



## Preparing Trial Documentation

### No. 004

#### Preparing the trial documents for printing

The trial documents can be downloaded from the TICH-3 website documents page. Please download the documents from here to ensure you are using the current version of the document. <http://tich-3.ac.uk/docs/>

Document Title	Preparation Requirements
Participant Short Information Sheet TICH-3	<ul style="list-style-type: none"> <li>Delete [form to be printed on local headed paper] and insert the site's logo/header</li> <li>Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of randomisation along with the name of the participant</li> </ul>
Participant Information Sheet TICH-3	<ul style="list-style-type: none"> <li>Delete [form to be printed on local headed paper] and insert the site's logo/header</li> <li>Do not enter the name(s) of Local Researcher(s) as the team may change over time, this must be handwritten in at the time of randomisation</li> <li>Insert local PALS information, then format this text to be black instead of green</li> <li>Insert 'East Midlands - Nottingham 2' for the Research Ethics Committee that has reviewed the study, then format this text to be black instead of green</li> </ul>
Participant Full Consent Form TICH-3	<ul style="list-style-type: none"> <li>Delete [form to be printed on local headed paper] and insert the site's logo/header</li> <li>Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of randomisation along with the name of the participant</li> </ul>

Document Title	Preparation Requirements
Relative (Legal Rep) Short Information TICH-3	<ul style="list-style-type: none"> <li>Delete [form to be printed on local headed paper] and insert the site's logo/header</li> <li>Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of randomisation along with the name of the participant</li> </ul>
Relative (Legal Rep) Information Sheet TICH-3	<ul style="list-style-type: none"> <li>Delete [form to be printed on local headed paper] and insert the site's logo/header</li> <li>Do not enter the name(s) of Local Researcher(s) as the team may change over time, this must be handwritten in at the time of randomisation</li> <li>Insert local PALS information, then format this text to be black instead of green</li> <li>Insert 'East Midlands - Nottingham 2' for the Research Ethics Committee that has reviewed the study, then format this text to be black instead of green</li> </ul>
Relative (Legal Rep) Full Consent Form TICH-3	<ul style="list-style-type: none"> <li>Delete [form to be printed on local headed paper] and insert the site's logo/header</li> <li>Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of randomisation along with the name of the participant</li> </ul>

Document Title	Preparation Requirements
Professional (Legal Rep) Short Information Sheet and Consent TICH-3	<ul style="list-style-type: none"> <li>Delete [form to be printed on local headed paper] and insert the site's logo/header</li> <li>Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of randomisation along with the name of the participant</li> </ul>

### **Professional (Legal Rep) Information Sheet TICH-3**

- Delete [form to be printed on local headed paper] and insert the site's logo/header
- Do not enter the name(s) of Local Researcher(s) as the team may change over time, this must be handwritten in at the time of randomisation
- Insert local PALS information, then format this text to be black instead of green
- Insert 'East Midlands - Nottingham 2' for the Research Ethics Committee that has reviewed the study, then format this text to be black instead of green

### **Professional (Legal Rep) Full Consent Form TICH-3**

- Delete [form to be printed on local headed paper] and insert the site's logo/header
- Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of randomisation along with the name of the participant

*Note: remember when the participant completes the written follow on consent the boxes need to be initialled by the participant (if they have capacity to do do). Please do not tick the boxes.*

### GP Letter

After a participant has been enrolled into the TICH-3 trial you will need to send a letter to their GP informing them of their patient's participation in the trial.

Preparing the template: Delete [form to be printed on local headed paper] and insert the site's logo/header. Insert the local research teams contact details.

Do not print GP templates, the letters will be specific for each participant. When completing the GP letter please enter

- Date letter is typed
- GP address
- Name of GP
- Name of patient
- DOB of patient
- Name of local PI, job title and signature

Don't forget to include a copy of the participant information sheet to be sent with the letter.

Please save the letter to the participant's medical records as well as their CRF.

### Documents ready for enrolment

Once you have localised

- Short information sheets
- Information sheets
- Consent forms

We recommend you print a small batch of each document ready for the emergency randomisation process and make sure all the local team know where these documents are stored. Please make sure you are using the most up to date version before consenting the participant.

### Emergency phone numbers

We advise printing off the emergency contact numbers due to rapid enrolment. Please call the emergency phone numbers for enquires regarding.

- Eligibility
- Urgent medical enquires (including unblinding)
- Randomisation problems

### Contact

If you require any further assistance in preparing the trial documentation please contact the trial team [tich-3@nottingham.ac.uk](mailto:tich-3@nottingham.ac.uk)