**[Insert name of Phase 1 Unit] Generic Screening information sheet and consent form**

The following Generic Screening assessments are being used to see if you may be suitable to take part in future clinical trials. The results of the following assessments may later be transferred to study specific files, but this would only happen if you have given your consent to take part in a particular clinical trial.

You will have all of the assessments that are included in the following list. A description of what each of the assessments entails is provided underneath the name of the procedure. Further information regarding each of the assessments will be provided to you by a member of the clinical team and you will have plenty of time to ask questions if there is anything that you are unsure of. If you would like to contact us at any time after this appointment, please contact: [Insert contact details for Phase 1 Unit telephone number and email address]

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| **Assessment**  |
| **Delete as applicable** – Any tests which will not be used as part of the generic screening must be deleted from the table. |
| 1You will be asked questions about your past and present health including clinically significant family history (a medical history). |
| 2You will be examined for signs of illness or disease (a medical examination). |
| 3Your height and weight will be recorded.  |
| 4Your pulse rate, blood pressure, temperature and breathing rate will be checked.  |
| 5Electrocardiogram (ECG) – an electrical tracing of your heart This assessment involves small metal electrodes being stuck to your arms, legs and chest. The ECG is harmless and painless and helps detect irregular heart rhythms. |
| 6Provide urine samples for [delete as applicable]1. health screen
2. test for pregnancy
3. for drugs of abuse
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| **You will have the following blood samples taken:**  |
| 7**Safety blood tests** Blood tests can be used to assess your general state of health, to confirm the presence of a bacterial or viral infection and to see how well certain organs, such as the liver and kidney, are functioning. Blood samples will be taken for a red cell count, white cell count and a standard range of chemical tests.  |
| 8 **Testing for virus antibodies** The body produces antibodies to fight viruses that it has been exposed to. If your antibody level for a particular virus is not within the required range, this is nothing to worry about, as it just suggests that you have immunity (protection) against that virus; however you will not be suitable to take part in a trial with that virus. |
| 9 **Samples for Hepatitis B and C and/or HIV (the virus that causes AIDS);** HIV and Hepatitis B and C are nearly always transmitted from infected blood or other infected body fluids. Your blood will be tested for these viruses to ensure your safety and the safety of our staff, as they will be handling your blood samples.  |
| **You will have the following tests performed:**  |
| 10  **Lung function tests**Lung function tests include breathing tests and tests that measure the oxygen level in your blood in order to assess how well your lungs work. Lung function tests can measure:* how much air you can take into your lungs.
* how much air you can blow out of your lungs and how fast you can do it.
* how well your lungs deliver oxygen to your blood.
* the strength of your breathing muscles.
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| 11 **Carbon monoxide breath test** A carbon monoxide breath test measures the amount of carbon monoxide which you have recently been exposed to (e.g. from cigarette smoke)  |
| 12**Sputum Induction** [If Sputum Induction to be offered as part of generic screening, it is expected that the Generic Screening Information Sheet and Consent form template is submitted to the Generic Document Review Committee along with a written justification for including the procedure].Sputum Induction assists with the diagnosis of various respiratory (breathing) diseases. In order to produce sputum samples during the study you will be given sterile salt water to inhale as steam, this will loosen any mucous in your chest making it easier to cough up.  This saltwater steam may narrow your airways a little, causing possible tightness of the chest and shortness of breath.  If you feel any symptoms, please notify a member of staff.  If you have an asthma attack, you may be given 2 puffs of a Salbutamol inhaler (such as Ventolin®). You will be asked to take a Salbutamol inhaler (such as Ventolin®) before this procedure. Side effects of Salbutamol inhalers can include shakiness, headache, fast heart rate, dizziness, and feeling anxious. |
| 13**A skin prick test**  [If a skin prick test is to be offered as part of generic screening, it is expected that the Generic Screening Information Sheet and Consent form template is submitted to the Generic Document Review Committee along with a written justification for including the procedure]. Skin prick testing checks for allergic responses to specific allergens. A drop of the allergen is placed on the skin and the skin in then pricked through the drop using the tip of the lancet – this can feel sharp, but it is only slightly painful. |
| 14**Non-invasive Ophthalmology Tests**Non-invasive Ophthalmology tests allow us to undertake a basic check of your general eye health. A light may be used to examine the front of your eye and we may also measure the fluid pressure inside of your eye using a puff of air.  |
| 15**A 24hr recording of the electrical tracing from your heart (24-hour Holter).** A Holter monitor is a machine that continuously records the heart's rhythms. You will be asked to wear the Holter monitor for 24 hours whilst you take part in your normal daily activities.  |
| 16**An exercise test** The exercise stress test involves exercising on a treadmill whilst you are closely monitored. You will begin to exercise by walking on a treadmill or pedalling a stationary bicycle. The rate of exercise or degree of difficulty will gradually increase. You will be asked to exercise until you feel exhausted. Some volunteers may find this unpleasant. At any stage you can tell the person doing the test if you feel it is too difficult, and the test will stop. It is normal for your heart rate, blood pressure, breathing rate, and perspiration to increase during the test and you will be observed for any symptoms or changes that suggest the test should be stopped. |
| 17**A stool sample** (if you are able to provide one). |

By signing this consent form, you agree to allow [insert name of Phase 1 Unit] to assess your suitability for possible future participation in clinical trials. By signing this consent form, you agree to allow appropriately qualified clinical staff to carry out the assessments listed in the above table.

All samples will be identified only by your [unit to insert relevant details e.g. volunteer registration number, subject number, date of birth, initials].

Your personal data will be held securely on a database, treated in strictest confidence and will be held in accordance with data protection legislation. Access to personal information will be limited to authorised staff within [insert name of Phase 1 Unit], organisations acting on behalf of [insert name of Phase 1 Unit], and regulatory authorities such as the Medicines and Healthcare products Regulatory Agency (MHRA). These organisations have a duty of confidentiality to me as a potential research participant.

Your records and personal information will be treated in the strictest confidence. You have right of access to any personal data [insert name of Phase 1 Unit] holds about you. In the event of any inaccuracies recorded in the data, you have the right to request that such data be corrected. Please contact [insert name of Phase 1 Unit] using the contact details which you have been provided if you would like to view any of the personal data which is held about you.

Undertaking any of the generic screening tests, may result in us noticing something that could be important to your health. If so, we will contact you to explain what was noticed and support you with information regarding where to go for further advice.

**Future private healthcare or life insurance may be affected if a previously unrecognised problem is found at generic screening.**

**Hepatitis B and C and/or HIV**

A positive HIV or Hepatitis B or C result can be difficult to cope with as it has both medical and social implications.  For example, it may affect your eligibility for life insurance, or your current or future career in which being a carrier of HIV or Hepatitis B or C virus could have particular implications, e.g. surgeon or dentist. If you have a positive result you will not be allowed to take part in any future study for your own safety and wellbeing, as well as to minimise the risk to our staff of possible infection when handling your blood. You will be informed of the result by [insert name of Phase 1 Unit]. The clinician at the unit will inform your GP of the result and may also refer you to a genitourinary medicine (GUM) clinic of your choice. This is to ensure that you receive the appropriate follow up and treatment. By signing the informed consent form, you are giving us your permission to inform your GP if the result is positive.

Your signed consent form will be valid for 12 months from the date of your signature. If you would still be interested in participating in clinical studies after this time, [insertname of Phase 1 Unit] will ask you to read and sign a new generic screening information sheet and consent form. You can ask for your details to be removed from our database at any time.

You are free to withdraw from the generic screening assessment at any time and undertaking the generic screening assessments does not mean that you must take part in future studies. The types of volunteers needed for particular studies varies and it is possible that you will not be contacted if there are not any studies which you might be eligible for.

The screening assessments are simple in nature and it is unlikely that anything will go wrong as a result of you having them done. However, if it does, compensation will be available in accordance with the Association of the British Pharmaceutical Industry (APBI) guidelines. A copy of the guidelines is available from the [APBI website](https://www.abpi.org.uk/publications/clinical-trial-compensation-guidelines/) or on request from [insert name of Phase 1 Unit].

**Please initial the box next to each statement to confirm that you agree with the following:**

**Please initial box**

1. I understand the information provided in this information sheet; I have been given the opportunity to ask questions and any that I asked were answered to my satisfaction.
2. I understand that it is important for my own safety if I participate in future clinical trials that I have answered all of the questions concerning my past medical care, the taking of any medicines and participation in any other research studies fully and honestly.
3. I agree to allow appropriately qualified staff to undertake the assessments as listed in this document.
4. I understand that previously unrecognised medical problems may be detected as a result of the screening assessments. If a previously unrecognised medical problem is detected [Insert Name of Phase 1 Unit] will inform me of the results and provide advice on what I should do next.
5. I understand that my personal identifiable information will be held in a secure database and may be accessed by [Insert Name of Phase 1 Unit], organisations acting on behalf of [Insert Name of Phase 1 Unit], and government regulatory bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA).

**Contact with General Practitioner (GP)**

1. I agree that my GP may be contacted regarding my medical history and I authorise my GP to disclose any information which would be relevant to my inclusion now or before any subsequent studies. I am aware I have the right to see the report by requesting a copy from [Insert Name of Phase 1 Unit]. I agree to allow my GP to be informed of any abnormal assessment results.
2. I agree that my GP will be informed if I receive a positive HIV or Hepatitis B or C result.

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Full name of volunteer Signature Date

 (dd/mmm/yyyy)

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Name of clinician giving information Signature Date

 (dd/mmm/yyyy)