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

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Cellular Senescence Network (SenNet) Method Development Community

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ABSTRACT

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

Excerpt from the UMN IRB for Human Liver procurement, section 9.0
Protocol title: Liver Collection Study
Last updated: 01/06/2023

Inclusion Criteria

1 Age 18 years old or older

2 Undergoing abdominal surgical procedure with general anesthesia.

Laparoscopic procedures to include/consider cholecystectomy, bariatric surgery, hernia repair (incisional or hiatal) in which the liver is accessible, esophageal surgery, or GI reconstruction. These procedures allow direct visualization of the liver with sufficient exposure and time to monitor for any complications related to liver biopsy.

3 Availability of data to screen current liver status and liver function. Data pertaining to liver function will be reviewed to determine which cohort the patient may fall within (see Section 10.1 of the IRB for further details).

4 Written informed consent

Exclusion Criteria

5 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.

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 in person or remotely, to review the study details and consent. Written consent will be confirmed before any further study activities are completed.

Our initial cohort of patients will be from UMMC, including the CSC. Should enrollment lag, then patients will be screened from across the health system. Patients will be screened on upcoming clinic schedules following their permission to be approached based on demographics, anthropomorphic factors, and comorbidities.

Vulnerable Populations

7

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
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded from Participation
Non-English speakers	Included/Allowed to Participate
Those unable to read (illiterate)	Included/Allowed to Participate
Employees of the researcher	Included/Allowed to Participate
Students of the researcher	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
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

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.
- Undervalued or disenfranchised social group:
- Active members of the military (service members), DoD personnel (including civilian employees):
- Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare:

- Individual or group with a serious health condition for which there are no satisfactory standard treatments
- Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).

All participants, including the groups listed above, will be screened for eligibility and approached by a member of the research team for participation. The research team is trained in the consent process and subject interaction. As is customary in consent, the research staff will be certain to describe the voluntary nature of participation, as well as the research (non-treatment) purpose and intent of the project.