Fluoxetine Or Control Under Supervision (FOCUS)

Steering Committee Charter

Trial Full Title	**Fluoxetine Or Control Under Supervision**
Protocol short title	**FOCUS**
REC No	**11/SS/0100**
EudraCT Number	**2011-005616-29**
ISRCTN Number	**ISRCTN83290762**
CTA Number	**01384/0221/001-0001**
Investigational Product	**Oxactin 20mg**
Chief Investigator(s)	**Professor Gillian Mead** **Professor Martin Dennis**
Co-Sponsors	**University of Edinburgh & NHS Lothian**

The background of the FOCUS trial, its objectives, assessments, interventions etc., are described in the trial protocol. The purpose of this document is to define the roles and responsibilities of the trial TSC and to guide its activities, its relationship with other trial committees, its membership, and the format, purpose and timings of its meetings in accordance with the NIHR TSC Standard Constitution & Terms of Reference. The day-to-day management of the trial is the responsibility of the Chief Investigator(s) and Trial Management Group (TMG) has been set up to assist with this function.

1. The Role of the TSC

The role of the Trial Steering Committee (TSC) is to provide overall supervision for the FOCUS Trial on behalf of the Trial Sponsor and the Trial Funder and to ensure that the trial is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

The main features of the TSC are:

- To provide advice, through its Chair, to the Chief Investigator(s), the trial Sponsor, the Trial Funder, the Host Institution and the Contractor on all appropriate aspects of the trial.
- To concentrate on progress of the trial, adherence to the protocol, patient safety and the consideration of new information of relevance to the research question.
- The rights, safety and wellbeing of the trial participants are the most important considerations and should prevail over the interests of science and society.
- To ensure that all relevant ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments.
- To provide advice to the investigators on all aspects of the trial

2. The Role of the TSC Chair

The Chair of the TSC is directly answerable to the NIHR HTA programme, as funder.

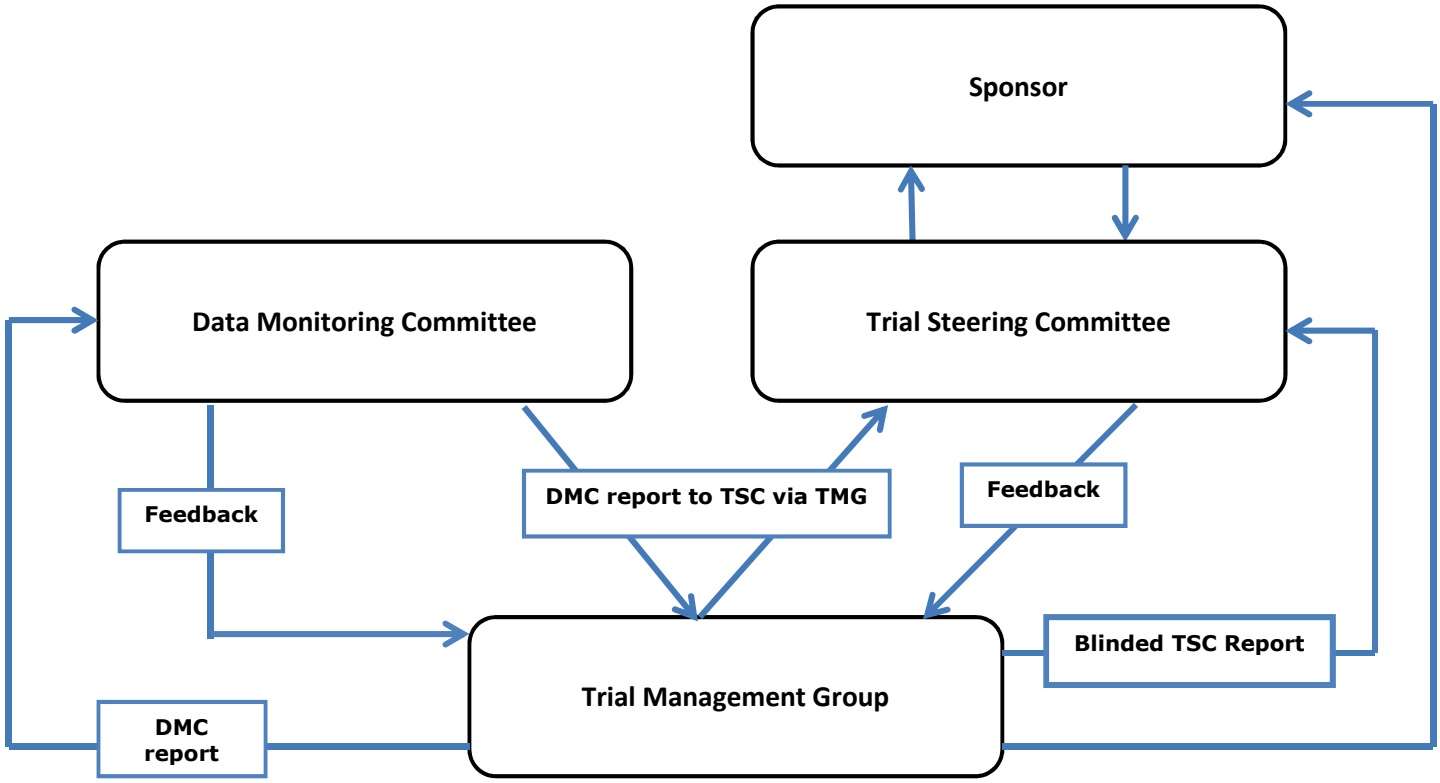
The Chair's responsibilities include:

- Arranging a schedule of meetings to align with the project plan.
- Establish clear reporting lines – to the Funder, Sponsor etc
- Being familiar with relevant guidance documents and with the role of the DMC
- Providing an independent, experienced opinion if conflicts arise between the needs of the research team, the Funder, the Sponsor, the participating organisations
- Leading the TSC to provide regular, impartial oversight of the trial, especially to identify and pre-empt problems
- Ensuring that major amendments to the protocol are debated and endorsed by other members of the TSC; letters of endorsement should be made available to the project team when requesting approval from the funder and sponsor for matters such as changes to the protocol.
- Being available to provide independent advice as required, not just when TSC meetings are scheduled.
- Commenting on extension requests and where appropriate, providing a letter of recommendation to accompany such a request
- Commenting in detail comment (when appropriate) regarding the continuation or termination of the project.

3. Membership and interaction of the FOCUS TSC

HTA appointed Chair	Professor David Stott	David.J.Stott@glasgow.ac.uk
Other HTA appointed members	Dr Graham Ellis	g.ellis@nhs.net
	Professor Pippa Tyrrell	pippa.tyrrell@manchester.ac.uk
HTA appointed Independent Statistician	Dr Jonathan Emberson	jonathan.emberson@ctsu.ox.ac.uk
HTA appointed Lay members	David Burgess	damburgess@tiscali.co.uk
	Judith Williamson	williamson@questant.fsnet.co.uk
Chief investigators	Professor Gillian Mead	Gillian.mead@ed.ac.uk
	Professor Martin Dennis	Martin.dennis@ed.ac.uk
Trial Management Group	Dr Stephanie Lewis	Steff.Lewis@ed.ac.uk
	Karen Innes, Trials Manager	Karen.innes@ed.ac.uk
	Carol Williams, Trial Co-ordinator	Carol.williams@ed.ac.uk
	Jonathan Drever, Data manager	Jonathan.drever@ed.ac.uk
Sponsor Representative	Alice Graves, ACCORD	Alice.graves@ed.ac.uk
HTA Programme Manager	Lesley Dodd	L.Dodd@southampton.ac.uk

Interaction between TSC/SSC and other study committees



4. FOCUS TSC meetings

- The Trial Manager or delegate will organise meetings on behalf of the Chief Investigator
- Prior to a TSC meeting a report will be prepared by the TMG with input from the trial manager, data manager and circulated to TSC members at least a week before the meeting.
- Wherever possible the TSC will meet in person at least annually however where this is not possible for some members teleconferencing facilities will be provided to allow members to participate. Additional meetings can also be held anytime at the request if the CI or Chair.
- All TSC members will be provided with study documents (e.g. protocol, proposed statistical analysis plan (SAP), PIS, CRF etc) and the TSC report for review at least 1 week prior to the meeting.
- The final TSC meeting will be arranged when target recruitment is completed, all data collected and cleaned and the database is locked. This final meeting will be held to discuss final/completed data and interpretation, and publication timeless. If the study is terminated prematurely, no final study meeting is required.
- Minutes will be prepared by the trial manager or delegate. These minutes will describe the proceedings and include the recommendations of the TSC. All members must agree the minutes and these will be signed off by the TSC Chair on behalf of all members. Minutes will be circulated to all TSC members, the TMG, the Sponsor and, if appropriate, the Trial Funder. Approved Minutes will be filed in the Trial Master File.

5. NIHR TSC Standard Constitution & Terms of Reference

•All primary research projects are required to establish a TSC (or occasionally a SSC)

•The NIHR HTA Programme Director will vet the nominees and appoint the chair and members

- All TSCs/SSCs are to have an independent chair
- All TSCs/SSCs are to have a minimum of 75% majority of independent members
- Only appointed members will be entitled to vote and the chair will have a casting vote
- The minimum quoracy for a meeting to conduct business is 67% of appointed members
- The chair and members to sign and maintain a log of potential conflicts and/or interests
- Attendance at TSC/SSC meetings by non-members is at the discretion of the chair
- The primary TSC/SSC reporting line is via the chair to the NIHR HTA Programme Director

Composition of the TSC/SSC

- The HTA Programme does not accept generic CTU TSCs
- An independent chair (UK based and/or holding a substantive UK based appointment)
- Independent clinicians with relevant expertise
- Independent statisticians/epidemiologists/diagnosticians with relevant expertise

- At least one individual who is able to contribute a patient and/or wider public perspective.
- Ideally, the TSC/SSC should invite observers, including a representative of the sponsor and a representative from the research network to meetings
- An indication of any proposed overseas members should have been given at the full application stage and feedback on such proposals supplied following the Commissioning Board's consideration of the application
- Although there may be periods when more frequent meetings are necessary, the TSC/SSC should meet at least annually
- Meetings should be scheduled to follow shortly after DM(E)C meetings so that reports from that group can be considered
- Minutes of meetings should be sent to all members, the sponsor, the funder and the trial master file

The responsibility for calling and organising TSC/SSC meetings lies with the Chief Investigator, in association with the Chair.

There may be occasions when the Trial Sponsor or the Trial Funder will wish to organise and administer these meetings for particular trials. In the NIHR HTA programme's case this is unlikely, but it reserves the right to attend any meeting and the right to convene a meeting of the TSC/SSC in exceptional circumstances.

6. References:

1. **NIHR HTA Research Governance Guidelines Trial Steering Committee (TSC) or Study Steering Committee (SSC) V3 25th April 2012**

Annexe 1

Agreement and competing interests form for independent members of the FOCUS Trial Steering Committee.

Please complete the following document and return by post or scan and email to: Karen Innes, Trials Manager, Centre for Clinical Brain Sciences (CCBS), University of Edinburgh, Chancellor's Building, Room FU303C, 49 Little France Crescent, Edinburgh, EH16 4SB, Tel: 0131 465 9610 karen.innes@ed.ac.uk

☐ I have read and understood the TSC charter Version 1.0 dated 28/01/2015

☐ I agree to join the TSC for this trial as an independent member

☐ I agree to treat all sensitive trial data and discussions confidential

The avoidance of any perception that members of the TSC may be biased in some fashion is important for the credibility of the decisions made by the TSC and for the integrity of the trial.
Possible competing interest should be disclosed via the trials office. In many cases simple disclosure up front should be sufficient. Otherwise, the (potential) TSC member should remove the conflict or stop participating in the TSC Table 1 lists potential competing interests:

Table 1: Potential competing interests for independent members

1. Stock ownership in any commercial companies involved. 2. Stock transaction in any commercial company involved (if previously holding stock) 3. Consulting arrangements with the Sponsor 4. Frequent speaking engagements on behalf of the intervention 5. Career tied up in a product or technique assessed by the trial 6. Hand-on participation in the trial 7. Involvement in the running of the trial 8. Emotional involvement in the trial 9. Intellectual conflict e.g. strong prior belief in the trial's experimental arm 10. Involvement in regulatory issues relevant to the trial procedures 11. Investment (financial or intellectual) in competing products 12. Involvement in the publication

☐ **NO,** I have no competing interests to declare

☐ **YES,** I have competing interests to declare (please detail below)

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Name: _____

Signed: _____ Date: _____