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Jeffery, R, *et al* (2013) Biomedical and Health Experimentation in South Asia: Critical Perspectives on Collaboration, Governance and Competition
 ESRC End of Award Report, RES-167-25-0503. Swindon: ESRC.



ESRC End of Award Report

For awards ending on or after 1 November 2009

This End of Award Report should be completed and submitted using the **grant reference** as the email subject, to reportsofficer@esrc.ac.uk on or before the due date.

The final instalment of the grant will not be paid until an End of Award Report is completed in full and accepted by ESRC.

Grant holders whose End of Award Report is overdue or incomplete will not be eligible for further ESRC funding until the Report is accepted. We reserve the right to recover a sum of the expenditure incurred on the grant if the End of Award Report is overdue. (Please see the ESRC Research Funding Guide for details.)

Please refer to the Guidance notes when completing this End of Award Report.

Grant Reference	RES-167-25-0503		
Grant Title	Biomedical and Health Experimentation in South Asia: Critical Perspectives on collaboration, governance and competition		
Grant Start Date	01/09/2010	Total Amount	£493913.19
Grant End Date	28/02/2013	Expended:	
Grant holding Institution	University of Edinburgh		
Grant Holder	Professor Roger JEFFERY		
Grant Holder's Contact Details	Address	Email	
	School of Social and Political Science, Room 2.09, 7 Buccleuch Place Edinburgh, EH8 9LD	r.jeffery@ed.ac.uk	
		Telephone 0131 650 3976	
Co-Investigators (as per project application):	Institution		
Professor Robert SIMPSON	University of Durham		
Dr Ian HARPER	University of Edinburgh		
Dr Salla SARIOLA	University of Durham		
Dr Amar JESANI	Anusandhan Trust		

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I. Non-technical summary

Please provide below a project summary written in non-technical language. The summary may be used by us to publicise your work and should explain the aims and findings of the project. *[Max 250 words]*

The growth in clinical and public health trials in South Asia has economic benefits and costs, but also has significance for the practice and theory of 'development'. We investigated whether such experimental interventions provide South Asian countries with the opportunity to move 'up the [knowledge] value-chain'; whether they impact on public health programmes; and how they articulate with global networks. Our research investigated how knowledge transfers and capacity building takes place in clinical trials and experimental public health programmes in India, Sri Lanka and Nepal. We studied how sponsors and local actors engage in collaboration activities such as developing research capacity and upgrading relevant training, skills and facilities; generating knowledge of neglected health problems; updating patient care systems; and improving overall research cultures. These collaborative assemblages connect international researchers with local institutions, personnel and populations in order to facilitate biomedical and public health research. Wherever possible we explored the movement of knowledge, resources and people that make up these assemblages, and processes of ethical regulation; we investigated how registration systems for clinical trials are developed, how capacity-building in institutional ethical review is promoted, and how compliance with international standards is ensured. Our research illuminates the organisational contexts within which citizens are recruited and rewarded for their epidemiological characteristics and become research subjects. We mapped and analysed these activities quantitatively and also provided ethnographic evidence about the overall situation of such trials, taking a small sample for detailed analysis of how the practical and ethical ambiguities are (or are not) resolved.

2. Project overview

a) Objectives

Please state the aims and objectives of your project as outlined in your proposal to us. *[Max 200 words]*

We aimed to understand the relationships that link experimental scientific enquiry in the field of medicine and public health, the pharmaceutical industry, and developmental programmes, in South Asia. Through detailed case studies of particular experimental projects in India, Nepal and Sri Lanka we charted the extent of the national and transnational networks involved, and analyse these through ethical, socio-anthropological, political and economic frames.

Our objectives were:

- 1) to generate policy-relevant knowledge on the growth in experimental scientific medical and health activity in India, Nepal and Sri Lanka and to construct a detailed

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- database of clinical and public health research activity;
- 2) To affect policy and practice by running workshops on ethical regulation of trials and curricula development for research ethics;
 - 3) To manage a website as an information portal;
 - 4) To conduct ethnographic research into the running of clinical and public health trials in five sites;
 - 5) To investigate the organisation of these trials and research activities; the patterns of international collaboration; the kind of knowledge being developed; the relationships developed between government, pharmaceutical companies, partner universities etc.; perceptions of relationships with development and poverty reduction; ethical standards being implemented; the role of international standardisation and norms.

b) Project Changes

Please describe any changes made to the original aims and objectives, and confirm that these were agreed with us. Please also detail any changes to the grant holder's institutional affiliation, project staffing or funding. *[Max 200 words]*

No changes were made to the project's original aims and objectives. Dr Sharma left Tufts University and relocated to a position in the University of Edinburgh. In order to carry out a variety of dissemination activities we were granted a 6-month extension. At the end of the original period of funding, Dr Sariola took up a new position at The Ethox Centre, Department of Public Health, University of Oxford.

The total expenditure was £493913.19 (100%) £419464.06 (RC Expenditure 80% + 100% Exceptions) There was an underspend of £10k on this award.

c) Methodology

Please describe the methodology that you employed in the project. Please also note any ethical issues that arose during the course of the work, the effects of this and any action taken. *[Max 500 words]*

The main methods used were ethnography and semi-structured interviews, alongside statistical analysis of the Clinical Trials Registry of India (CTR-I) and other databases and records on health experimentation in the region.

In Nepal we selected three institutions for in-depth study: a bilateral programme; a research laboratory in a mission hospital; and a state-run medical college. The core focus of the bilateral programme is maternal and child health. They conduct operational research studies and we studied intensively one of their interventional studies. Collaborations were largely institutional in nature. The focus of the laboratory is clinical research in leprosy, and collaborations are mostly with foreign academic institutions, and with local private and

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government labs. The academic institution is a government medical college with a long history of research engagement and collaborations with foreign academic institutions and also with international agencies.

In India, from the CTR-I database, we created a list of trial sites, and then from hospitals with more than 30 trials we chose one public hospital, one private hospital and one not-for-profit, trust-run hospital in Mumbai, Delhi and Bangalore. Because the clinical trial industry is very compartmentalized and commercial confidentiality is rigorously enforced, tracing entire trial chains was impossible. We traced individual studies wherever possible, and filled in by approaching different equivalent players in each hospital. We also mapped experimental public health projects, to overcome the absence of a reliable existing database. We identified 67 past and on-going projects and selected two for detailed study. The first was a Randomised Control Trial in mental health, testing the involvement of a lay person on outcomes. This was an international collaboration, funded by a European agency, with three sites in India, with a local organization as a collaborative partner. The second aimed to reduce the health and economic burdens of tobacco use, piloting multi-level initiatives in two states. This was a Clustered Randomised Trial funded by a western funding agency, centrally managed from Delhi, through partner institutions in two states. As this project had a strong component of strengthening legislation and existing Government programmes for tobacco control, there were close links with relevant Government departments.

In Sri Lanka, we created a database and chose four health experimentation projects – two clinical trials and two public health trials – to investigate in detail for one year through in-depth interviews and observation. The trials were chosen purposively with research teams that welcome us to investigate their studies and also to represent a cross section of different sectors involved in experimental health research; academic, pharmaceutical, government lead and private institution lead.

In the **US** and **UK** we interviewed sponsors and principal investigators, regulators and other key informants with detailed knowledge of experiments in public health and clinical trials.

Overall, we conducted 337 interviews: 73 in Nepal, 148 in India, 80 in Sri Lanka and 36 elsewhere. Of these, 55 were with investigators, 128 with contract research staff, 49 with sponsors, 26 with ethics committee members and 79 with regulators and other key informants. No specific ethical issues arose.

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d) Project Findings

Please summarise the findings of the project, referring where appropriate to outputs recorded on the ESRC website. Any future research plans should also be identified. *[Max 500 words]*

In Nepal, activity in this field is growing slowly, and most research is sponsored by aid agencies with a public health focus. The nature of collaborations has evolved. Nepalis are no longer seen as mere “sample deliverers” but as partners, having established their credibility [see papers 8 & 11]. The linkage between research and policy is weak, over-influenced by the evidence generated from randomised controlled trials compared to operational research studies but also prone to rapid decision-making on the basis of little validated evidence [see papers 4 & 9]. The Nepal Health Research Council regulates large scale research and deals with ethical review issues, having approved 19 Institutional Review Committees [IRCs] to assess internal research studies but not clinical trials, multi-centric studies, externally sponsored or funded research and research proposed at national and international levels [see paper 5].

In India, we have reported regularly on the changing patterns reported in the Clinical Trials Register of India [see papers listed as 10]. Sponsored clinical research is understood by practitioners as capacity building, to enable investigators to carry out their own research. But in such trials, the research questions are created elsewhere and Indian investigators often only collect data, with little access to the longer chain of research activities [see papers 6 & 11]. Responsibilities of ethical importance often fall on the shoulders of junior staff: serious ethical issues are often thereby overlooked [see papers 5 & 7]. Contract Research Organisations, who are middlemen between sponsors and researchers, have been accused of ‘flying under the radar’ because they are effectively unregulated [see papers 3 & 7]. In public health interventions, randomized controlled trials are perceived to prove interventions statistically, making them convincing to policy makers. There has been little discussion of whether alternative research designs might be more appropriate, or ethical (e.g. with respect to community-level informed consent in cluster randomised trials). Communities lack clarity about the nature and purposes of public health experimental trials, and post-trial benefits for participants [see paper 2].

Sri Lanka is trying to attract pharmaceutical trials, with new regulations being drafted by an independent advisory committee, which is drafting new rules for overseeing trials in the country. Sri Lanka’s 15 IRCs are meeting the demand for ethical clearance from journals and IRCs are key actors in health experimentation projects. Their workload has increased with new drug trials coming into the country, and their capacity and infrastructure is under strain, with IRCs looking to regional bodies for certification [see paper 5]. The Sri Lanka Clinical Trials Registry (SLCTR), managed by the Sri Lanka Medical Association, records health experimentation activities on a voluntary basis: nearly 76 trials were registered by end 2012 but registration with SLCTR is likely to become compulsory for ethical approval. Though Sri Lanka wants to accommodate health experimentation, pharmaceutical trials sponsors have been withdrawing in the face of prolonged ethical and regulatory clearances. As in Nepal, links between research and policy are complex [see paper 4].

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e) Contributions to wider ESRC initiatives (eg Research Programmes or Networks)

If your project was part of a wider ESRC initiative, please describe your contributions to the initiative's objectives and activities and note any effect on your project resulting from participation. *[Max. 200 words]*

Although we were members of the ESRC-DfID Joint Programme on Poverty Alleviation, there were few opportunities to meet with other grantees. Professor Jeffery became a member of the Strategic Advisory Team for the ESRC-DfID Joint Programme in October 2010 and was able to provide an insider's perspective and contribute to discussions on the direction taken by the scheme since then.

3. Early and anticipated impacts

a) Summary of Impacts to date

Please summarise any impacts of the project to date, referring where appropriate to associated outputs recorded on the Research Outcomes System (ROS). This should include both scientific impacts (relevant to the academic community) and economic and societal impacts (relevant to broader society). The impact can be relevant to any organisation, community or individual. *[Max. 400 words]*

Dr Amar Jesani (co-investigator) has been active in a variety of ways, including taking part in a debate with pharmaceutical industry representatives in the European Parliament. He also participates in the advisory committee of the DCGI (Drugs Controller General of India). We have held a series of meetings and impact workshops and our work has contributed to the public debate of trial activity in both civil society and government in South Asia and beyond the region

For example, we presented two papers at a national consultation of clinical trials in India (which had parliament members and members of groups that draft research regulation in the country and other powerful members of the civil and political society: for details see http://www.communityhealth.in/~commun26/wiki/images/3/34/DrugTrialsConsultation_2011_SAMA.pdf). Our finding entered into discussions on research regulation – e.g. recent changes to policies on ethics committees and their roles, and on compensation in case of injury and death during drug trials.

In all our dissemination activities we have endeavoured to ensure a mix of academic, practitioner and policy participants. At the 4th National Bioethics Conference (NBC), Hyderabad, India, 6-8 December 2012, our audience was a good combination of national and international level stake holders from various sectors, including representatives from ICMR, ethics committee members, CRO professionals, members from the pharmaceutical industry, philosophers, social scientists, journalists, members from the civil society and medical doctors. We played a major role at the 12th FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific) International Conference: Development,

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Ethnicity, Culture and Ethical Health Research, 18 to 21 November 2012 (for details see <http://www.fercap-sidcer.org/newsletter/2012/12/2012%20FERCAP%20Conference%20Programme%20Book.pdf>) We talked predominantly to members of IECs and government regulators of drug trials and other forms of experimental activity. In Nepal our dissemination activities – both formal and informal – generated considerable interest amongst the research community; we have engaged in various conversation with Nepal Health Research Council, and the wider research and policy community on trials through 1:1 meetings as well as two workshops.

b) Anticipated/Potential Future Impacts

Please outline any anticipated or potential impacts (scientific or economic and societal) that you believe your project might have in future. *[Max. 200 words]*

We expect that the activities reported here, along with other activities of the partners (especially Centre for Studies in Ethics and Rights) will have direct impacts on the organisation and regulation of clinical and other public health experiments in South Asia and elsewhere (e.g. through the activities of FERCAP). There are general tensions between pharmaceutical-driven research and public health concerns. Some of these have to do with the choice of disease treatment to be trialled, and with pressures to focus on neglected diseases coming into conflict with profit-seeking. Other tensions arise from countries wishing to gain financial benefits from research coming into conflict with active advocacy groups demanding better ethical review and protection for those involved in trials. These result in difficult policy decisions. Our research provides various kinds of evidence to inform these policy-making processes, and our partners in South Asia are well placed to see how it can most effectively be used.

You will be asked to complete an ESRC Impact Report 12 months after the end date of your award. The Impact Report will ask for details of any impacts that have arisen since the completion of the End of Award Report.

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4. Declarations

Please ensure that sections A, B and C below are completed and signed by the appropriate individuals. The End of Award Report will not be accepted unless all sections are signed. Please note hard copies are **not** required; electronic signatures are accepted and should be used.

A: To be completed by Grant Holder

Please read the following statements. Tick **one** statement under ii) and iii), then sign with an electronic signature at the end of the section (this should be an image of your actual signature).

i) The Project

This Report is an accurate overview of the project, its findings and impacts. All co-investigators named in the proposal to ESRC or appointed subsequently have seen and approved the Report.	<input checked="" type="checkbox"/>
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ii) Submissions to the Research Outcomes System (ROS)

Output and impact information has been submitted to the Research Outcomes System. Details of any future outputs and impacts will be submitted as soon as they become available.	<input type="checkbox"/>
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or

This grant has not yet produced any outputs or impacts. Details of any future outputs and impacts will be submitted to the Research Outcomes System as soon as they become available.	<input checked="" type="checkbox"/>
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iii) Submission of Data

Data arising from this grant have been offered for deposit with the UK Data Service.	<input checked="" type="checkbox"/>
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or

Data that were anticipated in the grant proposal have not been produced and the UK Data Service has been notified.	<input type="checkbox"/>
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or

No datasets were proposed or produced from this grant.	<input type="checkbox"/>
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