University Research
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University of Colorado Hospital | Denver Health Medical Center | Colorado Prevention Center | Children's Hospital Colorado | Denver Health and Hospital Authority | VA Eastern Colorado Health Care System (Denver VAMC)

Certificate of Approval

01-Apr-2019

Title:	SEARCH FOR DIABETES IN YOUTH
Subject:	COMIRB Protocol 01-934 Continuing Review
Investigator:	Dana Dabelea
Sponsor(s):	National Institutes of Health~Juvenile Diabetes Foundation~Centers for Disease Control and Prevention/DHHS~
Effective Date:	29-Mar-2019
Expedited Category:	9

Submission ID: CRV018-1

SUBMISSION DESCRIPTION:

Study Status: Enrollment Continues

This study was reviewed and approved under the “2018 Requirements” of the Federal Policy for the Protection of Human Subjects.

If continuing review is required for your research, your submission is APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 30 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

If continuing review is not required for your research, your study has not been assigned an expiration date.

Regardless of continuing review, you are required to submit changes to your research for approval prior to implementing those changes. You are required to report unanticipated problems and serious or continuing noncompliance to COMIRB. When your research is complete you must report the study closure to COMIRB.

Your responsibilities as Principal Investigator are posted here:
http://www.ucdenver.edu/research/Research%20Administration%20Documents/Responsibilities-of-Investigators.docx

REVIEW DETAILS– Please read carefully:

Continuing Review CRV018 was reviewed and approved concurrently with Amendment PAM045. The personnel form was reviewed with this continuing review. The new versions of these documents are approved with the associated amendment PAM045.

The following documents have been reviewed as part of this approval:
1. PDF CR Form
2. Agarwal_et_al-2018-Diabetic_Medicine.pdf
3. Application-for-Protocol-Review_10.12.18 (1).pdf
4. Cohort assent SPANISH v01.29.16 Stamped
5. Cohort assent SPANISH v01.29.16
6. Cohort Study Assent Form v3.24.17
7. Cohort Study Assent Form v3.24.17 Stamped
8. Cohort Study Consent Form SPANISH 7.17.17 Stamped
9. Cohort Study Consent Form SPANISH v7.17.17
10. Cohort Study Consent Form_v 5.17.18
11. Cohort Study Consent Form_v5.17.18 Stamped
12. Cover Letter Continuing Review v02.27.19
13. Flow diagram v.4 2.27.19.pptx
14. kahkoska_et al. 2018_Diabetes andEndocrinology.pdf
15. Kahkoska_et_al-2018-Pediatric_Diabetes.pdf
16. Li_et_al-2018-Pediatric_Diabetes.pdf
17. Personnel eForm v02.20.19
18. Pinto_et_al-2018-Pediatric_Diabetes.pdf
19. Registry assent SPANISH v01.29.16
20. Registry assent v SPANISH v1.29.16 Stamped
21. Registry Study Assent Form v1.29.16
22. Registry Study Assent Form v1.29.16 Stamped
23. Registry Study Consent Form SPANISH v 7.31.17
24. Registry Study Consent Form SPANISH v7.31.17 Stamp
25. Registry Study Consent Form v02.22.16 Stamped
26. Registry Study Consent Form v2.22.16
27. Reynolds et al. 2018.pdf
28. Reynolds et al. 2018.pdf
29. Sauder et al. 2019.pdf
30. SEARCH 4 Protocol v10.17.18

The reviewer determined that this research continues to involve minimal risk to children (45 CFR 46.404; 21 CFR 50.51) and involves minimal risk, as defined in 45 CFR 46.102(i).

The reviewer noted that subjects will be given the option to have their samples and/or data banked for future studies. It was noted that Attachment S (banking of data/specimens for future unspecified research) is in place, and the appropriate language regarding banking is also included in the consent form. The bio-/data-bank created under this study will not be accessible once this study is closed, and the samples and/or data must be destroyed with study closure per the destruction plan specified under the current study. Therefore, if the investigators plan on storing samples and/or data for future research, a separate bio-/data-bank protocol must be submitted to COMIRB. The submission of the bio-/data- bank protocol need not be submitted to COMIRB at this time; nevertheless, it should be submitted prior to closing this study.

If red-line changes were made, the tracked changes and clean versions have been uploaded into eRA (InfoEd). If the PI disagrees with these changes, submit a change form to COMIRB with the revised documents.

Click here to your submission: Submission Page

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

Information on how to submit changes (amendments) to your study, reports of unanticipated problems, and request for study closure to COMIRB can be found on the COMIRB website
http://www.ucdenver.edu/research/comirb/submissions/Pages/default.aspx

For the duration of this research the investigator must:

- Submit any change in the research design, investigator, and any new or changed study documents (including new/changed consent forms, questionnaires, advertisements, etc.) 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 Informed Consent from all subjects as required by COMIRB prior to the start of study procedures. COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed.
- Inform COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policies and Procedures.
- 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.

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.

Please reply to the email containing this letter, contact the COMIRB Help Desk at COMIRB@ucdenver.edu or call 303-724-1055 if you have questions or concerns.

Sincerely,

UCD Panel C