PRE-SCREENING QUESTIONNAIRE DATE:_____

RPL ID No.:	First name:	Middle Name(s):	Surname:

Telephone Numbers Home: ..... Work: ..... Mobile:	Address: .... Postcode: .....
Date of Birth:	E-mail address:

Male Female (circle applicable)	Race:	How did you hear about Richmond Pharmacology?	
Name and Surname of Next of Kin:	Relationship:	Address:	Phone Number:

Do you smoke?

Yes ☐ How many cigarettes per day? .....
How much tobacco per week? .....

No ☐ Are you an ex-smoker? Yes ☐ When did you stop? .....

Do you drink alcohol?

No ☐ Yes ☐ How many units per week? .....
(1 Unit = 125mL glass of wine, single measure of spirits or ½ pint of beer)

Please calculate your weekly alcohol intake using the following link:

http://www.nhs.uk/Tools/Pages/NHSAlcoholtracker.aspx (Windows and Mac)
http://www.nhs.uk/Tools/Pages/iPhonedrinks.aspx (iPhone)

Please make sure the correct alcohol strength is chosen and clear the tracker and start again if a mistake is made.

Do you drink tea and/or coffee?

No ☐ Yes ☐ How many cups per day? .....

To your knowledge, do you have any medical problems?	No ☐ Yes ☐ Please specify?.....
Do you suffer from any allergies to food or medicines, including hay fever?	No ☐ Yes ☐ Please specify? .....
Do you suffer from asthma?	No ☐ Yes ☐
Have you had any psychiatric illness, including depression or eating disorder?	No ☐ Yes ☐ Please specify? .....
Have you had a fit, epilepsy or significant head injury?	No ☐ Yes ☐ Please specify? .....
Have you had an operation on your stomach or intestines, or ever had any stomach disease?	No ☐ Yes ☐ Please specify? .....
Do you have any special dietary requirements (e.g., vegetarian, vegan, food intolerance)?	No ☐ Yes ☐ Please specify? .....

PRE-SCREENING QUESTIONNAIRE DATE:_____

Have you donated blood in the last 12 months?	No ☐ Yes ☐ Please give approximate date? .....
Have you taken part in a clinical trial in the last 12 months?	No ☐ Yes ☐ Please give approximate date? ..... Name of Research Unit? ..... . Name of tested compound? .....
Have you taken any medications in the last 4 weeks (including painkillers, antibiotics, cough/cold remedies, throat sweets, sleeping tablets, inhalers, foot powders, injections, vaccinations, herbal remedies, vitamins, minerals, creams, self-tanning lotions)?	No ☐ Yes ☐ **Please specify?** ....
Would you be able to abstain from <u>ALL</u> strenuous physical activity throughout the study?	No ☐ Yes ☐
Have you taken any recreational drugs in the last 6 weeks? (cannabis, speed, ecstasy)	No ☐ Yes ☐ Please specify? .....

How long have you been registered with your GP?

More than 6 months? ☐

Less than 6 months? ☐ **Does your GP have your medical records?** No ☐ Yes ☐

FEMALES ONLY	**What form of birth control do you use?** Combined Pill ☐ Injection ☐ Implant ☐ Condom ☐ Diaphragm ☐ IUD (Coil) ☐ Other ☐ Please specify? ..... None ☐ Are you sexually active? No ☐ Yes ☐
	Are you postmenopausal? No ☐ Yes ☐ Since? ..... **Are you surgically sterilised?** No ☐ Yes ☐ Since? .....

REGISTRATION POLICY:

Please ensure that you have completed the questionnaire accurately and to the best of your knowledge.

You will be excluded from study participation if:

- **You have omitted to declare any medical condition that is later reported by your family doctor,**
- **You are invited to attend a screening appointment, or have been given a study admission date, or have been given a study follow-up date and fail to attend,**

You have been invited to participate in a study and fail to comply with the study criteria as set out in the Information for Volunteers.

The Over-volunteering Prevention System (TOPS) will be performed for all volunteer(s):

Please provide National Insurance number and or provide Passport Number for all other Nationalities:

NI number: …… (For British Citizens only)

Passport Number: …… Country of Passport Held: ……

What will happen to my data?

The following applies regardless of whether I participate in the study or not:

I agree that RPL may contact my general practitioner (GP) (and/or my teaching or university authority if appropriate), to make known of my participation in this study. I authorise my GP to disclose (in confidence) details of my relevant medical or drug history.

I understand that RPL may pass on limited personal data and details of my participation in a clinical trial the National Research Volunteer Register. This and similar registers in other countries exist to generally ensure the safety of research participants, which may be impaired when participating in more than one trial simultaneously or when not strictly observing the required exclusion periods between different studies. RPL may also pass on limited personal data and details of my participation in a clinical trial to other Phase I Units where (a) a specific request is made by those units or (b) where staff at RPL suspects that a volunteer is participating in other research at the same time.

All personal data provided by me in the process of registration and all information that has been provided by my GP, will remain confidential. Access to this data is strictly controlled by authorised staff in accordance with this informed consent form and to the extent allowed by applicable laws and regulations. I understand that my personal and medical details will be held by RPL in paper and electronic format for later reference.

Documents revealing my identity such as my name, address, phone number, passport number and other data allowing RPL to contact me (referred to as “identifying personal data”), will be separated from all other personal data referred to in this document. These identifying personal data will solely be accessible by authorised members of RPL staff. This information will not be removed or copied to be taken outside the RPL premises other than for the purpose of routine computer backups and in any case be stored in a secure access controlled environment. This information may be made available to authorities for the purpose of inspecting and validating RPL’s work and may be disclosed on a strict need to know basis in case of medical emergencies.

Identifying personal data is held for my later identification related to this trial for as long this is required under currently applicable Good Clinical Practice guidelines and UK law, which is for at least the time the drug investigated in this study is under research and/or on the market anywhere in the world and in any case no less than 15 years. RPL also retains my identifying personal data to be able to contact me at a later date either by e-mail, mail or telephone, to supply or receive information including information about future studies in which I may want to participate. I understand that I may instruct RPL not to contact me regarding future studies. I understand that upon my request I will be given a printout listing the details of all my identifying (and other) personal data (such as my name, address and medical details) held by RPL. I may correct any inaccuracies in my personal data.

All other personal data which will not identify me by full name or include any information which may identify me, will be processed (including being disclosed) for the purpose of the study, and for any additional scientific research, for product registration purposes, for research purposes in general, and for ensuring compliance with medical, ethical, and pharmaceutical laws and regulations.

I permit authorised staff participating in the research as collaborators of RPL, representatives of the sponsoring company, regulatory authorities, and/or the Ethics Committee to review and use my study documents. I understand my personal data may be reviewed and copied (my identifying personal data will not be copied) by such people for verification of clinical and scientific research procedures and/or data to the extent permitted by applicable laws and regulations and without breaching the confidentiality of the records. I understand that even if I do not pass the screening examination or if I withdraw my consent as given in this form, certain personal data may still be processed to the extent it is necessary to verify our work. I understand that some of the countries to which my personal data may be transferred may not offer as comprehensive a level of protection of personal data as within the UK, but the sponsoring company will take all reasonable steps to protect my right to privacy.

I agree that I will not seek to restrict the use to which the results of the study may be put and they may be used for publication in scientific publications. In any scientific publications my identity will remain confidential.

I understand that I should only sign it if I have no further questions.

_____ _____

Signed Date

Initials |__|__|__| RPL Number |__|__|__|__|__|__| DoB |__|__|.|__|__| |__|__|

Day Month Year