

GREATER GLASGOW NHS BOARD

**Minutes of a Meeting of the NHS Greater Glasgow
Research Ethics Governance Committee
held in Meeting Room A, Dalian House,
350 St Vincent Street, Glasgow
on Wednesday 25 January 2006 at 12.30 pm**

PRESENT

Professor D Barlow (in the Chair)

Dr R Groden

Mrs A Stewart MBE

IN ATTENDANCE

Mr J C Hamilton
Mrs A Torrie
Mr W S Marshall

Head of Board Administration
OREC Manager
Secretariat Officer

ACTION BY

1. APOLOGIES

Apologies for absence were intimated on behalf of Mr R Cleland and Dr L de Caestecker.

2. MINUTES

The Minutes of the meeting of the NHS Greater Glasgow Research Ethics Governance Committee held on Monday 12 July 2004 (NHSGGREGC(M)04/1) were approved as a correct record as agreed with the previous Committee.

NOTED

3. MATTERS ARISING

There were no Matters Arising not otherwise on the agenda.

4. UPDATE ON PROGRESS

The Governance Committee received for information copies of a paper providing an update on progress to date since the last meeting of the Committee.

The OREC Manager opened the meeting by outlining the background to the establishment of the Governance Committee and detailing its progress to date for the benefit of the new members. She pointed out that the NHS Board had agreed to establish a Research Ethics Governance Committee as a Standing Committee of the Board in 2002. The Committee did not consider applications or day-to-day ethical research business and its primary responsibility was to have an oversight of all matters pertaining to the proper functioning of all Local Research Ethics Committees (LRECs) in NHS Greater Glasgow.

At the time the Committee was set up there were ten LRECs within NHS Greater Glasgow.

When the Governance Committee was established national guidance in the form of the Governance Arrangements for Research Ethics Committees (GAFREC) was published and required a complete review of how LRECs operated, including major changes to membership and the support and training offered to members.

The Governance Committee undertook a detailed and sustained programme of work during this complete review of the various LRECs. It was carried out following meetings with the LREC Chairs, Vice Chairs and Administrators and the process was completed in 2003 and implemented thereafter.

Professor Michael Farthing had initially chaired the Research Ethics Governance Committee and had been replaced by Professor Stephen Smith in early 2004. Professor Smith then moved to a new post and chaired his last meeting on 12 July 2004.

The OREC Manager pointed out that for one reason or another the Governance Committee had not met since that date, however, the work of the LRECs had been ongoing and no major policy issues or governance issues had arisen in that time which required the Research Ethics Governance Committee to meet and consider. All of the LRECs continued to be GAFREC compliant and the training for members of these Committees had been ongoing.

On the specific question of training, the OREC Manager referred to the following:

New Members “GAFREC Compliance Training” – 25 April 2005

The Board had commissioned the Centre for Professional Ethics at Keele University to come to Glasgow to train its twenty-seven new members who had joined since the previous training session undertaken by Keele in 2003. This training session was held at the University of Glasgow and had been very well received.

Existing Members “Annual Update Training “ – 23 May 2005

The Board commissioned amongst others Mrs Joan Perou, a national research ethics trainer working independently to speak on ICH/GCP and the effects of the new European Union Directive on LRECs. The training also included local speakers in the form of Professor Barry Gusterson who spoke on the issue of stored tissue and Professor Hazel Watson from Glasgow Caledonian University and a current LREC Member. There was also a session on Data Protection from Ms I Brown, NGD Data Protection Officer. Around one hundred lay and expert members attended and again the programme was exceedingly well received.

The OREC Manager then referred to the massive recruitment drive of over seventy-six new members which had taken place in 2003/2004 to ensure that all of the Board’s Ethics Committees were GAFREC compliant that is fifteen/eighteen members. Recruitment also continued at a steady pace with the Board’s OREC Manager replacing existing expert members and lay members as and when resignations took place. All LRECs were membership compliant.

The OREC Manager advised that the Dental Ethics Committee had been disbanded in July 2004 due to a lack of submissions. It had been agreed that all future dental submissions would go to the West Ethics Committees with dental representatives recruited to these Committees.

The OREC Manager concluded her update by referring to the annual reports which for the past two years had been prepared by LREC Administrators and Chairmen and in all cases had been passed to the Chief Scientist's office within the six month end of year deadline.

The Head of Board Administration then explained how the Governance Committee related to both the Board and the various LRECs throughout Greater Glasgow. In response to a question from Dr Groden, the OREC Manager clarified the admissions procedure to LRECs. She suggested that members access the COREC (Central Office for research Ethics Committees) website as this offered a very informative commentary on current research ethics procedures.

NOTED

5. FUTURE REMIT AND MEMBERSHIP ARRANGEMENTS

The Governance Committee received for consideration copies of a paper enclosing a revised Constitution amended to reflect its new membership and asking members to consider whether the Committee should be increased to include representation from medical management.

The Head of Board Administration advised that with the re-organisation of NHS Greater Glasgow into single system working the membership of the NHS Greater Glasgow Research Ethics Governance Committee had been revised. A new membership had been agreed and as a consequence the Constitution of the Committee had been amended. The changes to the Constitution were mostly semantic and reflected the fact that the number of Non Executive Members of the Committee had been increased from three to four. It had been suggested that the quorum for meetings of the Committee should now be the Chair and two other members.

The Head of Board Administration suggested that before coming to any firm decisions regarding its new Constitution, members may wish to consider whether representation from medical management would be appropriate. It was noted that the previous Committee included the Medical Directors of the four former NHS Trusts within Greater Glasgow as full members. Some discussion followed and Mrs Stewart suggested that the Medical Director of Greater Glasgow NHS Board should be asked to join the Committee as a full member and on those occasions he was unable to attend meetings of the Governance Committee, the Associate Medical Director of the Board should be asked to attend in his place. The Governance Committee agreed to this proposal.

DECIDED:

- (i) That the Medical Director of Greater Glasgow NHS Board be invited to join the Governance Committee as a full member and that the Associate Medical Director deputise in his absence at meetings of the Governance Committee, and
- (ii) That an amended Constitution reflecting these changes be submitted to the next meeting of the Governance Committee for approval.

**Head of Board
Administration**

**Head of Board
Administration**

6. LREC APPROVAL FOR RESEARCH INVOLVING CHILDREN

The Governance Committee received for information copies of correspondence regarding LREC approval for research involving children

The OREC Manager pointed out that in August 2005 she had received a letter from the Medical Director of the Yorkhill Division suggesting that all proposals relating to research involving children should be submitted to the Yorkhill LREC. The OREC Manager had responded to the Medical Director of Yorkhill by pointing out that UKECA (United Kingdom Ethics Committees Agency) did not recognise any committees UK wide which specifically reviewed clinical trials involving children. She had further pointed out that any LRECs reviewing research involving children had appointed on to their Committees two or three clinicians who had the required children's expertise to consider such proposals. These arrangements had worked very well over a number of years.

NOTED

7. REVIEW OF AND RECOMMENDATIONS PERTAINING TO LRECs IN GREATER GLASGOW

The Governance Committee received for consideration copies of a paper detailing the activity data for 2004/05 for the various LRECs within Greater Glasgow and making a series of recommendations regarding the future functioning of these LRECs.

By way of background, the OREC Manager pointed out that there had been a considerable reduction in submissions since the implementation of the EU Directive in April 2004 whereby prior to the EU Directive four or more UK Ethics Committees could review the same project. Once a fifth team came on board, the study was required to go to an MREC (Multi Centre Research Ethics Committee of which there were seven UK wide). This process had ceased with only one ethical review being required UK wide and this had contributed to the downturn in submissions to Committees with the potential for the overall workload to be reduced by 75%.

The NPSA (National Patients Safety Agency), UKECA and COREC in London were reviewing the findings of Lord Warner who was commissioned by the Department of Health to set up an ad hoc advisory group to report on the operation of NHS Research Ethics Committees. This report was published around June 2005 and commented on the need for a dramatic reduction in the number of ethics committees even suggesting as little as one committee per strategic Health Authority.

Another recommendation in the report was that site specific assessment might be best be carried out by Research and Development Departments who it was thought were in a better position to assess the capabilities and facilities of the local researcher. This was presently being put out for consultation due in the main to the perceived increase in workload for Research and Development Departments. If this was agreed and the indications were that this could be in place within the next twelve months, then there were even greater implications for some of the local LRECs within Greater Glasgow where their workload would reduce even more.

Taking all this into consideration, the OREC Manager advised that the Southern General Hospital LREC and the Victoria Infirmary LREC had already merged due to the dramatic fall in the number of submissions. The merger of these two LRECs had the agreement of the management team at the South Glasgow Division. The Chair of the new South Glasgow Research Ethics Committee was Mr Gerald Belton and the Vice Chair was Mr Tim Hems.

The OREC Manager appraised the current situation regarding the falling number of submissions being processed by the two LRECs at Glasgow Royal Infirmary and suggested that these two Committees be amalgamated. She pointed out that this suggestion had the full support of the current Chairman and Vice Chairman of both Committees and that they had initiated mechanisms to implement a merger proposal for the very near future. The Governance Committee agreed to this merger in principle and look forward to receiving an update on progress.

The OREC Manager appraised the current situation regarding the falling number of submissions being processed by the Primary Care Division 2 LREC and suggested that this particular LREC be merged with the Primary Care Division 1 LREC. At only seventeen submissions per year, the Primary Care Division 2 LREC was not GAFREC compliant. In view of this, the Governance Committee agreed to the merger of the two Primary Care Division LRECs in principle and looked forward to receiving an update on progress.

The OREC Manager appraised the current situation regarding the falling number of submissions being processed by the Yorkhill LREC. It was noted that these had fallen to only thirty-four per year which was neither sustainable for the future nor GAFREC compliant. The Governance Committee had already noted that other LRECs had paediatric membership for dealing with their proposals involving research with children. In view of this, it was agreed that the Yorkhill LREC be disbanded and any future proposals involving children in the acute sector be submitted to the West LRECs and any involving children in the community be submitted to the new amalgamated Primary Care Division LREC.

DECIDED:

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|---|---------------------|
| (i) That the Governance Committee note the merger of the Southern General Hospital LREC and the Victoria Infirmary LREC and the resultant establishment of the South Glasgow LREC. | OREC Manager |
| (ii) That the Governance Committee agree in principle to the merger of the two LRECs at Glasgow Royal Infirmary and await a further progress report on their amalgamation plans. | OREC Manager |
| (iii) That the Governance Committee agree in principle to the merger of the two LRECs at the Primary Care Division and await a further progress report on their amalgamation plans. | OREC Manager |
| (iv) That the Governance Committee agree to the disbandment of the Yorkhill LREC and any future proposals involving children be submitted to the appropriate LRECs in West Glasgow and the Primary Care Division. | OREC Manager |

**8. NEW NHS GREATER GLASGOW COMMITTEE ARRANGEMENTS :
FUTURE INTEGRATION OF ARGYLL AND CLYDE**

The Governance Committee received for consideration copies of a letter with enclosures from the Head of Board Administration requesting it to ensure equality of membership across the expanded Board boundary as from 1 April 2006.

The OREC Manager tabled a paper outlining the data activity for 2004 and 2005 of the current Argyll and Clyde LREC. She pointed out that the current levels of activity indicated that this Committee would not be GAFREC compliant in the future. In view of this, discussions should be held with colleagues in Argyll and Clyde to find ways of integrating their future research ethics proposals into the current Greater Glasgow network as soon as possible. It was noted that the Argyll and Clyde LREC was a Type II Committee.

Some discussion followed and it was suggested that a given number of members from the Argyll and Clyde LREC could be invited to join the South Glasgow LREC. Should this happen, it may be possible for some of the meetings of the South Glasgow LREC to be held in Paisley. It was agreed that the Head of Board Administration and the OREC Manager, along with the Chairman if possible, should meet with representatives of the Argyll and Clyde LREC to take this matter further. It was recognised that they may have their own views as to the best way forward.

DECIDED:

That the Head of Board Administration and OREC Manager proceed accordingly and report back to the Governance Committee on the outcome.

**Head of Board
Administration/
OREC Manager**

9. ACCREDITATION OF LRECs : ELEVATION OF WEST 1 COMMITTEE TO TYPE III AND WEST 2 COMMITTEE TO TYPE II CLINICAL TRIALS COMMITTEES

The Governance Committee received for information a paper detailing the accreditation of the two LRECs in West Glasgow.

The OREC Manager pointed out that the West Ethics Committee 1 had been selected by COREC to be in the first group of Scottish Ethics Committees to go through the “accreditation” process. Five Committees had been selected throughout Scotland, West Ethics Committee being the only one currently reviewing Type III clinical trials. Dates had been arranged on 6 February and 7 February 2006 for the inspection and accreditation review to take place. The Review Team would consist of three external reviewers.

The OREC Manager pointed out that the review team would spend a day with the Administrator verifying that the procedures in place were GAFREC compliant and on the second day attend the committee meeting, verbally reporting back at the end of the day to the Chair and the Administrator.

The outcome of the review and any recommendations would be followed up in writing.

DECIDED:

That the OREC Manager keep the Governance Committee informed of developments regarding this matter.

OREC Manager

10. ANNUAL REPORTS OF LRECs FOR 2004/05

The Governance Committee received for information copies of the Annual Reports for 2004/05 received from the various LRECs across Greater Glasgow.

The OREC Manager pointed out that under the terms of the Constitution of the NHS Greater Glasgow Research Ethics Governance Committee it should receive from all LRECs within Greater Glasgow their Annual Reports. Copies of these documents were available at the meeting for the perusal of members.

NOTED

11. DATE OF NEXT MEETING

The next meeting of the NHS Greater Glasgow Research Ethics Governance Committee would be held on Tuesday 4 July 2006 at 3.00 pm in Meeting Room A, Ground Floor, Dalian House, 350 St Vincent Street, Glasgow.

