EMBARGOED UNTIL MEETING

Greater Glasgow NHS Board

Board Meeting

Tuesday 17 August 2004 **Board Paper No. 04/53**

DIRECTOR OF PUBLIC HEALTH

MEMORANDUM OF UNDERSTANDING BETWEEN NHS GREATER GLASGOW AND THE UNIVERSITY OF GLASGOW ON THE CONDUCT OF CLINICAL TRIALS

Recommendation:

The Board is asked to approve the enclosed draft Memorandum of Understanding between the University of Glasgow and NHS Greater Glasgow on the conduct of clinical trials within the Board's area.

1 Background

On 1 May 2004 new regulations came into force which changed the legal framework within which clinical trials on medicines take place. These new regulations implement in the UK, the European Union Clinical Trials Directive 2001/20. The new regulations clarify specific legal duties of the various sponsors and investigators in clinical trials of medicines and the regulations are based on internationally agreed principles.

The regulations do not alter responsibilities and potential liabilities of researchers or of the NHS. The Department of Health and UK universities have sought to reassure the service that these new regulations do not change the underlying allocation of responsibilities and potential liabilities in clinical trials, rather they seek to remind all participants of the need for continuing high standards in clinical research governance.

The Memorandum of Understanding has been reviewed by the Central Legal Office and the document incorporates some minor amendments suggested by them.

Dr H Burns (201 4602)

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Memorandum of Understanding

between

University of Glasgow and Greater Glasgow Health Board regarding the implementation of good clinical practice in the conduct of non-commercial clinical trials of medicinal products for human use, under the Medicines for Human Use (Clinical Trials) Regulations 2004[1].

The University of Glasgow and the Greater Glasgow Health Board ("GGHB") are committed to working closely together on all aspects of clinical and research governance relating to clinical trials. This commitment has already been demonstrated by:

- the launch of the University/NHS Partnership Agreement in March 2004,
- the establishment of the Glasgow Research Governance Group, chaired by Professor Chris Packard, in 2002, and
- the creation of 'Glasgow Biomedicine' in 2003.

The University of Glasgow and the GGHB now agree to act as co-sponsors in specified non-commercial clinical trials of medicinal products for human use, on the following basis:

1. Insurance and indemnity for liability of the sponsors and investigators

1.1. The GGHB will remain liable for clinical negligence and other negligent harm to individuals covered by their duty of care. The duty of care of the GGHB applies both:

- when a health care professional employed by the GGHB is negligent in the course of their employment; and
- when the negligent health care professional was contracted to the GGHB to provide services to people to whom the GGHB owed a duty of care.

1.2. In either case, if there is negligent harm as defined in 1.1, the GGHB will accept full financial liability. If there is negligent harm during a clinical trial when the GGHB owes a duty of care to the person harmed, who may be a patient or a healthy volunteer, the

[1] 'The Medicines for Human Use (Clinical Trials) Regulations 2004' (SI 2004 No. 1031) that implement the Clinical Trials Directive were laid before both Houses of Parliament on 1 April 2004 and came into force on 1 May 2004. The full text can be viewed at http://www.legislation.hmso.gov.uk/si/si2004/20041031.htm

indemnity provided by the GGHB will cover GGHB staff, medical academic staff with honorary contracts, and those conducting the trial.

1.3. The University of Glasgow, as employer of the chief investigator, will remain liable for negligent harm caused by the design and initiation of clinical trials by Glasgow University staff in the course of their employment. The University will insure against the risk of claims, arising from authorship of the protocol, against the University or its staff, relating to clinical trials it, or anyone acting on the University's behalf, designs and undertakes in their University employment. All trials will undergo full and proper independent expert scientific review to ensure that all reasonable care is taken in designing the protocol.

1.4. Neither the GGHB nor the University will automatically be responsible for providing compensation for non-negligent harm. If an ethics committee requires no-fault compensation, this will be discussed separately with the University's insurers prior to sponsorship being accepted.

2. Allocation of functions of sponsor

2.1. Unless otherwise specified in writing, the University of Glasgow and the GGHB agree to the following allocation of functions of sponsor, under the UK regulations, for all non-commercial clinical trials of medicinal products for human use which they agree to co-sponsor.

2.2. The University of Glasgow will be responsible for carrying out the functions of a sponsor listed under Part 3 of the Directive ('*authorisation for clinical trials and ethics committee opinion*', including regulations 17, 18, 19, 20, 21, 22, 24, 25, 26 and 27) and shall make the request for authorisation to conduct the trial in accordance with regulation 17.

2.3. After the clinical trial has been authorised by the licensing authority, the GGHB will be responsible for carrying out the functions of the sponsor under Part 4 ('*good clinical practice and the conduct of clinical trials*', including regulations 28 and 30).

2.4. After the clinical trial has been authorised by the licensing authority, the GGHB will be responsible for carrying out the functions of the sponsor under Part 5 ('*pharmacovigilance*', including regulations 32, 33, 34 and 35).

2.5. For any given trial, the University of Glasgow and the GGHB may arrange for their employees to complete the necessary tasks, or engage someone else to do so, on their behalf, under a written agreement or contract.

Sir Muir Russell
Principal and Vice-Chancellor, University of Glasgow

Professor Sir John Arbuthnott
Chairman of Greater Glasgow Health Board

EMBARGOED UNTIL DATE OF MEETING.

Annex 1:

Allocation of functions of sponsor between the University of Glasgow and Greater Glasgow NHS under the Medicines for Human Use (Clinical Trials) Regulations 2004

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Regulation number	Sponsor function	Allocation of function	Carried out by:
Part 3: ***Authorisation for clinical trials and ethics committee opinion***			
17 - Request for authorisation to conduct a clinical trial	Request for authorisation from licensing authority, including fee payment	GU	Chief Investigator
18 – clinical trials involving general medical products	Amended request to licensing authority within 14 days if required	GU	Chief Investigator
19 – clinical trials involving medicinal products for gene therapy etc	Amended request to licensing authority within 14 days if required	GU	Chief Investigator
20 - clinical trials involving medicinal products with special characteristics	Amended request to licensing authority within 14 days if required	GU	Chief Investigator
21 – clinical trials conducted in third countries	Give undertaking to permit inspection of third country premises	GU	Chief Investigator
22 – amendments to clinical trial authorisation	Make amendment to CTA in accordance with regulations 24 or 25	GU	Chief Investigator
24 – amendments by the sponsor	➢ Keep records of amendments made and supply to licensing authority on request ➢ Send valid notice of amendment, including fee, for substantial amendments, to licensing authority if required ➢ Send valid notice of amendment, including fee, for substantial amendments, to ethics committee if required	GU	Chief Investigator
25 – modifying or adapting rejected proposals for amendment	Give notice to licensing authority and ethics committee 14 days prior to proposed amendment of protocol if required	GU	Chief Investigator
26 – reference to the appropriate committee or the Medicines Commission	Give written notice within 28 days of wish to make representation to the appropriate committee if required	GU	Chief Investigator
27- conclusion of clinical trial	Notify licensing authority and ethics committee of termination of trial - within 15 days of date of termination if prior to that specified in protocol, or within 90 days if in accordance with protocol	GU	Chief Investigator

Author: [Name & Tel No.]

Part 4: ***Good Clinical Practice and the conduct of clinical trials***			
28 – GCP and the protection of clinical trial subjects	Ensure GCP is put in place and adhered to Ensure that IMPs and any required devices are made available to the subjects free of charge if appropriate	GGHB	Chief investigator and/or specified persons at multiple trial sites
30 – urgent safety measures	Take urgent safety measures if appropriate to protect the subjects of a trial against any immediate hazard to their health or safety, and notify the licensing authority and ethics committee within 3 days	GGHB	Chief investigator and/or specified persons at multiple trial sites
Part 5: ***Pharmacovigilance***			
32 – notification of adverse events	Keep detailed records of all adverse events which are reported by the investigators	GGHB	
33 – notification of suspected unexpected serious adverse reactions	Record and report SUSARs, within 7 days if fatal or life-threatening or within 15 days otherwise, to licensing authority, competent authorities and ethics committee (e.g. via European database) Inform investigators of relevant SUSARs	GGHB	
34 – clinical trials conducted in third countries	Record all SUSARs in European database	GGHB	
35 – annual list of suspected serious adverse reactions and safety report	Report annually (at end of 'reporting year') all suspected serious adverse reactions to the licensing authority and ethics committee together with safety report	GGHB	