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Donor Selection Criteria for Adipose Procurement -- University of Minnesota Human TMC

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Cellular Senescence Net...

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We use this protocol and it's working

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Abstract

This document outlines the inclusion and exclusion criteria for donors of adipose (visceral, subcutenous) and blood for the SenNet Consortium program from the University of Minnesota Human TMC (Niedernhofer).

Excerpt from the UMN IRB for Human Adipose procurement, section 8.0
Protocol title: Profiling of Adipose Tissue Depots and Immune Correlates
Last updated: 2/10/2023

Inclusion Criteria

1 Age 18 years old or older

2 Undergoing abdominal surgical procedure with general anesthesia

3 Written informed consent

Exclusion Criteria

4 Pregnancy or nursing -- Pregnancy is routinely an exclusion for surgery. If patients are scheduled for surgery, they receive a pregnancy test per clinical care. The study team will utilize the results available in the medical record to determine eligibility related to pregnancy status.

5 Exclusion at the discretion of attending physician or Eligibility Committee.

Screening

6 Potential participant identification will be completed by PI or delegated team members, as appropriate.Patients within the clinical practice, meeting all inclusion and none of the exclusion criteria, will be contacted by clinic staff to determine if they are possibly interested in the study. Eligible individuals that are interested in participating will be contacted by a research team member, either remotely or in-person, to review the study details and consent. Written consent will be confirmed before any further study activities are completed.

Vulnerable Populations

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	Population / Group	Identify whether any of the following populations will be targeted, included (not necessarily targeted) or excluded from participation in the study.
	Children	Excluded from Participation
	Pregnant women/fetuses/neonates	Excluded from Participation
	Prisoners	Excluded from Participation
	Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Excluded from Participation
	Non-English speakers	Included/Allowed to Participate
	Those unable to read (illiterate)	Included/Allowed to Participate

	Population / Group	Identify whether any of the following populations will be targeted, included (not necessarily targeted) or excluded from participation in the study.
	Employees of the researcher	Included/Allowed to Participate
	Students of the researcher	Included/Allowed to Participate
	Undervalued or disenfranchised social group	Included/Allowed to Participate
	Active members of the military (service members), DoD personnel (including civilian employees)	Included/Allowed to Participate
	Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Included/Allowed to Participate
	Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Included/Allowed to Participate
	Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Included/Allowed to Participate
	Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Included/Allowed to Participate
	Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Included/Allowed to Participate

This table identifies populations/groups of vulnerable populations and defines whether any of them will be targeted, included (but not necessarily targeted), or excluded from participation in the study/collection.

Additional Safeguards

8 Individuals that checked in section 7.1 that fall under the definition of vulnerable populations may be included in the study in an effort to ensure that data collected is

representative of the clinical population affected by this condition. These populations will not be targeted, but will be included if eligible for the study.

The following safeguards will be implemented to protect the rights and welfare of the groups listed below:

- *Non-English speakers:* Guidance regarding the short form consent process will be followed as listed in Section 20.4 below.
- *Those unable to read (illiterate):* The consent form will be read to these individuals and they will be asked to make their mark on the consent form. A witness will be present during the consent discussion and will also sign the consent form.
- *Employees of the researcher:* If an employee of the researcher is eligible for the study, a member of the study team that is not the employee's supervisor will obtain consent.
- *Students of the researcher:* If a student of the researcher is eligible for the study, a member of the study team who does not have a student/instructor relationship with the student will obtain consent.