University of Colorado Anschutz Medical Campus

Colorado Multiple Institutional Review Board, CB F490
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University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
Children's Hospital Colorado
University of Colorado Denver
Colorado Prevention Center

Certificate of Approval

29-Apr-2015

Investigator:	Trevor Nydam
Subject:	COMIRB Protocol 15-0330 Initial Application
Review Date:	4/17/2015
Effective Date:	17-Apr-2015
Expiration Date:	16-Apr-2016
Sponsor(s):	
Title:	Donor Preoperative Oxygen Delivery and Post-Extubation Hypoxia Impact DCD Hypoxic Cholangiopathy
Expedited Category:	5

Submission ID: APP001-2

SUBMISSION DESCRIPTION:

APP001-2
Response to Minor Modifications

1) Please submit your data collection tool (list of variables you will collect).
This has been attached to the minor modifications submission.
2) Application Section H3a: enter 1000 (even though subjects will not be consented).
The above requested change has been made and updated versions of the application have been attached.

APP001-1
Initial Expedited Application

submitted concurrently with HIP001-1

Your COMIRB Initial Application submission APP001-2 has been APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 45 days prior to the expiration date.

Study personnel are approved to conduct the research as described in the documents approved by COMIRB, which are

listed below the REVIEW DETAILS section.

Please carefully review the REVIEW DETAILS section because COMIRB may have made red-line changes (i.e. revisions) to the submitted documents prior to approving them. The investigator can submit an amendment to revise the documents if the investigator does not agree with the red-line changes. The REVIEW DETAILS section may also include important information from the reviewer(s) and COMIRB staff.

COMIRB stamps the approved versions of documents in the top right hand corner. Stamped copies of documents are available for download through COMIRB's electronic submission website, eRA(InfoEd).

Click here for instructions on how to retrieve stamped documents.

REVIEW DETAILS:

APP001-2:
The following documents have been reviewed and stamped APPROVED or NOTED as part of this approval:
Application Form and Attachments F, Attachment M: Full Waiver of Consent—Determined to meet criteria for full waiver of consent, Attachment O: Full Waiver of HIPAA Authorization—Determined to meet criteria for full waiver of HIPAA authorization; version date 3/30/2015
Personnel Section C, version date 2.19.15
Protocol; version date 2/18/2015
Data Collection Tool; version date 3/30/2015
Response Submission Cover Letter; dated 3/31/2015
Portal Clearance Letter; dated 2/18/2015

Affiliated Sites:
UCD Anschutz Medical Campus
University of Colorado Hospital (Clearance Letter Received)

Non-Affiliated Sites: 0

For the duration of this research the investigator must:

- Submit any change in the research design, personnel, and any new or changed study documents (including new/changed consent forms, questionnaires, advertisements, ect.) to COMIRB and receive approval before implementing the changes.
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "Informed Consent" as required by COMIRB. COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language or use a Consent Short Form, as approved for the study.
- Inform COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policies and Procedures.
- Maintain approval for the research. COMIRB approval is generally given in one year increments, but the period may be shorter. Research is required to be submitted for continuing review and re-approval at least 45 days prior to the expiration date. If a study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the COMIRB office for guidance.
- Remain actively engaged in the conduct of the research. The investigator must ensure that all enrolled participants are appropriate for the study prior to study procedures beginning. For FDA-regulated research the investigator must sign the investigator line on the consent form prior to participants receiving study-related interventions.

Information on how to submit changes (amendments) to your study, requests for continuing review, and reports of unanticipated problems to COMIRB can be found on the COMIRB website http://www.ucdenver.edu/COMIRB.

Contact COMIRB with questions at 303-724-1055 or COMIRB@ucdenver.edu.

As part of this review it was determined that for this research:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, §46.116.
5. Informed consent will be appropriately documented in accordance with, and to the extent required by, §46.117.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Appropriate safeguards are in place to protect potentially vulnerable populations from coercion and undue influence.

Sincerely,

UCD Panel D

Please provide your feedback on IRB processes and support