# **Clinical Investigation Activity**

## Clinical research interests you ...

Help us advance medical knowledge.

The Pasteur Institute is recruiting healthy volunteers aged 18 to 70 years for single samples of biological samples.

### Subscribe to a search

To participate in a research, we inform you that:

- you must be of age
- you must be covered by social security benefits, except AME (Aide Médicale d'Etat)
- you will receive a compensatory allowance, the amount of which varies according to the projects. Please note that the annual amount received as volunteer for research is capped.

## How to participate?

The course of a research on man involves several stages:

- 1. Volunteer recruitment and pre-selection
- 2. Pre-Inclusion
- 3. Inclusion
- 4. Follow-up
- 5. Closing of participation

Research conducted within the ICAReB platform are essentially research outside health products that allow us to advance scientific and medical knowledge.

### 1. Volunteer recruitment and pre-selection

When a research is underway or will start, we recruit volunteers either by way of display or via our website.

The volunteer wishing to participate contacts us. To find out if the volunteer meets the criteria for inclusion of a given protocol, further information is needed. If the criteria are met, we inform him/her of the progress of the study and we send him/her by mail the information and consent form that summarizes the study so that (s)he reads it before the medical visit known as "pre-inclusion".

## 2. Pre-inclusion

During the medical visit, the investigator will explain to you the progress of the research and will answer all your questions. He will collect the signature of your free and informed consent and sign it in turn. He will perform a clinical examination and a blood sample to verify your blood parameters and HIV, HBV and HCV serotypes (Hepatitis B and C) which must be negative or correspond to a vaccination or healing profile (Hepatitis B).

Following this first visit which lasts on average 1 hour and 30 minutes and if you meet the inclusion criteria of a protocol, we will contact you to take appointment for the inclusion visit.

## 3. Inclusion

During the inclusion visit, the investigator will give you the results of the pre-inclusion report. It will perform a clinical examination and samples will be made within the framework of the research protocol. You will receive an indemnity as compensation for research constraints.

### 4. Follow-up

Depending on the research protocols, participation may take place at one time or involve follow-up visits.

We therefore ask you to pay particular attention to:

- report any medication intake and any health problems you encountered between follow-up visits, taking any medications (eg, aspirin) that may influence research results.
- do not forget to cancel your appointments by phone as soon as possible if for any reason you cannot get there.

## 5. Closing of participation

It is at the end of the volunteer's participation (at the last visit). A 48-hour deadline must usually be met in case of participation in a new protocol.

## Your rights

#### Principle of volunteering for human research

## All research projects must first be:

- a favorable opinion of a Committee for the Protection of Individuals (CPP) which assesses the scientific quality and ethical acceptability of the project on the basis of the recognized rules on research on the person.
- authorization from a competent authority. In the case of research on the human person, the competent authority is the National Agency for the Safety of Medicines and Health Products (ANSM) which must give its authorization.
- a declaration to the Ministry of Research in the case of a collection protocol.
- an authorization from the French National Commission for Information Technology and Civil Liberties (CNIL) to establish a database or a commitment by the applicant to comply with a Reference Methodology.

When proposing to participate in a research on the person, a physician doctor will explain the research protocol (justification of the study, examinations and samples, duration of the study, risks incurred). You will have enough time for reflection during which you can discuss it with your family or with your doctor if you wish.

Before taking part in the research, you will receive a medical examination whose results will be communicated to you. The physician doctor will be required to answer all your questions before proposing to you to sign the informed consent.

## To participate in a research, we inform you that:

- You will be informed of the conservation and purposes of the biological samples that will be taken from you. At the end of the research and if you do not object, these samples may be used in a secondary field in the same research area, excluding genetic research. In case of genetic research, you will be contacted again, if you agree, to sign a new specific consent.
- You will be informed of the overall results of the research.
- At any time, you are free to interrupt your participation permanently without having to justify yourself. In the event of withdrawal of your consent to participate in the research, it will be necessary to specify the fate of your samples (ie preservation or destruction) by contacting the investigating physician of the study.

### Respect for privacy

The law concerning the collection and automated processing of personal data, for the purpose of research in the field of health, amending the law known as "Informatique et Liberté" (CNIL), indicates that you must be informed that a file in which your personal data are located is constituted and protected, that you have a right of access and rectification.

The data concerning you which will be collected during this research will remain confidential and can only be consulted by the investigator and his collaborators, by persons mandated and bound by the professional secrecy and by persons mandated by the sanitary and judicial authorities.

## **Continuity of Information**

Even if you decide not to participate anymore, it is important to send us your contact information in case of a change so that we can inform you of the results of the previous researches in which you participated. In the same way, these will be useful if we wish to consult you on new purposes of use of your already stored samples.

## If you are interested, please contact the following people:



Christine Fanaud
Administrative
staff



Gloria Morizot Projet manager



Hélène Laude Clinical research investigator



Philippe Esterre Projet manager



Marie-Noelle
Ungeheuer
Head of facility
and
Clinical research
investigator