Standard Operating Procedures (SOP) for: Randomisation and Unblinding Procedure for the CONFIDeNT Study			
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Effective Date:	**5 JAN 2012**	Review Date:	**5 JAN 2015**

Author:	**Emma Horrocks, Clinical Research Fellow**

Authorisation:	
Name / Position	**Professor Charles Knowles/ Chief Investigator**
Signature	**XXXX**
Date	**4/1/12**

Staff signatures: I have read, understood and will comply with this SOP		
Name (please print)	Signature	Date

Purpose and Objective:
To define the procedure for randomisation of study participants for the CONFIDeNT Study.

SOP Text

	Responsibility	Activity
1.	Research Team	**Performing Randomisation:** On visit 2, participants will be randomised, using a web-based computer program, to receive either PTNS or sham. Prior to allocation, the participant must have provided informed consent. CRF 1 and CRF 2 (Eligibility Criteria and Initial Assessment) must have been completed and checked by another member of the research team. CRF 3 (Questionnaires) must also have been completed. These documents should be completed.in accordance with SOP 10 – Document Completion. Details of the randomisation website are as follows: `https://ctu4.nottingham.ac.uk/1141/login.asp` The randomisation programme is a bespoke system designed and held at the Nottingham Clinical Trials Unit (NCTU) and run by the NCTU data manager. The system is fully tested by the trial team and PCTU statistician. The research nurse/researcher at each site will log on using a site specific username and password, which will be provided by the Research Fellow during the Site Initiation Visit. Following successful log on the researcher will select their site from the drop-down menu (the only other choice being the test site). They will then select 'Enrol new participant' from the list of options. The screen automatically appears which requires input of the unique participant identifier, sex, date of birth and initials of participant. Once these are entered, 'click submit'. The next screen allows the researcher to check the details are correct, and if not, to amend them, or if they are correct, click 'next form'. The next page requires the researcher to again check the details, and if incorrect, click 'prev form' to go back to the previous form and amend the details. If the details are correct, the researcher is asked to check two boxes, one agreeing that the data entered is correct, and the other agreeing that the participant meets the entry criteria for the CONFIDeNT Trial, as outlined in the Protocol. If these two boxes are checked, the researcher can then press the 'randomise' button. This will allow immediate on-screen randomisation with the allocation showing on the next screen. The researcher will then fill in the randomisation information on CRF 4. This CRF will be held in a 'Randomisation File' in each site, which contains only CRF 4. Each participant's CRF 4 will be kept in a concealed envelope within this Randomisation File to prevent accidental unblinding to researchers not completing

		treatment for this participant.. This ensures that prior to each treatment the unblinded researcher performing the treatment can check the randomisation allocation, but it will not be in the participants CRF folder to avoid accidental unblinding of other site researchers. The participants Unique Participant Identifier is made up of 3 letters followed by 3 numbers. The letters are unique to each site and are documented in the CONFIDeNT trial protocol(Appendix A). The numbers are allocated at each site and are allocated sequentially to each participant during screening for the trial, beginning with 001. The allocation will be known by the researcher carrying out the first treatment. Thereafter, at each visit, the participant will receive the PTNS or sham as identified by the randomisation CRF 4. Once the randomisation has been performed, an automated, blinded, pseudo-anonymised email will be sent to the PI at that site, informing them that the randomisation has taken place. An automated, unblinded, pseudo -anonymised email will also be sent to the Trial Manager, Natasha Stevens, in order to keep a centralised trial randomisation log. Each site will be able to log on to the randomisation tool and view the participants that have been randomised at their site. This can be done by logging on to the website, and selecting 'View a summary of randomisations performed' from the list. This will show details of the participants randomised but will NOT show randomisation allocation, in order to prevent unblinding. If CRF 4 containing the randomisation allocation is not completed immediately following on screen randomisation, it will not be possible for the research sites to access information about the allocation. If this occurs, the site should contact the Trial Manager, Natasha Stevens, contact details below, who will be able to access the allocation for all participants.
2.	PI/ Research Team	**Procedure if Randomisation Tool not working:** If, for any reason, a site is unable to perform a randomisation using the online tool, in the first instance the site should contact the Research Fellow Emma Horrocks, or Trial Manager, Natasha Stevens (see details below). Assistance can be given over the phone regarding the use of the online randomisation tool. If the website or internet is not working at a particular site, Natasha Stevens, Trial Manager, can perform randomisation on behalf of the site, and relay the randomisation to the site over the phone and via a pseudo-anonymised email. Failing this, if the website is not functioning at any site, the Nottingham Clinical Trial Unit should be contacted to conduct randomisation. Contact details:

		Dan Simpkins IT/Data Manager Nottingham Clinical Trials Unit Office 2009, C Floor, South Block Queen's Medical Centre Tel: XXXX Email: XXXX
3.	PI/Research Team	**Unblinding:** If, for any reason, un-blinding is required, in the first instance the permission of the Local Principal Investigator should be sought. If they are unavailable, or this is not possible, the Academic Clinical Fellow, Emma Horrocks, or the Chief Investigator, Charles Knowles should be contacted. Emma Horrocks Email: XXXX Tel: XXXX Charles Knowles: Email: XXXX Tel: XXXX Once permission is sort, the local investigator can break the randomisation code by looking at CRF 4 for the appropriate participant. If this is not possible, because the information is unavailable out of hours, the lead site should be contacted. In the first instance the Trial Manager can be contacted, who can access the randomisation code by the computer programme, and if she is unavailable the Data Manager, Sandy Smith, should be contacted. Only the trial manager and data manager will have access to the randomisation data within the database. Natasha Stevens (Trial Manager) Email: XXXX Tel: XXXX Sandy Smith (Data Manager) Email: XXXX Tel: XXXX

Version	Reason for Change	Date Approved
1.0		
2.0		