

## **RESEARCH SUBJECT INFORMATION AND CONSENT FORM**

**TITLE:** FloodLAMP COVID-19 Biobank and Test Validation Protocol

**PROTOCOL NO.:** 20210401

**SPONSOR:** FloodLAMP Biotechnologies, Public Benefit Corporation

**INVESTIGATOR:**  
Randall True  
FloodLAMP Biotechnologies, PBC  
930 Brittan Ave  
San Carlos, CA 94070  
USA

**STUDY-RELATED**

**PHONE NUMBER(S):** xxx-xxx-xxxx between 9:00 AM - 5:00 PM PST

### **Part 1: Information and Consent Form**

#### **Why is this research being done?**

The purpose of this study is to collect biological samples (also called specimens) for research use in FloodLAMP's laboratory. Examples of biological samples include blood, saliva, nasal swabs, throat swabs, nostril swabs, and cheek swabs. These samples may be used to develop new tests and/or evaluate and improve existing tests such as tests to detect viruses such as SARS-CoV-2.

The researchers in this study are employees of and own equity interest in the sponsor company, FloodLAMP Biotechnologies, PBC. Please feel free to ask any further questions you might have about this matter.

#### **How many people will be in this study?**

We may enroll up to 100,000 people in this research study.

#### **What will happen if I join this study?**

We will ask you to sign this Consent Form prior to collection of your biological specimens, and we may ask you to complete a short survey. Your participation in this study is voluntary. You are not required to answer any additional questions and can always say "No". If you choose to participate in this study, we will ask you to affirm that you have read and agree to the study consent form by signing your name.

We will then ask you to provide one or more biological samples including blood, saliva, sputum, nasal (nasopharyngeal), throat (oropharyngeal), nostril (anterior nares), and cheek (buccal). Samples will be self-collected and/or collected by trained personnel.

- **Blood Draw:** To donate a blood sample, you will have your blood drawn (about 1 tablespoon). It will take you about 10-15 minutes to donate a blood sample.
- **Saliva Spit:** To donate a saliva sample, you will spit (about 2 teaspoons) directly into a collection container. It will take you about 5 minutes to donate each saliva sample.
- **Sputum Cough:** To donate a sputum sample, you will first rinse your mouth with water and then produce a deep cough that produces mucus, which you will spit directly into a collection container. It will take you about 5 minutes to donate each sputum sample.
- **Nasopharyngeal (NP) Swab:** To donate a nasopharyngeal sample you will tilt your head back, and a swab will be inserted in your nostril. The swab will be left in place for several seconds to absorb secretions before removing. This procedure may be performed in both nostrils. It will take you about 5 minutes to donate each nasopharyngeal sample.
- **Oropharyngeal (Throat) Swab:** To donate an oropharyngeal sample, a swab will be inserted into your mouth and the back and sides of your throat will be swabbed (posterior pharynx and tonsillar areas). It will take you about 5 minutes to donate each oropharyngeal sample
- **Anterior Nares (AN, Nasal) Swab:** To donate an anterior nares sample, you will insert a swab into your nostril and swab the inside of your nostril. Repeat for the other nostril. It will take you about 5 minutes to donate each anterior nares sample.
- **Buccal (Cheek) Swab:** To donate a buccal sample, you will insert a swab into your mouth between the cheek and upper gum and swab the inner cheek. It will take you about 5 minutes to donate each buccal swab sample.

At the time of donation, we will also describe the collection method for each sample type in-person. You are not required to provide any or all of the requested sample types, and you can always say "No".

All samples will be collected on an as-needed and volunteer basis. Your sample will not be labeled with any of your identifiable information but will be assigned a unique code for re-contacting purposes. We may re-contact you by phone or email sometime in the future to collect another set of samples. You are not required to provide another set of samples, and you can always say "No".

Your participation in this study involves you giving broad consent. This means that you allow your information and samples to be used for a variety of future research which will be reviewed by an Independent Review Board (IRS), but which cannot be specified at this present time.

### **Will I receive results?**

No, you will not receive any results as part of this research study.

### **What are my other options?**

This is not a treatment trial. You may choose not to participate in this study.

**What are the benefits of participating in the study?**

There is no direct benefit to you for participating in this research study. However, by participating in this research study, you are contributing to scientific knowledge that may lead to new discoveries that could indirectly benefit you or your family members.

**What are the risks or discomforts of the study?**

The risk of participating in this study is minimal. For blood draws, you may experience bruising and swelling around the puncture site, dizziness or fainting, or infection (rare) during the blood draw.

For nasal swabs and throat swabs, you may experience some mild pain or feel a little discomfort during the collection process. You may gag a little or experience a minor nosebleed after some of the swab collection processes. You can stop or withdraw from providing a sample at any time.

There is a potential risk of breach of confidentiality.

There may be other risks to you that are unknown.

**Will it cost me anything to be in this study?**

No, there is no cost to you to participate in this research study.

**Will I be paid if I join this study?**

Participation in this study is voluntary and you are not guaranteed payment. However, some sample collection visits and/or surveys may be eligible for monetary or cash equivalents in the form of gift cards, as compensation for your time, travel, and/or any other inconveniences related to your participation. If you are eligible for a sample collection visit and/or survey that offers compensation, you will be provided additional information about compensation prior to your visit.

**How long is the study?**

The study does not currently have a set end date, but your active participation ends after completion of specimen collection and the survey. We may re-contact you by phone or email sometime in the future to request another set of samples

**Can I leave the study early?**

Yes. Your participation in this research study is voluntary. You may choose not to participate or change your mind at any time and for any reason without penalty or loss of benefits to which you are otherwise entitled. If you decide to leave the research study, contact FloodLAMP at xxx-xxx-xxxx between 9:00 AM - 5:00 PM PST or email support@FloodLAMP.bio. If you withdraw from this study, your samples and the data derived from your samples and other information will be destroyed if possible. Data that are already being used for research cannot be destroyed or removed.

## **How will my privacy be protected?**

The information we gather from you for this study will be kept confidential and managed according to the requirements of HIPAA. These include the right to know who will be able to get your information and why they may be able to get it. Our lab will assign an anonymous identifier to each sample, which will be used in our research. For FloodLAMP research purposes, all individually identifiable information will be de-identified using the HIPAA Safe Harbor method for de-identification of protected health information (see 45 CFR 164.514).

## **Who will have access to my information?**

FloodLAMP will have access to your information. All information will be stored in a secure password protected database or, in the case of paper documents, in a secure location at FloodLAMP. Your sample and information will be de-identified, meaning certain identifying information that associates such samples and information with you will be removed. Samples will be coded with a number which can only be linked to your identifying information by FloodLAMP. FloodLAMP will use information collected through this study for research purposes, including product development and/or improvement.

At FloodLAMP, we believe that sharing scientific data will help accelerate the pace of discoveries. Your deidentified sample and information may be accessed by third-party research institutions. Any identifying information that associates such samples and information with you will be removed.

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

## **Potential Commercial Interest**

By signing this consent, you agree that your specimen and any data associated with such specimen will be owned by FloodLAMP. If a commercial product or service is developed from this study, the commercial product will be owned by FloodLAMP or its designee. By taking part in this study, you agree that FloodLAMP (and other research groups or organizations) are free to apply for and use intellectual property (including patents) relating to any inventions arising from this research.

There are no plans to provide any financial compensation (money) or financial benefit or other benefit to you for such commercialization, and you will not profit financially from any products or services developed from your participation in this study.

**What do I do if I have any questions, concerns, complaints or feel I have a research-related problem about the study?**

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

FloodLAMP does not expect that any injury will result from your participation in this study. However, if you are injured as a direct result of study procedures, you will receive medical treatment. You and/or your health plan/insurance will be billed for this treatment. FloodLAMP has no plans to pay for this treatment. There are no plans to offer any type of payment for injury. However, by signing this form, you have not given up any of your legal rights. In the unlikely event that an injury does result from your participation in this study, you can contact FloodLAMP at 844-352-6567 between 9:00 AM - 5:00 PM PST or email support@FloodLAMP.bio.

**What other things should I know about this research study?**

This study is approved by Western Institutional Review Board (WIRB). WIRB's objective is to protect the rights and welfare of the people taking part in human research studies. You may contact WIRB if you have questions about your rights as a participant, if you have questions, concerns, or complaints, or if you think you have not been treated fairly, at 360-252-2500 or Help@wirb.com.

**Part II. Certificate of Paper Consent or Signed Electronic Consent**

I have read this Consent Form describing how my information will be stored, used, and disclosed for the FloodLAMP COVID-19 Biobank and Validation Protocol. My sample will be de-identified at the time of collection. I will not receive any results as part of this study. This study is voluntary; I am not required to provide any or all specimens and/or specimen types as part of this study. I have had a chance to ask questions about the storage, use, and disclosure of my information. My questions have been answered to my satisfaction, and I agree to participate in the FloodLAMP COVID-19 Biobank and Validation Protocol Study.

Name of participant: \_\_\_\_\_ Date: \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_

Home address: \_\_\_\_\_

Signature of participant: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of witness: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of person obtaining consent: \_\_\_\_\_ Date: \_\_\_\_\_

[Agree and Complete Enrollment]