Attachment 4b. Local IRB Approval – Wayne State University IRB

WAYNE STATE UNIVERSITY

IRB Administration Office
87 East Canfield, Second Floor
Detroit, Michigan 48201
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Full AAHRPP Accreditation

CONCURRENCE OF EXEMPTION

To: Julie Gleason-Comstock
Family Medicine
2126 A/AB

From: Dr. Scott Millis S. Millis, PhD /40.
Chairperson, Behavioral Institutional Review Board (B3)

Date: July 19, 2011

RE: IRB #: 056911B3X

Protocol Title: Community Health Awareness Group (CHAG): Demonstration Project of HCV Rapid Tests in HIV Testing Settings

Sponsor: COMMUNITY HEALTH AWARENESS GROUP, INC.

Protocol #: 1105009744

The above-referenced protocol has been reviewed and found to qualify for **Exemption** according to paragraph #2 of the Department of Health and Human Services Code of Federal Regulations [45 CFR 46.101(b)].

- Protocol Summary Form (received in the IRB Office 05/19/2011)
- The request for a waiver of the requirement for written documentation of informed consent has been granted according to 45 CFR 46.117(1)(2). Justification for this request has been provided by the PI in the Protocol Summary Form. The waiver satisfies the following criteria: (i) the research involves no more than minimal risk to participants, (ii) the research involves no procedures for which written consent is normally required outside of the research context, (iii) the consent process is appropriate, and (iv) an information sheet disclosing the required and appropriate additional elements of consent disclosure will be provided to participants.
- Evaluation Research Information Sheet (dated 05/20/2011)
- Hepatitis C- Information About Testing Brochure
- Hepatitis C- Living with Chronic Hepatitis C Brochure
- Data Collection Tools: Demonstration Project Formative Questions

This proposal has not been evaluated for scientific merit, except to weigh the risk to the human subjects in relation to the potential benefits.

- Exempt protocols do not require annual review by the IRB.
- All changes or amendments to the above-referenced protocol require review and approval by the IRB **BEFORE** implementation.
- Adverse Reactions/Unexpected Events (AR/UE) must be submitted on the appropriate form within the timeframe specified in the IRB Administration Office Policy (http://irb.wayne.edu/policies-human-research.php).

NOTE:

1. Forms should be downloaded from the IRB Administration Office website at each use.
2. Submit a Closure Form to the IRB Administration Office upon completion of the study.