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602.2 Donor Acceptance Criteria for URMC HTC SenNet Inclusion

Forked from 602.2 Donor Acceptance Criteria for URMC HTC HuBMAP and LungMAP Inclusion

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ABSTRACT

Purpose and Scope of the Procedure

- Standardize process for receiving lung donations
- Scope: Coordination of screening, acceptance and receipt of tissue for research programs

Principles

- Lung donations rejected for transplantation can be used to understand human lung structure and development, ultimately to improve care of patients with lung disease
- Rapid, standardized and safe processing of human tissue for the HTC requires coordination of a team of staff, materials and attention to protocols
- Rapid processing is required to maintain the tissues in a state as close to normal as possible
- Ultra-high resolution CT Scan in an inflated state will provide a high-level comparative assessment of human lung structure across developmental ages (See Protocol 603)

GUIDELINES

Safety and Regulatory Considerations:

- Needs and Privacy of donating family should be respected at all times
- Consent for tissue donation for research should be freely given
- Proper consent process will be assured.
- Organs and biospecimens should be shipped safely and expeditiously
- Shipping will meet the minimum requirement for dangerous goods under 49 CFR 172.700 and IATA 1.5.

MATERIALS

Contact Information for Referral Groups

NDRI - https://ndriresource.org/for-researchers
IIAM - https://iiam.org/researchers
Seattle HTC – Dr. Gail Deutsch

Review Case: accept or decline based on eligibility

1 Take referral call or BRINDL screening report

1.1 Start Case Record in BRINDL Inventory Screening Log

2 Review Eligibility Criteria

2.1 Inclusion Criteria

1.Gestational age >/= 37 0/7 weeks and live born
2.Age < 110 completed years of age
3.Known time of death
3.1.Priority to donors after declaration of brain death by clinical care team, if appropriate, and planned recovery with minimal WIT
3.2.Death in hospital (ex. delivery room, NICU, PICU, Emergency or Operating Room)
3.3.Known time of death prior to arrival in referral hospital
3.4.Warm Ischemia Time (WIT) prior to organ cooling as short as possible;
may accept up to 6 hours, max of 12 hours in unusual circumstance
4.Sample is to be lung unable to place for transplantation, biopsy of lung to be used for transplant or explanted diseased lung at transplant.
5.Bystander normal tissue from lung resection, less preferred

6. Correctly completed consent by donor, or authorization by next of kin, for donation for research

2.2 Exclusion criteria

1.Warm Ischemia Time Unknown or > 12 hours
2.Infection with high-level organism (Category A) representing risk for processing and shipment.
3.Disease/Exposure exclusions: Diabetes, Cystic Fibrosis, current smoker (minimum of 2 years since),
4.Evidence of acute respiratory failure ($PaO_2/FiO_2 \leq 300$) due to pneumonia/ARDS or other cause not associated with diseases of interest
5.Evidence of significant lung trauma
6.More than 5 days on mechanical ventilation with potential exception for chronic lung disease of interest or neurologic disease without lung disease

2.3 Priority acceptance

1.Normal lungs

Requested processing protocol for Donation following Brain Death Declarat...

3 Organ Procurement Organization Recovery Team prepares for organ recovery as consistent with organ transplant protocol with cross clamp and in situ cold flush body cooling with minimal warm ischemic time.

Includes flush with UW/SPS-1, HTK or similar organ transplant buffer, until solution runs clear

4 Recover 1-2 Whole Lung(s) en bloc with at least the lower 1/3 of the trachea.

5 Complete a minimum back-table lung flush with transplant buffer of 500ml into the pulmonary artery and 500ml into the pulmonary vein.

Do not flush with saline.
Do not wrap in surgical towel.

6 Staple, clamp, or tie the trachea closed prior to shipping.

7 Place Lung(s) in a Specimen Bag and submerge with chilled UW/SPS-1 or HTK. Triple bag the tissue.

8 If available, recover the Whole Thymus.

Place in a conical tube/specimen cup filled with chilled UW/SPS-1 or HTK.

9 If available, recover at least 3 cm x 3 cm x 3 cm of Spleen.

Place in a Specimen Bag or a Rigid Container filled with chilled UW/SPS-1 or HTK.

10 If available, recover a 10 CC sample of Blood in a Blood Tube - Green Top (Heparin).

Immediately following recovery, invert the tube several times to mix with the anticoagulant.

Requested processing protocol for Donation following Cardiac Death /Arres...

11 Organ Procurement Organization / Recovery Team prepares for organ recovery as quickly following Cardiac Arrest while in comfort care as authorized by next of kin.

12 Remainder of organ / tissue recovery should be as consistent with organ transplant protocol (section above) as possible.

Includes organ flush with UW/SPS-1 or HTK until solution runs clear.

13 While warm ischemic time is to be minimized, tissues may be accepted up to 6 hours WIT, 12 hours in unusual circumstances where disease is rare and research critical

13.1 Times of cardiac death and beginning of cold perfusion of organ or cross clamp is to be recorded and reported with Metadata

Preparation for Shipping

14 Recovery Team to package and ship such as to meet requirements of 49 CFR 172.700 and IATA 1.5.

Shipment is to reach HTC within 24 hours of recovery.

15 Label each Specimen Bag or Rigid Container with project code, tissue, and recovery team donor number.

16 Place Lung, Thymus, and Spleen tissues in the organ box on wet ice and maintain at 2-8°C until shipment.

17 The Blood vial should be placed outside the organ box but within the shipping container within a biohazard bag.

Recommend to cut a small well in the Styrofoam container for vial security.

Blood sample should not be immersed or placed in direct contact with wet ice to avoid freezing and loss of WBC viability.

18 HTC: Track case, arrange for transfer from courier to URMC HTC Processing Lab

Metadata

19 Recovery team to provide clinical metadata to include at minimum:
1.cause and events occurring during hospitalization prior to death,
2.any CPR required prior to determination of death,
3.time of brain death (DBD),
4.time of cardiac arrest (DCD),
5.time of cross clamp and cold flush,
6.donor age (if less than 6 months in days/weeks; if over 6 months in weeks/months; if over 2 years in years),
7.gestational age at birth in weeks/days or born full term,

8.any complications around birth,
9.demographics and anthropometrics including race and ethinicity, weight, height,
10.medication exposure in hospital,
11.number of days on mechanical ventilation leading up to recovery,
12.most recent ventilator settings and minimum of last arterial blood gas with vent settings and FiO2,
13.recent chest XRay reports including any CT/MRI type imaging,
14.recent bronchoscopy reports,
15.test results of any blood, urine, respiratory tract, including sputum, samples
16.recent CBC,
17.current diagnoses,
18.current serologies (at minimum HepB, HepC, HIV, syphilis, CMV, EBV),
19.past medical history including diagnoses,
20.medications taken at home,
21.history of smoking, vaping, drugs of abuse,
22.immunization history.