



MADRAS DIABETES RESEARCH FOUNDATION

INSTITUTIONAL ETHICS COMMITTEE

Registered with Office for Human Rights Promotions (OHPR), US Dept. of Health & Human Service
IRB No. IRB00002640; IORG No. IORG0002118; Assurance No. FWA0002981

Date: 08 June 2012

To
Dr.V.Mohan
Principal Investigator
Madras Diabetes Research Foundation
Chennai-600 086

Protocol Title: "Centre for cArdiometabolic Risk Reduction for South-Asia (CARRS)-
Surveillance Study".

Subject: Approval of the study documents by the Institutional Ethics Committee for the
above referenced protocol.

Dear Dr. Mohan,

This is with reference to your submission letter dated 04 June 2012 the
following documents were reviewed and approved by the Institutional Ethics Committee
of Madras Diabetes Research Foundation.

- ❖ Clinical Protocol
- ❖ Informed Consent Form in English Version date 12 Apr 2012
- ❖ Informed Consent Form (GHI Migration FGD) in English Version date 12
Apr 2012
- ❖ Focus Group Discussion – Protocol and questions
- ❖ Participant Information sheet version: 1.2 Date: 13 June 2011 (Protocol
Version: 1.3 Date: 7 May 2012)
- ❖ Migration Instrument Survey Questionnaire Version: 1.0 Date: 7 May
2012
- ❖ CARRS surveillance project expenses

The Institutional Ethics Committee of Madras Diabetes Research Foundation
approves conduct of this study in its presented form under your supervision in Madras



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Diabetes Research Foundation. This approval is for one year and a periodic renewal is required every year.

The Institutional Ethics Committee of Madras Diabetes Research Foundation expects to be informed about the progress of the study, any changes in the protocol and patient information/informed consent and asks to provide a copy of the final report.

The Institutional Ethics Committee is constituted according to the Schedule Y of Indian & Drugs Cosmetic Act 1940 and Good Clinical Practice Guidelines issued by the Government of India Ministry of Health & Family Welfare (Department of Health), The Drugs & Cosmetic Act 1940 and The Drug and Cosmetic Rules 1945, Ethical Guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Research New Delhi 2006 and ICH GCP guidelines & the Clinical Trials act 1987 (amended 1990). This Institutional Ethics Committee operates to the standards laid down in the ICH GCP guidelines published in 1997 and implemented in January 1998.

Yours Sincerely,

Dr.M.Balasubramanyam
Member Secretary
Institutional Ethics Committee of Madras Diabetes Research Foundation
Chennai-600 086

Date: 8/6/2012