STANDARD OPERATING PROCEDURE

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/research-sops

Provision of virology test information to clinical trial volunteers

SOP No: T11

Version No: 2.1

Effective Date: Jan 2019

Supersedes: Version 2.0, Aug 2017

Page: **1** of **7**

Last Review Date: Jan 2019 Next review date: Dec 2022

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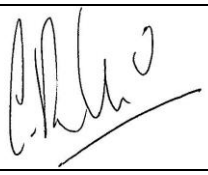
Signature:	
Date:	21st Jan 2019

1 Purpose and Scope

To define the procedure for provision of virology test information to trial volunteers.

This Standard Operating Procedure (SOP) is to ensure that:

- individuals requiring a Human Immunodeficiency virus (HIV) test and or a Hepatitis (B or C) test receive appropriate discussion prior to testing so that they can decide whether to have a HIV/Hepatitis test in a properly informed way, and
- the extent of provision of pre-test discussion reflects the varying needs of different clinical situations.

This SOP is to ensure consistency in the content of pre-test discussion and the subsequent tests and the dissemination of test results.

In scope: research hosted by, and/or sponsored by University Hospitals Plymouth NHS Trust (UHPNT).

Definitions

PI	Principal Investigator
SHIP	Your Sexual Health in Plymouth clinic
HIV	Human Immunodeficiency virus
HbsAg	Hepatitis B surface antigen
HCV	Hepatitis C Virus.
RD&I	Research Development & Innovation
RO	Research Office
SOP	Standard Operating Procedure
UHPNT	University Hospitals Plymouth NHS Trust

2 Who should read this document?

Nursing staff responsible for providing any pre-test information the patient requests and for arranging any required repeats. Physicians or an appropriately trained & competent nurse are responsible for advising the patients of any positive results, discussing them with the patient and arranging any follow-up or referral.

3 Procedure to Follow

In the case of clinical studies where it is a requirement that screening investigators shall include a HIV/Hepatitis antibody test, it is essential that the following protocol be adhered to.

3.1 Pre-test counselling

- On booking a screening appointment, volunteers will be advised that screening will include a routine virology test for HIV and hepatitis pathogens.
- Prior to screening, the volunteer will be provided with leaflet on 'Pre-screening HIV and Hepatitis information' by the investigator or nurse carrying out study recruitment. This will outline the nature of the tests to be carried out and the actions to be taken following a 'positive' result. It also advises that pre-test counselling is available on request. Consent for the blood samples must also be obtained (this will be included in the study consent form).
- If requested by the volunteer, a one to one counselling session can be provided during the screening session. If a counselling session is requested the following guidelines will be followed:
    - A suitable competent member of the clinical team will:
        - Give an explanation of the reason for, and the nature and implications of the virology tests.
        - Explain viral transmission and risk factors.
        - Inform the subject that should the result be positive that the study research staff are unable to give ongoing counselling or treatment but this would be available from their GP.
        - Advise the volunteer that all test results will be confidential.

3.2 Procedure for informing the volunteer of their virology result.

- In the event of a positive virology result, (proven positive twice from the initial sample) the subject will be contacted by the clinical team and requested to attend the next clinic and see the investigating physician and for a repeat blood sample.
- No explanation should be given at the time of contact. If the volunteer requests clarification they should be informed that the initial test result had proved inconclusive and a repeat is required.
- If the volunteer cannot be contacted by telephone, it may be necessary to send a letter to the volunteer requesting they telephone the clinic to arrange a convenient time for a repeat sample to be taken.
- The Principal Investigator (PI) involved with the study needs to be informed of the intended visit time so he/she can be free to see the subject and explain the implications of the result. Following advice, consent for the taking of another blood

sample should be sought and two 4ml SST samples should be taken; one of which is sent to an outside Laboratory for confirmation and the other re-tested on site.

- The volunteer must be made aware of the fact that the independent test results could take up to 3 weeks to come through, and that no action can be taken until these confirmed results are released.
- The PI will be responsible for informing the subject of the results of these tests, and will remind the volunteer of the availability of support counselling services. They will discuss the issue of confidentiality, and will ask if the subject wishes their GP to be informed. If the volunteer agrees to this, the Investigator is responsible for documenting this in the patient's medical notes and in the CRF, and for contacting the relevant GP. A copy of the letter to the GP should be filed in the site study file. If the volunteer does not agree to their GP being contacted this should be documented in the patient's medical notes and in the CRF. The Investigator should make all reasonable efforts to persuade the subject that it would be in their best interests for their GP to be informed.
    - Following a positive result the Investigator will ensure a referral is made for the volunteer to see the Nurse Specialist and the Consultants in the Genito-Urinary Medicine - Your Sexual Health in Plymouth (SHIP) clinic.
- The Investigator will liaise with the volunteer and their GP concerning the results of the follow up tests. Any further written or telephone conversations should be documented as outline above.

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a Senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I

intranet site. Internal Trust Staff are expected to use the RD&I intranet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

N/A

Appendix: Counselling: A Brief Overview — Appendix 1

Only qualified and trained counsellors should provide HIV / Hepatitis counselling. Counsellors must protect confidentiality and counselling must be conducted in private where others cannot overhear the conversation between counsellor and the patient.

1. Counselling is communication.
Counselling is communication, both verbal and nonverbal, made in response to and in the presence of feelings. It is the work of supporting someone in making decisions when their willingness or ability to act is affected by their feelings. Effective counselling can help a patient to explore, express, understand, and accept feelings so that s/he can make decisions.

2. Counselling is not education.
Counselling is different from education, although education can be a component of counselling. Good counselling does not equal good information giving. Good counselling is "patient-centred", it is tailored to the behaviours, circumstances, and needs of the person being served.

3. Counselling is not solving the problem or giving advice.
Counselling is not solving the patient's problem for them or giving advice, it is facilitating problem solving. In the counselling process, the counsellor avoids taking on the patient's problem or telling the patient how to solve the problem or what decision or action to take.

Instead, the counsellor brings a set of skills to the interaction that can enable the patient to reach a better understanding of the problem, deal with their related feelings and concerns, and assume responsibility for evaluating alternatives and making choices.

Patient centred counselling:

- is tailored to the behaviour, circumstances and needs of a person;
- focuses on personal risk assessment and development of a personalized action plan;
- takes into account person's emotional reactions, interpersonal situations, specific risk behaviours and the person's readiness to change their behaviour;
- content depends on the person's level of knowledge and their specific concerns about HIV/Hepatitis;
- develops individualized risk-reduction plan for each person;
- identifies the general problem; and
- makes a referral based upon the person's needs.

6 Amendment History

Version Number:	2.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name; Reduce signature requirement to single senior RD&I Manager.

Version Number:	2.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated SOP template and numbering system. Reviewed and updated SOP.

Version Number:	1.1 (minor amendment)
Date Of Amendment:	Mar 2012
Details Of Amendment:	Cover page - Change of SOP location address.