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23 MAY 2003
North West Multi-centre Research Ethics Committee

Our ref: MREC 00/8/53

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21 May 2003

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Dr Kath Watson
BSRBR Study Co-ordinator
ARC Epidemiology Unit
Stopford Building
The University of Manchester
Oxford Road
MANCHESTER M13 9PT

Dear Dr Watson

MREC 00/8/53 Please quote this number on all correspondence

**Prospective observational study of the long term hazards of anti-TNF therapy
in rheumatoid arthritis**

- **Covering letter from Dr Kath Watson dated 14/1/03**
- **Letter of response from Dr Kath Watson dated 29/4/03**
- **Progress report form**
- **Summary of changes to patient questionnaires**
- **Revised patient information sheet and consent form, changes highlighted –
version 4 dated 1/12/00**
- **Consultant 6 monthly follow up questionnaire - version 5**
- **Patient baseline questionnaire - version 3 dated 8/3/02**
- **Patient 6-monthly follow-up questionnaire - version 3 dated 12/4/02**
- **Patient held diary - version 3 dated 8/3/02**
- **Consultant baseline questionnaire - version 4 dated 17/3/02**

The North West MREC considered the response to the Committees earlier concerns
as set out in our letter dated 5th March 2003

The Chairman of the North West MREC, acting under delegated authority, has
agreed there is no objection on ethical grounds to the proposed amendment to the
study. I am therefore happy to give you our approval on the understanding that you
will follow the protocol as agreed.

Yours sincerely

C. A. Stokes

Cathie Stokes
Manager, MREC North West