WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD.

MEMORANDUM

To: Donald Bowden, Ph.D.
Biochemistry

From: Chair,
Institutional Review Board

Date: 9/28/2016

Subject: Human Protocol: BG99-197
Diabetes Heart Study - A Study of Diabetes and Heart Disease in Families

Study Documents:
Protocol Version: Addendum_IMT Study Amendment 8_3.2.2012, DHS Protocol Addendum_Amend 11_10.30.12, DHS Protocol Addendum_Amend 26 CLEAN_June 2016, DHS Renewal Pilot Protocol_CLEAN Amend 16_03.13.2014, Diabetes Heart Study Protocol_Amendment 4_8.5.2010, IMT Addendum_DHS Informed Consent_3.4.2003, Medication Adherence_Protocol Addendum; Informed Consent Version: DHS Consent Form (approved), DHS Pilot 2013 Consent_CLEAN Amend 15_12.10.13 (approved); Advertisements: DHS Pilot 2013_Recruitment Letter Amend 15_New Brand_12.10.13, DHS Reconnect Letter_Amend 8_3.2.2012, Recruitment Flyer, Recruitment Flyer; Other Documents: AADHS_phone questionnaire_8.12.10.docx, Appointment Letter_DHS Pilot_12.10.2013, CRU Physical Exam_DHS Pilot 2013_CS_6.19.13, Medication Adherence Questionnaire_2.9.2015.docx, Medication Adherence_cover letter_2.9.2015.docx, Medication Adherence_Telephone Script.docx, MMAS Copyright Agreement, MMAS copyright notification letter_5.7.2015, Pregnancy Determination Form_DHS Pilot 2013, Proband Questionnaire_DHS Pilot 2013_DB_6.12.13, Results Letter_DHS Pilot_12.10.2013, Telephone Screener_DHS Pilot 2013_DB_6.12.13, Update letter to DHS participants_6.29.2015

This is to confirm for your record that the Institutional Review Board reviewed your progress report and consent form, containing compounded HIPAA authorization language, if applicable, for the above-named protocol. IRB approval was activated on 9/27/2016 and will expire on 9/26/2017. If the protocol is to remain active longer, a written request for renewal, together with a summary progress report, and a copy of the current consent form, if applicable, should be submitted to the Board at least one month prior to expiration.

This approval includes a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA autorization will be sought. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

Data submission plans meet the following expectations defined in the GWAS policy:
The data submission is consistent with all the applicable laws and regulations as well as institutional policies;
The IRB has determined that the uses of the data as described in the protocol are appropriate;
The identities of research participants will not be disclosed to the NIH GWAS repository; and
The WFUHS IRB has reviewed and verified that:

The submission of data to the NIH GWAS data depository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
The investigator's plan for de-identifying datasets is consistent with the standards outlined in the policy;
It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the NIH GWAS data repository; and
The genotype and phenotype data to be submitted will be/were collected in a manner consistent with 45CFR46.

This application indicates that advertising materials will be used for research purposes. Please consult with Creative Communications to ensure the appropriate visual identity is put forth.

This research, which was originally approved by the Full Board, is being renewed by the IRB under Expedited Review, Category 8c. The research has been closed to the accrual of new subjects and all subjects have completed intervention/interaction. Renewal is granted for data analysis only.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

This IRB is in compliance with the requirements in Part 56, Subchapter D, Part 312 of the 21 Code of Federal Regulations published January 27, 1981 and Part 46, Subpart A of 45 CFR published January 26, 1981.

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