with a single partner, especially where a corporate sponsor is supporting the major portion of a staff member's research.
  - While the partnership will share a common goal, there will be other aspects of the partner's activities that are not necessarily shared. It will be worth reviewing the overall activities and perception of the partner in deciding the appropriateness of the collaboration. Companies might be asked to provide information on social responsibility. Criteria might include
    - ◇ Core standards on labour relations, especially with regard to ethical standards and management of work-forces in developing countries
    - ◇ Worker health and safety standards
    - ◇ Public relations activities, and the amount of resources allocated to such activities (although this is a difficult criterion, it might give an indication of how important image is, or what might be expected from researchers – meeting the press for example)
    - ◇ Social, ethical and environmental principles
    - ◇ A review of the public face of the company, for example on company web-sites, and consultation with others, for example a LSHTM review body (see 7 and 8), may provide additional perspectives.

3. LSHTM should avoid participating in indirect collaboration unless it is comfortable with a direct relationship with the partners
  - Indirect relations may occur when LSHTM serves as an advisory group for another project in which LSHTM does not directly participate. There may be advantages to indirect relationships, for example, as a way of maintaining scientific independence, but these should be entered into with open eyes. They should be subject to the same criteria as for entering a direct collaboration. As is the case in some of the new global public-private partnerships, advisory roles that involve multiple collaborators including international health agencies entail less risk than indirect single-partner collaborations.
4. LSHTM should not work directly or indirectly with companies whose activities or interests threaten public health, but will need to decide where to draw the line. While the examples below may be absolutely unacceptable, there may be others that require careful consideration and discussion:
  - Tobacco and tobacco related products
  - Arms dealing or manufacturing

### **Terms and conditions of contracts**

5. Independence and objectivity of scientific judgement should be paramount, and should be considered in relation to scientific independence and utilisation of outputs (including conferences, publications and intellectual property rights). Issues to be considered and formally agreed include the following:
  - LSHTM would have control over the research design, implementation and data analysis, in order to defend the work scientifically.
  - LSHTM will control decisions with regard to publication, dissemination of results and materials. The form of such agreements will need to be made with companies, to allow them to comment on or ask for changes, or delays, in publications and written documents. It may be necessary to agree pre-conditions about anonymisation of commercial entities. [eg Harvard says ‘With principal investigator approval, sponsors may be given an advance period of 30 days to review manuscripts before they are submitted for publication ...if necessary to permit the preparation and filing of patent applications before publication, the principal investigator may agree to delay submission for an additional period of up to 30 days. Agreements with industry may not otherwise restrict the rights of investigators to publish their findings nor to communicate their research results freely....’]. It may be necessary to negotiate over the number of days, but this should be done before contracts are signed.
  - LSHTM will only agree to keeping information from industry sponsors confidential when all partners agree that it is appropriate to do so.
  - LSHTM will have control over messages – review and approve any public statements or dissemination about the project, its findings and implications.
  - LSHTM staff should always acknowledge any relations with partners in publications and other material.
  - Consideration and agreements will be drawn up regarding patents, intellectual property rights. See paper by Professor Paul Kaye and group entitled *Intellectual property: options for the future*.

**Agreement on these issues should be made in advance and form part of a signed contract. Once in the public domain reports and publications will be subject to the normal scientific debate and media scrutiny.**

6. Private partners should be informed that the relationship will be made a matter of public record
  - To meet the highest standards of conduct, both LSHTM and partners must be comfortable with disclosing the nature of the relationship in the public domain.
  - LSHTM must ensure that any stand taken on issues of public health importance is not in any way compromised by other interests or activities of the private sector partner.
  - LSHTM staff should always seek advice from the Head of Department and Dean, and be prepared to declare any financial gain, current or future, potential or actual, resulting from the collaboration, except where it is part of School policy (eg in relation to consultancy fees).
  - LSHTM should assess how its name will be used, and whether such usage is consistent with the School's mission and public role. Both partners should agree how the collaboration might be publicised, and LSHTM should have the opportunity to review and approve if and how its name might be used.
  - LSHTM should assess how any collaboration might be portrayed by the media, and whether this might be damaging to the School's reputation.
  - Questions around endorsements of products must be identified early, negotiated and agreed. Normally LSHTM, as an institution, does not endorse specific products.
  
7. Mechanisms should be put in place to protect independence and objectivity
  - The current group (see names at the end) should be called upon to advise on, or oversee collaborations where requested, and act as an appeal body in case of disagreement.

### **LSHTM Screening and Monitoring Procedures**

8. Potential collaborations should be reviewed and monitored using existing processes – through an amendment to the Pink Form, which shows that the chief investigator has read these guidelines. LSHTM researchers embarking on partnerships should draw on the ad hoc group to:
  - Examine the proposed collaborations and advise LSHTM staff on whether the partner fulfils the pre-requisites for a collaboration with LSHTM
  - Advise staff on the negotiable and non-negotiable terms and conditions for such a collaboration
  - Review the proposed collaboration, prior to LSHTM entering into a contract

## **Appendix: Staff experiences working with the private sector**

Some members of staff have been involved in research collaborations with industry in a variety of different projects. The points below come from short extracts describing experiences (from Alison Grant, Liz Corbett; Jo Lines, Kara Hanson, Sylvia Meek; Steve Bennett; David Bradley; Ruth McNerney; Debby Watson-Jones; Brendan Wren; Simon Croft; Neil Stoker and Shabbar Jaffar). The large majority have been positive, but some have posed restrictions, or had negative effects. In reviewing these different experiences, a number of broader concerns were raised.

- The positive aspects of collaborations with the private sector mentioned included
- New opportunities to tackle research problems relevant to developing countries, but with unusually good infrastructure and data systems;
- Rapid implementation of interventions perceived to be valuable;
- Professional, accommodating, and rapid two-way communication;
- Opening up of research opportunities in companies allied to the original;
- Fast turnaround of decisions and contracts.

Concerns were expressed around the following experiences

- Attempts by the company to dictate the research agenda
- Some blurring of the line between research and implementation
- Potential conflicts of interest, leading to delays, and withdrawal of companies
- Dishonest dealings over patents
- Unauthorised use of individual staff and the School's name
- Inaccurate claims made for a diagnostic test
- Attempts to restrict dissemination of work done at the School, but funded by other bodies
- Huge amounts of time in meetings giving help and expertise, all unpaid
- Dispute over Intellectual Property Rights (IPR)

Potential dilemmas were expressed about the following

- A lack of clarity with regards to who owns IPR and what the expected deliverables are (especially in case of students)
- Understanding what the motivations are of companies funding the research
- Under what circumstances it is legitimate to accept or seek pharmaceutical funding
- What confidentiality issues are legitimate in restricting presentations (internal seminars) and publications
- Small companies are often less professional and less experienced in setting the boundaries for collaboration
- Under what circumstances payments to staff, or staff shares in small companies were legitimate

For future collaborations, staff should review this document, and contact members of the ad hoc group where they feel the need to discuss the implications of any potential collaboration. See footnote on page 1 of the Guidelines for the names of members of the ad hoc group.