

Wakefield Local Research Ethics Committee

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1 December 2005

Dr M Donmall
National Drug Evidence Centre
Manchester Science Park
Rutherford House
40 Pencroft Way
Manchester
M15 6GG

Dear Mr Donmall

Full title of study: **National Drug Treatment Outcomes Research Study (DTORS)**
REC reference number: **05/Q1204/43**

This revised letter is to confirm that Wakefield REC has given you approval to carry out this study on a nationwide basis at any NHS Trust. Thank you for your letter responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Committee held on 1st November 2005. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Details of Proviso

You will recall, during your attendance at the above meeting that the Committee requested that the final sentence on Consent Form 2 (end of interview) which read: "This consent will remain valid until revoked by me in writing", be either deleted or amended.

You requested that, following an approach to NatCen, you would be willing to state that participants could opt out of the agreement at any time by contact NatCen. Having had the opportunity to discuss this issue with them, we confirm that your letter dated 3rd November 2005 responds satisfactorily to the request of the Committee.

Confirmation of ethical opinion

On behalf of the Committee, therefore, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised and mentioned previously.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out above. You are advised to study the conditions carefully.

This favourable opinion is valid nationwide and the approval is for any NHS Trust in the UK.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application	1	27 July 2005
Investigator CV	1	27 July 2005
Protocol		None specified
Covering Letter		27 July 2005
Letter from Sponsor – Letter from Funder		15 April 2005
Copy of Questionnaire Non validated questionnaire	3.0	26 July 2005
Letters of Invitation to Participants	4.0	26 July 2005
Participants Information Sheet	4.00	26 July 2005
Participant Consent Form	4.0	26 July 2005
Statement of indemnity arrangements		26 July 2005
DAT/Agency letters and leaflets	4.0	19 July 2005
Covering Letter		3 October 2005
Revised Information Sheet	6.0	18/10/2005
Consent Form 1 (before interview)	5.0	18/10/2005
Consent Form 2 (end of interview)	6.0	18 October 2005
Information for respondents	6.0	18 October 2005
Covering Letter with further response		3 November 2005
Revised Consent Form 2 (end of interview)	7.0	3 November 2005

Research governance approval

All researchers and research collaborators who will be participating in the research must obtain research governance approval from the relevant care organisation before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/Q1204/49

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Margaret L Faulk
Chair

