

Participant Information Sheet and Informed Consent Form

Study Title: A phase I clinical trial to assess the reactogenicity, tolerability and immunogenicity of a self-amplifying ribonucleic acid (saRNA) vaccine encoding the surface glycoprotein of rabies virus (RAB-Vac)

Study ID: RAB-Vac

IRAS ID: 1013204

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Invitation:

- We are looking to develop a new vaccine (RAB-Vac) against Rabies infection
- We invite you to participate in this first-in-human clinical trial to assess its safety and ability to induce immune responses that may provide protection from infection or disease
- Before you decide to take part, it is important for you to understand why the study is being done and what it involves
- Please take time to read the following information carefully
- You are free to decide if you want to take part. Just ask us if there is anything that is not clear or if you would like more information
- Thank you for reading this

Brief Summary:

- We are testing a vaccine against Rabies virus
- You will get three injections at one of three concentrations (moderate, low or very low) space either 4 or 12 weeks apart. You won't be told what you received until the study is over, so the results stay fair and unbiased.
- We don't know yet whether the vaccine will work, or what its side effects will be; we'll monitor your health very closely and you will be asked to remain in the clinic for an hour after each injection.
- You will be in the study for about 12 months, making 14 scheduled visits to the research site at Chelsea and Westminster Hospital in London
- Visits will last between 30 minutes and 3 hours
- There will be 3 visits when you will receive the injection into the deltoid muscle of your arm. You may choose which arm to receive these injections.
- You will be paid for your time, travel and inconvenience: £200 per completed visit. This will come to a total of £2800, inclusive of travel expenses.
- If you attend a screening visit, but are not selected to join the trial, we will reimburse £40 for attending your first pre-screening appointment, which includes a blood sample and other assessments.

Lead Researcher Contact:

If you have any questions about this study, please talk to the lead researcher:

Dr Marta Boffito

Tel 020 3315 6148

Email: marta.boffito@nhs.net

1. What is the Purpose of the Study?

RAB-Vac is a study aiming to develop a self-amplifying RNA vaccine (Vac) against the rabies virus, the cause of rabies.

The study aims to evaluate the safety of this vaccine across three different dose levels, as it is the first time it has been used in humans. However, this trial does not assess the vaccine's effectiveness in protecting against rabies. It only examines the safety of the product and how the immune system responds to it.

Since this is the first time this vaccine has been used in humans, safety will be evaluated in healthy young adults. Forty-eight participants aged 18-50 years will be randomly assigned to one of six groups, receiving one of three doses of the vaccine (very low, low, and moderate), administered either at 0, 4, and 24 weeks or 0, 12, and 24 weeks. You will not be informed of which treatment you receive until the study concludes, ensuring fairness and unbiased results. Participants will receive three injections. The second injection will be given 4 or 12 weeks after the first, and the third 24 weeks after the initial dose. You will be closely monitored for any reactions to the vaccine. After vaccination, blood samples will be collected to assess your immune response.

2. Why have I been chosen?

You have been chosen based on meeting the criteria for the study detailed below. We will be enrolling a total of forty-eight participants. You can take part only if you give your consent after being fully informed about what participation involves. A study doctor/nurse will discuss this written information with you.

There are strict eligibility criteria for participation:

- Healthy male and female volunteers aged between 18 and 50 years.
- Available for ALL follow-up visits for the duration of the study.
- Entered and clearance obtained from The Over volunteering Prevention System (TOPS) database (to avoid impact of any co-administered investigational products or treatments on our outcomes).
- Willing to avoid all other vaccines from within 4 weeks before the first injection through to 4 weeks after the second injection
- Women capable of becoming pregnant willing to use a highly effective form of contraception from enrolment through to at least 18 weeks after the second injection
- Willing and able to give written informed consent.
- Willing to abstain from donating blood for three months after the end of their participation in the trial or longer, if necessary

You will not be able to take part if you

- If you have ever previously received a rabies vaccine
- History of any medical, psychological or other condition, clinically significant laboratory result at screening, or use of any medications which, in the opinion of the investigators, would interfere with the study objectives or volunteer's safety.
- History of anaphylaxis (severe allergic reaction) or angioedema (sever swelling).
- History of a severe allergic reaction after receiving a previous dose of any COVID-19 mRNA vaccine.
- History of severe or multiple allergies to drugs or pharmaceutical agents
- Any history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart).
- History of severe local or general reaction to any vaccination defined as:
 - Local: extensive, indurated (thickened) redness and swelling involving most of the arm, not resolving within 72 hours.
 - General: fever, >39.5°C within 48 hours; bronchospasm; laryngeal oedema; collapse; convulsions or encephalopathy within 72 hours.
- Immunocompromised or on a medicine that affects the immune system.

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- Are HIV or HCV positive.
- Are pregnant or plan to become pregnant.
- Are breastfeeding.
- Unable to read and/or speak English to a fluency level adequate for the full comprehension of study procedures and consent.

There may be other reasons why you cannot take part – if so, the study doctor/nurse will discuss these with you.

At the end of the consenting process, which usually takes about 1 hour, the study doctor/nurse will ask you to sign a consent form.

3. Do I have to take part?

No. It is your decision whether to participate. If you choose to take part, you will receive this information sheet to keep and be asked to sign a consent form. Even if you decide to participate, you are free to withdraw at any time and without providing a reason. Withdrawing or choosing not to take part at any point will not affect the standard of care you receive. Participation is voluntary, and you can withdraw at any time without giving a reason (though we will usually ask why), and your medical care or legal rights will not be affected.

4. What will happen to me if I take part?

14 visits will take place at the Clinical Research Facility at Chelsea and Westminster Hospital, 369 Fulham Rd, London, SW10 9NH, and one visit will be conducted over the phone. We will register you as a patient of Chelsea and Westminster Hospital NHS Foundation Trust before obtaining your consent to participate in the study.

Screening visit

After you have given your consent, we will screen you to ensure that you satisfy all the study's eligibility criteria. Screening will take about two hours, and includes:

- A discussion about medical history, including medication
- A symptom-directed physical examination
- Height, weight, blood pressure, heart rate, ECG, and oral temperature measurements
- Blood samples to check your health, and urine samples for pregnancy (women only).
- If any of your blood tests or other health checks come back as abnormal, these results will be passed onto your local GP.
- If you test positive for a notifiable disease (e.g., hepatitis or HIV, etc) during the screening procedures, you will be referred promptly to the correct clinic within the Hospital to ensure appropriate clinical management. The clinic will also notify the UK Health Security Agency, if required.

Injection visits

Injection visits will last about 3 hours. Before you are injected, we will conduct a basic health check (symptoms, medication, upper arm motor function assessment, symptom-directed physical exam [if required], blood pressure, heart rate, ECG, and oral temperature), perform a urine pregnancy test (women only), and collect blood samples.

You will be randomly assigned to one of *Six* groups, and *you will get one injection* in your arm (you can choose which arm) at one of three doses (very low, low, moderate). *You won't be told what you receive until the study is complete, ensuring the results remain fair and unbiased.*

<i>Groups</i>	<i>Vaccine</i>	<i>Dose</i>	<i>Vaccination Schedule</i>
<i>Group 1</i>	<i>LNP-RABVsaRNA</i>	<i>Very Low</i>	<i>0,4, 24 weeks</i>
<i>Group 2</i>	<i>LNP-RABVsaRNA</i>	<i>Low</i>	<i>0,4, 24 weeks</i>
<i>Group 3</i>	<i>LNP-RABVsaRNA</i>	<i>Moderate</i>	<i>0,4, 24 weeks</i>
<i>Group 4</i>	<i>LNP-RABVsaRNA</i>	<i>Very Low</i>	<i>0,12,24 weeks</i>
<i>Group 5</i>	<i>LNP-RABVsaRNA</i>	<i>Low</i>	<i>0,12,24 weeks</i>
<i>Group 6</i>	<i>LNP-RABVsaRNA</i>	<i>Moderate</i>	<i>0,12,24 weeks</i>









































































The second, injection visit will be either 4 or 12 weeks after the first injection. The third injection will be 24 weeks after the first injection. These will be the same as the first injection visit.

After each injection, you will remain in the clinic for at least one hour so that we can monitor your health.

Follow-up visits and blood sampling

You will need to attend the hospital for blood tests on one day, one, two, and four weeks after your first injection; and one, one, and two weeks after your second injection; and two, four, twelve, and twenty-eight weeks following the second injection. These visits will last approximately 1 hour. Visits must occur on the specified days.

The visit schedule is summarised in the table below.

		Weeks after first vaccine													
Up to 8 weeks before first vaccine		Groups 1-3													
Visit Timings		0	0+1 day	2	4	4+1 day	8	10	12	24	24+1 day	26	28	36	76
Screening visit															
															
Participant activity															
															
															
															
		Groups 4-6													
Visit Timings		0	0+1 day	2	4	12	12+1 day	14	16	24	24+1 day	26	28	36	76
Screening visit															
															
Participant activity															
															
															
															
Symbols used															
		Blood collected in clinic													
		Vaccine administered in clinic													
		Record any symptoms from vaccination													
		Safety checks in clinic													

Total blood draw

We expect to draw no more than 512 millilitres (just over half a pint) of blood during the entire study.

Completion of diary cards

We'll also ask you to keep a symptom diary during the first 7 days after each vaccination.

5. What do I have to do?

Every visit is very important to the study, so please agree to take part only if you genuinely expect to be able to attend them all.

You will need to avoid all other vaccines from within 4 weeks before the first injection through to 4 weeks after the second injection, and also avoid giving blood during the study and through to 4 weeks

after your last visit.

This vaccine has not been tested for safety in pregnancy. Women who might become pregnant must use a highly effective method of contraception during this study. The types of suitable effective contraception will be discussed with your research doctor or nurse. Male participants with partners who are pregnant or might become pregnant should use male contraception (condom) during this study.

If you become pregnant while taking part in the study you must immediately tell the study team.

6. What is being tested

The vaccine currently being tested uses specially made pieces of RNA that contain instructions for producing an important protein from the Rabies virus. This protein helps the body generate protective antibodies against the Rabies virus. Because the vaccine only includes this protein and not the entire virus, there is no risk of becoming infected with the Rabies virus directly from the vaccine.

Once injected into the muscle, this RNA vaccine can copy itself, allowing us to use smaller doses than usual. However, this self-copying process doesn't last long—only a few hours to days—after which the RNA breaks down naturally. Importantly, this vaccine cannot change your DNA or make any genetic changes.

Although there have not been specific studies on this vaccine yet, a previous study (COVAC-1) tested a similar RNA vaccine for COVID-19 in over 200 people. The results showed that it was safe and well-tolerated, with most side effects being mild or moderate.

7. What are the possible side-effects, disadvantages and risks of taking part?

Side effects from this vaccine are expected to be very similar to those seen with COVID-19 RNA vaccines, as observed in our previous studies. Common, mild side effects (affecting more than 1 in 10 people) may include pain, tenderness, redness, warmth, itching, or swelling at the injection site. These usually go away within 1 to 7 days. You may also experience general side effects like fever, chills, muscle aches, tiredness, headaches, nausea, vomiting, or dizziness, which are also expected to clear up within a few days.

Less common side effects (affecting about 1 in 100 people) might include stomach pain, diarrhoea, sore throat, swollen lymph nodes, trouble sleeping, or mild allergic reactions like a rash or itching. These usually resolve within a week as well.

Serious side effects are very rare. For instance, mild allergic reactions such as hives or swelling of the face may occur in about 1 in 1,000 people, while severe allergic reactions are extremely rare (around 1 in a million). Individuals with a history of severe allergies will not be eligible to participate in the study. There have also been very rare instances of heart inflammation (myocarditis or pericarditis), particularly in adolescent males, but this remains uncommon (1 in 37,000). If you have previously experienced either of these conditions, you will not be able to join the study.

Some individuals might faint during or after the injection or when having blood taken, particularly if they have a fear of needles. We will take precautions by asking you to lie down during these procedures.

Blood tests may cause minor discomfort, such as pain or bruising, and in rare cases, a blocked vein or slight nerve injury, which may lead to temporary numbness. These issues usually resolve over time.

The vaccine has not been tested for safety during pregnancy, so if you are pregnant or planning to become pregnant, you cannot take part in the study. You must also avoid becoming pregnant for four

months after your last injection. If you do become pregnant, please inform the study team immediately.

8. What are the possible benefits?

Participating in this study won't offer any immediate health benefits for you, but the information we collect might aid in developing a vaccine to prevent Rabies infection or disease.

We will compensate you for your time, inconvenience, and travel expenses. You'll receive £200 for each completed visit. At the end of your participation, you'll get a lump sum payment for all completed visits. If you attend all visits on time and follow the study requirements, you'll receive an additional £200. The maximum payment will be £2,800, which covers all travel costs. If the Principal Investigator withdraws you from the study for medical reasons, you will still receive full payment.

If you attend a screening visit but are not selected to join the trial, we will reimburse £40 for your first pre-screening appointment, which includes a blood sample and other assessments.

9. Supporting information

What will happen if new information becomes available?

Sometimes, during a research project, new information about the agent being studied may become available. If this occurs, your research doctor will inform you and discuss whether you wish to continue with the study. If you choose to proceed, you will be asked to sign an updated consent form.

Additionally, upon receiving new information, your research doctor may consider it in your best interests to withdraw you from the study. Your doctor will explain the reasons and ensure your care continues.

What happens if the study stops early?

If the study is halted early, you will be compensated based on the scheduled visits you have completed, and the reasons for stopping the study will be fully explained to you.

What if something goes wrong?

Imperial College London holds insurance policies applicable to this study. If you suffer harm or injury as a result of participating in this study, you can claim compensation without needing to prove that Imperial College London was at fault. This does not affect your legal right to seek compensation.

If you are harmed due to someone's negligence, you may have grounds for legal action. Regardless, if you wish to complain or have any concerns about how you have been treated during this study, you should immediately contact the Investigator (Dr **Marta Boffito**: Tel 020 3315 6148; Email: marta.boffito@nhs.net). The usual National Health Service procedures are also available to you. If you remain unsatisfied with the response, you may reach out to the Imperial College Research Governance and Integrity Team (RGIT@imperial.ac.uk).

What if I have a complaint?

If you wish to make a complaint or have any concerns about your treatment, please contact:

- Dr **Marta Boffito**: Tel 020 3315 6148

If you would rather speak to someone independent of the study, the standard NHS complaint

procedures are also accessible to you.

- Patient Advice and Liaison Service (PALS): Tel 020 3315 6727 (Mon–Fri 9am–5pm), or email chelwest.cwpals@nhs.net

What will happen to the results of this study?

We aim to publish the results in open-access, peer-reviewed medical journals and present them to the wider scientific community at international conferences. You will not be named in any of these publications or identified in any other manner. The results and description of the study will also be accessible on the public website www.clinicaltrials.gov.

Will my taking part in this study be kept confidential

Yes. In this research study, we will use information from you. We will only use the information that we need for the research. We will inform very few people of your name or contact details, and only if they genuinely require it for this study. These will include Imperial research team members and support staff.

Everyone involved in this study will keep the data collected as part of this research, including your personal information, safe and secure. We will also adhere to all relevant privacy laws and legislation applicable to the specifics of the study.

At the end of the study, we will store some of the data in case we need to review it or for future research. We will ensure that no one can identify you from the reports we produce.

If a volunteer who has given informed consent loses the capacity to consent during the study, the participant and all identifiable data or tissue collected will be withdrawn from the study. Data or tissue that is not identifiable to the research team may be retained.

A description of the study will also be available on the public website clinicaltrials.gov. This website will not include any information that could identify you. You will be able to access a summary of the results through the website once the study has been completed. You can ask a member of staff for more details about which website the information is available on.

Your details will be entered on The Over-volunteering Prevention System (TOPS), which aims to prevent volunteers from taking part too frequently in clinical research studies. This is not a public database and can only be accessed by various registered clinical sites.

How will we use information about you?

Imperial College London is the sponsor of this study and will act as the Data Controller. As a Data Controller, we are responsible for managing your information appropriately and explaining this to you. Imperial College London will retain your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study data will then be fully anonymised and securely archived or destroyed.

The study is expected to finish in February 2028

For more information / confirmation regarding the end date please contact the study team, see **'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact

information.

We will need to use information from you and your medical records for this research project.

This information will include your NHS number, name, date of birth and contact details.

People within the University/Trust and study team (see section sharing your information with others) will use this information to conduct research or to verify your records to ensure that research is being carried out properly and that the information held (such as contact details) is accurate.

People who do not need to know your identity will not see your name or contact details. Instead, your data will be assigned a code number.

Imperial College London sponsors this research and is responsible for safeguarding your information. We will keep all your data safe and secure by:

- Data management plans have been created and reviewed in line with Imperial's Information Governance Policy Framework. This covers the collection, movement, processing and storage of the data.
- Data to be stored in a dedicated secure environment which underpins security measures.
- Robust pseudonymisation has been implemented to prevent identification
- Access controls have been implemented to ensure only key personnel can access the data.
- Some of your information may be sent to other countries. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can verify the results. We will write our reports in a way that no one can figure out that you took part in the study.

As a university, we use personally identifiable information to conduct research that aims to improve healthcare and services. As a publicly funded organisation, we must ensure that our use of personally identifiable information from individuals who have consented to participate in research is in the public interest. This means that when you agree to take part in a research study, we will use your data in the ways necessary to carry out and analyse the research. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 is as follows:

- Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we must demonstrate that our research benefits society as a whole. We do this by adhering to the UK Policy Framework for Health and Social Care Research.

Where special category personal information is involved (most commonly health data, biometric data, e.g., fingerprints or facial recognition, and genetic data, racial and ethnic information, etc.), Imperial College London relies on "scientific, historical research, or statistical purposes."

International Transfers

We may share data about you outside the UK for research related purposes to:

- Where necessary to provide access to a service provider who will utilise your personal data as instructed by us.

If this occurs, we will only share the necessary data. We will also ensure that you cannot be identified from the data shared, wherever possible. This may not always be feasible – for example, if you have a rare illness, it might still be possible to identify you. If your data is shared outside the UK, it will be with other researchers.

We will ensure your data remains protected. Anyone who accesses your data outside the UK must follow our instructions so that your data maintains a similar level of protection as it does under UK law. We will keep your data safe outside the UK by taking the following steps:

- we use specific contracts which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner’s Office (ICO) website - www.ico.org.uk
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says

Sharing your information with others

We will only share your personal data with certain third parties for the purposes outlined in this participant information sheet and based on the legal grounds for processing your data as described above.

- Other employees of Imperial College London, Chelsea and Westminster Hospital NHS Foundation Trust (including staff involved directly with the research study or in secondary activities such as support functions, internal audits, and verifying contact details), as well as agents, contractors, and service providers of Imperial College London and Chelsea and Westminster Hospital NHS Foundation Trust (for example, providers of printing, mailing, email communication, or web services, or those assisting with the activities described above). Our third-party service providers are required to sign data processing agreements with us. We only allow them to process your personal data for specific purposes and according to our policies.

Potential use of study data for future research

When you agree to participate in a research study, the information collected, whether as part of the study or in preparation for it (such as contact details), may, subject to your consent, be shared with researchers conducting other studies at Imperial College London and at other organisations. These organisations may include universities or research bodies involved in research within this country or abroad. Your information will only be used for research purposes in accordance with relevant legislation, including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will retain the information we already have about you.

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- You have the right to request access, removal, modification, or deletion of the data we hold about you for the purpose of the study. You can also object to how we process your data. However, we may not always be able to comply if it prevents us from using your data for research purposes. If that happens, we will explain why.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism we use when transferring your personal data out of the UK.

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to dpo@imperial.ac.uk
- by ringing us on **020 7594 3502**.

Contact Us

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

The Clinical Research Facility (CRF) will collect information from you for this research study in accordance with our instructions. The CRF will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Imperial College London and regulatory organisations may look at your research records to check the accuracy of the research study. The CRF will pass these details to Imperial College London along with the information collected from you. The only people in Imperial College London who will have access to information that identifies you will be people who need to contact you to discuss your results or the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. The CRF will keep identifiable information about you from this study for 10 years after the study has finished.

What will happen to any samples I give?

As part of the study, some samples will be tested at the host NHS site, while others will be examined at Imperial College London. Additional samples might be sent from Imperial College London to other laboratories both within and outside the UK. These laboratories will not have access to your personally identifiable information. Once the study concludes, we will retain your samples for up to 10 years in case we need to repeat any experiments. Furthermore, we may use some of your samples to assist with

other vaccine research. However, if you do not wish for your samples to be used in additional research, you can opt out of this in the consent section below, and it will not affect your eligibility to participate in this current trial.

Who is organising and funding the study?

The study is organised by Imperial College London, UK. The study is funded by a grant from the Coalition for Epidemic Preparedness Innovations (CEPI). The investigators do not receive any payment for this study. The host NHS site is the Chelsea and Westminster Hospital NHS Foundation Trust.

Who has reviewed the study?

This study has been reviewed and approved by the XXX Research Ethics Committee, the Health Research Authority, and by the Research & Development office of the host NHS site.

Contacts during the study, including emergencies

You can contact the study nurses and doctors on Tel 0203 315 5601 (Mon–Fri 9am–5pm).

For **emergencies** outside those hours, please call 07825 681110 and tell the person who answers that you are a volunteer in the RAB-Vac study at the CRF, and the nature of the emergency; a call-back will be arranged. Alternatively, please dial 111, visit your GP or the nearest NHS Drop-In or Accident and Emergency Department if you have any medical concerns.

Thank you for your interest in taking part in this study. If you choose to proceed to the screening assessments, you will be given a copy of this information sheet and your signed consent form to keep.

10. Consent Form

Subject ID: _____

Study Title: A phase I clinical trial to assess the reactogenicity, tolerability and immunogenicity of a self-amplifying ribonucleic acid (saRNA) vaccine encoding the surface glycoprotein of rabies virus (RAB-Vac)

Study ID: RAB-VAC

IRAS ID: 1013204

CI: Marta Boffito

Write initials in box to confirm your consent to each statement below:

I confirm that I have read the participant information sheet version 1.0_14 OCT 2025 for the RAB-VAC study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

*

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

*

I understand that my relevant medical history, and data collected during the study, may be looked at by individuals from Imperial College London or from the host NHS Trust, where it is relevant to my taking part in this study. I give permission for these individuals to have access to my records.

*

I give permission for my samples and data to be analysed, at various sites within and outside the UK, and the results published in a way that doesn't identify me.

*

I understand that blood samples and / or data collected from me are a gift donated to Imperial College and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service.

*

I agree to my General Practitioner being informed of my participation in the study

*

I agree to being entered onto The Over-Volunteering Prevention System (TOPS).

*

I give permission to be contacted by the trial team via email or telephone to be informed of the results of the RAB-Vac trial

*

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I give permission for my samples to be stored and used for ethically approved studies after the end of this study

(This is a voluntary consent. If you do not wish for your samples to be used after the end of this study, please select " Do not give permission". This will not affect your eligibility to participate in EML-Vac

Give Permission

Do not give permission

I agree to take part in the above study.

Name of participant

Date

Signature

Name of person taking consent

Date

Signature

When completed: 1 copy for participant; 1 copy for investigator site file; 1 copy to be kept in medical notes.