NIHR | King's Clinical Research Facility

Use of The Over-Volunteering Prevention System (TOPS) for Phase 1 Healthy Volunteer Trials in the King's Clinical Research Facility

Document Detail	
Document type	Standard Operating Procedure
Document name	CRF-STU-SOP-6: Use of The Over-Volunteering Prevention System (TOPS) for Phase 1 Healthy Volunteer Trials in the King's CRF
Document location	Q-Pulse \ CRF Documents
Version	6.0
Effective from	25 May 2022
Review date	25 May 2024
Author	Angelina Twumasi, CRF Quality Assurance Manager
Approved by	Elka Giemza, CRF Manager
Authorised by	Professor Peter Goadsby, CRF Director
Related documents	CRF-STU-FRM-5: TOPS Participant Information and Consent Form CRF-STU-SOP-7: Healthy Volunteer Studies in the King's CRF TOPS User Manual
Keywords	TOPS, consent, CTIMP, Phase 1, volunteer
Supporting references	See Section 6.0

Change History		
Date	Change details, since approval	Approved by
August 2017	1. Updated related documents and references (including new links to the TOPS database and user manual) 2. Minor administrative changes to the text 3. No change to the procedure is required	E. Giemza
February 2018	1. Section 5.3: additional information added regarding the registration requirements for UK citizens and non-UK citizens, clarifying when the NI number or passport number should be used 2. Section 5.13: guidance added on correcting errors and deleting data 3. Section 6.0: updated links for the HRA website and for the current version of the TOPS manual	E. Giemza

February 2020	1.Updated header to incorporate new NIHR logo. 2. Section 5.13: updated e-mail contact for TOPS. 3. All links checked and working. 4. 5.6: included more information regarding site administration abilities. 5. 5.15 Guidance on how to contact TOPS if any queries.	E. Giemza
April 2022	1. Minor administrative changes 2. Section 5.3- Clarification regarding a non-UK passport	E.Giemza
May 2022	1. Clarification and additional instructions added on how to contact other research departments	E. Giemza

Review History		
Date	Review details	Approved by
August 2017	Review of v1.0 conducted by Georgia Bullock, CRF QA Manager, as per the review date. Changes made as per 'Change History' and re-issued and v2.0	E. Giemza
February 2018	Review of v2.0 conducted by Georgia Bullock, CRF QA Manager, due to a query over the registration requirements and a new version of the TOPS manual. Changes made as per 'Change History' and re-issued as v3.0	E.Giemza
February 2020	Review of v3.0 conducted by Tracey Fong, CRF Clinical Research Nurse as per the review date. Changes made as per 'Change History' and re-issued as v4.0.	E. Giemza
April 2022	Review of v4.0 conducted by Angelina Twumasi, CRF Quality Assurance Manager as per the review date. Changes made as per 'Change History' and re-issued as v5.0.	E. Giemza
May 2022	Review of v5.0 as result of CAPA conducted by Elka Giemza, CRF Interim Quality Assurance Manager as per the review date. Changes made as per 'Change History' and re-issued as v6.0	E.Giemza

1.0 Background

1.1 The Over-Volunteering Prevention System (TOPS) is a database of consented healthy volunteers who are participating in a Phase 1 CTIMP (Clinical Trial of an Investigational Medicinal Product) in the UK. It is free to all UK organisations undertaking such trials. The database is hosted and managed by the Health Research Authority (HRA).

1.2 TOPS aims to reduce the risk of volunteers participating in more than one trial at the same time and also aims to prevent volunteers from participating too frequently in trials of new medicines.

1.3 There are ethical, scientific and medical reasons why healthy volunteers should not participate in trials of potential new medicines too regularly, for example, having an excessive volume of blood taken or receiving medicines which may interact with each other in consecutive studies. It is also unethical for volunteers to be exposed to medicinal products on a regular basis, from which they receive no benefit.

1.4 It is now a standard condition of ethical approval that all healthy volunteer Phase 1 trials register research participants onto TOPS and that the record for each volunteer is completed to specify whether or not they received a dose of the study medicine. The MHRA Phase 1 Accreditation Scheme also requires a system to be in place for addressing over-volunteering in healthy volunteer Phase 1 studies.

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for obtaining consent for TOPS from healthy volunteers participating in a Phase 1 CTIMP in the King's Clinical Research Facility (CRF).

2.2 The purpose of this SOP is also to describe the procedure for registering consented healthy volunteers on the TOPS database.

3.0 Scope

3.1 This SOP is applicable to all core CRF staff who may need to access TOPS and register volunteers.

3.2 This SOP is also applicable to all Principal Investigators, and their study teams, who are running Phase 1 CTIMPs involving healthy volunteers in the CRF.

3.3 This SOP applies **only** to Phase 1 CTIMPs involving healthy volunteers. It does not apply to any other healthy volunteer studies or to Phase 1 trials involving only patients.

4.0 Responsibilities

4.1 It is the responsibility of the Principal Investigator, or appropriate member of the study team, to inform volunteers that they will need to provide the required information for TOPS at their first visit to the CRF.

4.2 It is the responsibility of the Principal Investigator, or appropriately qualified member of the study team, to obtain consent for TOPS. This may be delegated to the CRF Research Nurses if appropriate and agreed in advance.

4.3 Once consent has been obtained, the person who registers the volunteer on TOPS will be responsible for ensuring that TOPS is updated as required for that volunteer.

5.0 Procedure

Consent

5.1 All healthy volunteers participating in Phase 1 CTIMPs in the CRF need to give informed consent to have their details entered onto TOPS.

5.2 Consent for TOPs can be included in the Informed Consent Form for the relevant trial. If this has not been done, consent should be taken using the CRF's TOPS Participant Information and Consent Form *(CRF-STU-FRM-5)*. The form has received approval from the HRA.

5.3 TOPS requires the following information to be provided by the volunteer:

- National Insurance Number (UK citizens) **or**
- Passport Number and Country of Origin (Non-UK citizens)

Please note:

- If the volunteer is a UK citizen, their National Insurance (NI) number must be used for registration (and not a passport number).
- If the volunteer is a foreign national with a non-UK passport, their passport number must be used for registration along with the country of issue, even if they have an NI number.
- When using the passport number to register a foreign national in TOPS, the unit should check whether the passport has been issued in the last year. It is good practice to check because the passport number changes when an individual's passport is renewed or updated (e.g. if a volunteer has changed their name) and so you should ask for the previous passport number (if available) to check TOPS as well.

5.4 The Principal Investigator for the trial, or appropriate delegate, should obtain the volunteer's consent for TOPS.

5.5 Healthy volunteers who decline to give consent for TOPS cannot participate in Phase 1 CTIMPs in the CRF.

TOPS

5.6 Administrators for TOPS in the CRF can set up usernames and passwords for other users so that they can access the system and add volunteer details. Site administrators can also view and edit contact details for staff at their unit.

5.7 TOPS can be accessed here: TOPS

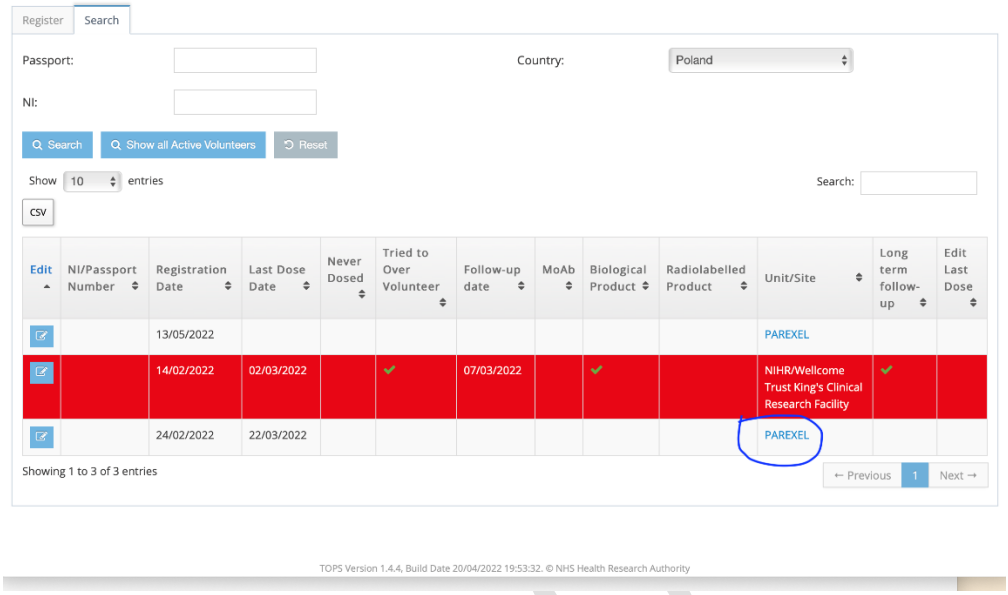
5.8 The current version of the **TOPS User Manual** User Manual should be used to enter and update a volunteer's details. This is updated by the HRA as required. It has step-by-step instructions on how to access TOPS, how to enter the volunteer's data and the trial details, including the IRAS ID. It also explains how to search for volunteers and how to update their records. It has guidance on how to issue usernames and passwords for users of the system (this can only be done by the Site Administrators).

5.9 Once consent has been given, a volunteer's data should be entered by a nominated member of CRF staff into the database **before** the **first dose** of the Investigational Medicinal Product (IMP).

5.10 Once a volunteer has been registered, the database will show any previous history for that volunteer. If the database shows that a volunteer has received an IMP within the last **12 weeks**, this should be discussed with the Principal Investigator and/or Sponsor for a decision to be made regarding the volunteer's participation in the trial. This may require further investigation, ie: contacting the unit where the previous study took place.

5.11 How to contact other research units: In order to find out if a volunteer has received the study medication, you can contact the staff at the unit which registered the volunteer. The name of the units in which the volunteer has previously been registered will appear in the volunteer's registration history.

Clicking on the name of the unit will display the contact details for staff based at the unit. See below, circled in blue to find contact details:



5.12 **Last Dose Date:** when the volunteer has received the **last dose** of the IMP, the date of this should be entered into TOPS by the person who made the original entry. Refer to the user manual for further guidance on this. A calendar reminder of the due date of the last dose should be set up by the responsible staff member to ensure that they remember to update TOPS.

5.13 **Never Dosed:** if a volunteer is registered on TOPS but then never given a dose of the trial medication, there is an option to enter '**Never Dosed**'. Refer to the user manual for further guidance on this.

5.14 Once data has been entered and saved, any errors have to be corrected by the HRA. This also applies to any data which needs to be deleted. An email should be sent to tops@hra.nhs.uk with details of the changes required.

5.15 Other units may contact the CRF for information on volunteers and the information entered into TOPS.

5.16 For any further help regarding using TOPS please e-mail tops@hra.nhs.uk

6.0 Related Documents & References

6.1 CRF-STU-FRM-5: TOPS Participant Information and Consent Form

6.2 CRF-STU-SOP-7: Healthy Volunteer Studies in the King's CRF

6.3 Health Research Authority: HRA

6.4 TOPS Database: TOPS

6.5 TOPS User Manual: User Manual

7.0 Appendices

N/A

8.0 Approval and sign off

Author:

Name: Angelina Twumasi

Position: CRF Quality Assurance Manager

Signature: Date:

Approved by:

Name: Elka Giemza

Position: CRF Manager	
Signature:	Date:
Authorised by:	
Name: Professor Peter Goadsby	
Position: CRF Director	
Signature:	Date: