SOP for External Patient Recruitment
Stanford CVI Biobank

The purpose of this document is to outline the standard operating procedures (SOP) for consenting external (to Stanford) patients for inclusion in the Stanford Cardiovascular Institute Biobank. We appreciate your collaboration and look forward to working with you.

To include your patients in our Biobank efforts, your patients must agree to join our Biobank project. As such, all patients to be included in the SCVI Biobank **MUST** sign the **Stanford Consent** form. Our approved process for external patient consent is as follows:

1) Your staff gives the patient the Stanford consent form and mentions why they are being recruited. They can say, "Stanford is developing a bio-repository of patient specific stem cell lines to enhance the study of cardiac diseases. We would like to have access to a stem cell line derived from your blood to help us better understand your condition for our own studies. If you are interested in participating in this project, please look over this consent form and call the study coordinator at Stanford. They will go over the project with you in detail and obtain your informed consent."

2) Your patient calls our staff at (650) 725-6744, and we will obtain your patient's informed consent. At that time, your patient will be instructed to make a follow up appointment for a blood draw and bring their signed consent form. It is your responsibility to get approval from your institution's IRB or equivalent to collect a blood sample that can be sent to Stanford. Please see our **SCVI SOP for Sample Processing and Shipment** for detailed instructions and a list of consumables needed to process and ship cells. We also ask that you include the signed consent form and basic de-identified information such as age, sex, diagnosis, and known genetic variants with the package you use to ship the patient's blood.

3) When we receive the sample and consent, our study coordinator will countersign the consent, and we will process the blood sample and put it into our reprogramming pipeline. The patient will be assigned a de-identified study ID, the consent form will be attached to that study ID in our secure database, and a hard copy of the consent will be stored in a secure location here at Stanford. From this point the patient samples are labeled and referred to only by their study ID, date received, and type of cell. Only our study coordinators and Biobank manager, who receive specific training in handling PHI, will ever see the patient's PHI, as approved by our IRB.

4) At our yearly continuing review you and your institution and will be added to our IRB protocol as contributors. Our IRB has allowed for this approach because of the high volume of institutions interested in contributing to our Biobank. We do understand that this is a somewhat new approach to recruiting patients. The goal of our project is to develop a resource that is available to the scientific community. It is not driven by any specific research goals. Because we de-identify the samples and do not share PHI this project qualifies for non-human subject research determination. The language in our consent allows for any research project to be undertaken with

the resources we develop, with the explicit statement that the cells will not be used in any therapy or clinical application in humans. The resources are developed for lab research purposes only. It is the responsibility of the investigators and institutions that wish to use the resources we develop to define their goals and obtain approval to use our resources for their specific research aims.

5) Once we have successfully reprogrammed and tested your patient's iPSC line we will establish a simple MTA for transfer of the new materials to your institution. Once fully executed, we will ship the patient iPSC line to your institution. Both Stanford CVI and the contributing investigator can assert joint and independent ownership of the lines generated. The SCVI Biobank retains full rights to distribute the line to other investigators with proper approval. The contributing investigator retains the same rights.

To obtain a copy of the current Stanford Consent form and the Stanford Minor Assent form, please contact the Biobanking Manager, Justin Vincent. Return the signed consent forms along with the patient samples to:

Justin Vincent
Biobank Manager
265 Campus Dr
Lorry Lokey Stem Cell Building, Rm G1105
Stanford, CA, 94305

Thank you for your interest in the Stanford Cardiovascular Institute Biobank!

For more information please contact:

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