University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

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University of Colorado Hospital
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Veteran's Administration Medical Center
Children's Hospital Colorado
University of Colorado Denver
Colorado Prevention Center

Certificate of Approval

Not Approved to Enroll Subjects! Recruiting of new subjects will require new COMIRB approval

03-Oct-2017

Investigator:	Evalina Burger-Van der Walt
Subject:	COMIRB Protocol 14-1258 Continuing Review
Review Date:	02-Oct-2017
Effective Date:	02-Oct-2017
Expiration Date:	01-Oct-2018
Sponsor(s):	None~
Title:	Retrospective Review of Outcomes in Complex Spine Surgery

Submission ID: CRV003-2

SUBMISSION DESCRIPTION:

CRV003-2: Response to Minor Modifications

CRV003-1: Study Status: Data Analysis (Closed to Enrollment of New Subjects)

Your COMIRB Continuing Review submission CRV003-2 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.

Effective May 23, 2017, COMIRB will only approval-stamp consent documents (e.g. consent forms, assent forms, information sheets, etc.) and local advertisements. Stamped copies of these documents are available for download through COMIRB's electronic submission website, eRA(InfoEd). COMIRB approval letters will continue to list all reviewed and approved documents.

Click here for instructions on how to retrieve stamped documents.

REVIEW DETAILS:

The following documents have been reviewed as part of this approval:

PDF CR Form
Application Form with Attachments F, M, O v 09.25.17
Personnel Form (eForm) CRV v 09.13.17
Protocol v 07.02.14
Research letter v 09.29.17
Response Submission Cover Letter v 09.29.17

If this protocol requires full-board review and includes attachment C and/or D, the PI will be required to complete GCP training. COMIRB will begin enforcing this new requirement on 9/1/15. It is highly recommended that you complete this training as soon as possible to prevent delays on approvals after the 9/1/15 deadline.

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.

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/research/comirb/training/.

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