NHS
National Research Ethics Service
Ealing & West London Research Ethics Committee
Room 4W/12, 4th Floor West
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

Telephone: 020 8846 7255
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18 March 2010

Dr Susan Young,
Dept of Forensic Mental Health Science
PO Box 23
Institute of Psychiatry
De Crespigny Park
LONDON SE5 8AF

Dear Dr Young,

Study Title:	**An evaluation of the Reasoning and Rehabilitation programme for adults with mental health problems. A trial of a pro-social competence programme with patients residing in medium and low secure settings. REF: 09H071-70**
REC reference number:	**09/H0710/70**
Protocol number:	**1**

Thank you for your letter of 15 March 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of

the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

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

Document	*Version*	*Date*
Covering Letter		13 November 2009
REC application		19 November 2009
Protocol	1	01 November 2009
Investigator CV	Young	03 March 2009
Evidence of insurance or indemnity	Zurich	31 July 2009
Questionnaire: R&R2 MHP		
Questionnaire: Pre-Treatment Assessment		
Questionnaire: Post Treatment		
Questionnaire: Control Assessment (Time 1)		
Questionnaire: Control Assessment (Time 2)		
CV	Oliver	
CV	Rees-Jones	
Questionnaire: Pre Treatment Assessment (Time 1)	Group PRE	
Questionnaire: Post Treatment Assessment (Time 2)	Group Post	
Questionnaire: Three Month Follow-Up Assessment		
Covering Letter		05 February 2010
Participant Information Sheet: Control	2.0	01 January 2010
Participant Information Sheet: Group	2.0	01 January 2010
Participant Consent Form: Control	2.0	01 January 2010
Participant Consent Form: Treatment	2.0	01 January 2010
Response to Request for Further Information		15 March 2010

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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0710/70	**Please quote this number on all correspondence**

Yours sincerely,

Colin Standfield
Chair

Email: Alene.Pointon@imperial.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: SLaM/IoP R&D Office
Room W1.08, Institute of Psychiatry
King's College London
De Crespigny Park
London
SE5 8AF

National Research Ethics Service
Ealing & West London Research Ethics Committee
Room 4W/12, 4th Floor West
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

Telephone: 020 8846 7255
Facsimile: 020 8846 7280

30 November 2009

Dr Susan Young
Consultant Clinical Psychologist
Dadd Centre
Broadmoor Hospital
Crowthorne
Berkshire RG45 7EG

Dear Dr Young,

Study Title: **Reasoning and Rehabilitation in ADHD adults; a waiting list controlled trial of a pro-social competence programme on DSPD patients detained in high security.**
REC reference number: **09/H0710/46**
Protocol number: **1**

Thank you for your letter of 4 August 2009 (incorrect date), responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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, subject to the conditions specified below.

Ethical review of research sites

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Approved documents

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Document	*Version*	*Date*
Covering Letter		04 August 2009
Participant Information Sheet	2	23 September 2009
Participant Consent Form	2	23 September 2009
Response to Request for Further Information		
Covering Letter	Young	04 August 2009
REC application		08 September 2009
Investigator CV	Young	10 July 2009
Letter from Statistician	Muhammad	
Questionnaire: Antisocial Personality Disorder	SCID-II	
Questionnaire: Patient Motivation Inventory	PMI	
Questionnaire: The Barkley Current Symptoms Scale - Self-report Form		
Questionnaire: Personal Affect/Reactions to Provocation Scale		
Questionnaire: Ways of Coping Scale		
Protocol	1	15 April 2009
Referees or other scientific critique report	Tsappis	09 July 2009
Interview Schedules/Topic Guides	R&R2 Interview for Dropouts	
Questionnaire: MVQ		
Questionnaire: SPSI-R:S		
Questionnaire: Rate-S		
Questionnaire: R&R Data Collection Form		

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09/H0710/46	**Please quote this number on all correspondence**

Yours sincerely,

p.p. **Colin Standfield**
Chair

Email: Alene.Pointon@imperial.nhs.uk

Enclosures: "After ethical review – guidance for researchers", *SL- AR2*

Copy to: *Ms Maria Tsappis*
R&D office