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Participant Recruitment and Enrollment V.1

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Human Cell Atlas Metho...



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Protocol status: Working

We use this protocol in our group and it is working. We do still make tweaks and evaluate circumstances on a case-by-case basis.

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Abstract

The Immune Cell Census aims to collect expression data from 1000 blood samples collected from healthy individuals. This protocol outlines our inclusion/exclusion criteria and enrollment process.

Guidelines

If you have any additional questions, our study team can be reached at immunecensus@ucsf.edu

Participant Recruitment

- 1 Our study team maintains fliers that direct participants to the immunecensus.org website and give our study email address (immunecensus@ucsf.edu). After participants express interest, we schedule a phone screen.

Phone Screen

- 2 Explain study goals, design, and sample processing. Check in frequently to ensure understanding.
 - 2.1 Ensure participants understand that the de-identified (no names, contact information, dates of birth, or other information that could directly lead back to the participant) data will be deposited in the NIH databank, the ImmunoX database, and the Human Cell Atlas Data Coordination Platform. Of note to participants, the data coordination platform is open access, which means that other people can download the genetic information. They would likely need your DNA from another method or the DNA of a close familial match to re-identify you, but that is a possibility.
 - 2.2 Explain study compensation.
 - 2.3 Ask if they have now or in the past had any immune-related conditions. Any autoimmunity? Some people don't realize that eczema or psoriasis count for our study, so it can help to list out some of these common conditions that are **exclusion criteria**:
 - Asthma (active in the last 10 years)
 - Eczema (active in the last 10 years)
 - Crohn's disease
 - Autoimmunity (e.g. Celiac disease, Hashimoto's disease)
 - Diseases with unclear etiology and systemic effects (e.g. fibromyalgia)
 - Chronic organ inflammation (e.g. chronic pancreatitis)
 - 2.4 Ask if they have ever been diagnosed with cancer. Any history of cancer is an **exclusion criterion**. We have also excluded participants with high-grade dysplasia.
 - 2.5 Ask if they have any infections. Any chronic infection that can be reasonably excluded is an **exclusion criterion** (e.g. HIV, viral hepatitis). Some infections are too common/symptomless to be reasonably excluded (e.g. latent HSV, HPV). We are asking people if they have had mono, but not excluding EBV.
 - 2.6 Ask if they have any allergies - we are primarily interested in seasonal allergies or anything that would require a variance in our venipuncture protocol. Because allergies are subjective, we are excluding those that would need to take even over-the-counter

medications during the time of blood draw. For example, a subject with severe pollen allergies in June could donate blood in December, but not in June. A subject that takes antihistamines year-round to control a dust allergy would be excluded.

- 2.7 Ask for their approximate height and weight. Because BMI was not developed to be used on an individual basis and has documented inaccuracies in some of the populations we are sampling, we do not have firm BMI cut-offs. We have a soft cut off of 35 without complications of obesity (including diabetes and hypertension).
- 2.8 Ask for their race/ethnicity. We are sampling four populations at this time:
 1. East Asian ancestry (excluding southeast Asia), defined as Chinese, Taiwanese, Korean, and Japanese ancestry, without known mixing outside of the same
 2. European ancestry
 3. Hispanic ancestry (we are accepting all types and admixes)
 4. African/African-American (we are accepting all types and admixes)
- 2.9 Ask for their sex. If female, ask whether they have regular periods and whether they take any birth control (if so, what type). One of our study designs excludes women on hormonal birth control, but we have found participants do not always know whether their contraceptive is hormonal.
- 3 Let them know that since we're looking at healthy people, we would ask that they reschedule any draw appointments if they are sick or recently vaccinated (especially important on a medical campus during flu season!)
- 4 Detail the rest of the process, what a study visit looks like, and what we're asking of them. Ask again if they have any questions.