

Name of Study:

Participant Identification Number:

CONSENT TO ENTER VOLUNTEER DETAILS IN 'The Over Volunteering Prevention System' database (TOPS)

At the University of Leicester, and the University Hospitals of Leicester NHS Trust, we ask our research volunteers not to participate in more than one interventional study at any time. We also request that they leave a minimum interval of 3 months between studies. To safeguard volunteers, we and other organisations like ours in the UK keep a database of healthy volunteers and when they take part in studies.

WE WILL ENTER ONTO THE DATABASE:

- your National Insurance number (if you're a UK citizen); or
- your passport number and country of origin (if you're not a UK citizen); and
- the date of your last dose of study medicine
- the date of your last blood sample (where over 100mls is drawn over the course of the study).

If you withdraw from the study before you receive any study medicine, the database will show you did not receive a dose. Only staff at the University of Leicester, University Hospitals of Leicester NHS Trust and other medicines research units can use the database. The details you provide will be kept on the TOPS database for at least 2 years. We may call other Units, or they may call us, to check your participation in studies.

Information on the TOPS database is found on the website: <http://www.tops.org.uk/site/cms/>

Please Initial box

- I confirm that I have read and understand the information above. I have had the opportunity to ask questions and have had these answered satisfactorily
- I agree to my details being entered into the UK database of healthy volunteers for the purposes stated above

Name of participant

Date

Signature

Name of person taking consent

Date

Signature

When completed, 1 for participant (copy); 1 for Investigator Site File (original); 1 Medical Notes (copy)