



East & North Hertfordshire Hospitals
Local Research Ethics Committee

Chairman: Dr Steve Eckersall
Administrator: Mrs Jenny Austin

Our ref: JCA/ .03

4 July, 2003

The Mezzanine
QEII Hospital
Howlands
Welwyn Garden City
Herts
AL7 4HQ

Tel: 01707 365397 or 328111 ext 5035
Fax: 01707 369010 or ext 5078
Email: jenny.austin@nhs.net

Dear Heather

Re: ENHLREC/03-06-18/M109 : The effectiveness of a user-led lifestyle development group training intervention for people with bipolar disorder

The chairman on behalf of the Committee has considered your response to the issues raised by the Committee at the first review of your application on 25th June 2003 as set out in our letter dated 3rd July 2003. The documents considered were as follows:

- Introductory Letter to Clients, Version 2 dated 2.7.03
- Patient Information Sheet, Version 2 dated 2.7.03
- Consent Form, Version 2 dated 2.7.03

The Chairman, acting under delegate authority, is satisfied that your response has fulfilled the requirements of the Committee. You are therefore given approval for your research on ethical grounds provided that you comply with the conditions of approval set out below:

Conditions

- You do not undertake this research in a NHS organisation until the relevant NHS management approval has been received.
- You do not deviate from, or make changes to, the protocol without prior written approval of this Committee, except where this is necessary to eliminate immediate hazards to research participants or when the change involves only logistical or administrative aspects of the research. In such cases the Committee should be informed within seven days of the implementation of the change.
- You send a progress report to this Committee one year from the date on this letter and thereafter on an annual basis.
- You send a final report to this Committee when your research is completed which must be sent within 3 months of completion.
- If you decide to terminate this research prematurely you must send a report to this Committee within 15 days, indicating the reason for the early termination.
- You must advise this Committee of any unusual or unexpected results that raise questions about the safety of the research.
- The project must be started within 3 years of the date on this letter.

Please ensure that you have received approval from the Research & Development Department before commencing your research.

All correspondence should be sent to the administrator. Please ensure that you quote our study reference numbers on **all** future correspondence.

Yours sincerely

Jenny Austin

Jenny Austin
Administrator - East & North Hertfordshire Hospitals LREC

cc Dr Tim Gale, R&D Office, Hertfordshire Partnership NHS Trust, Dept of Psychiatry, QEII

Enc List of Members