DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Public Health and Science

Office for Human Research Protections
1101 Wooton Parkway Suite 200
Rockville, MD 20852

Telephone: 301-496-7005
FAX: 301-402-0527
http://ohrp.osophs.dhhs.gov/polasur.htm

FROM: Division of Policy and Assurance
Office for Human Research Protections

RE: OHRP Approval of Federal-Wide Assurance (FWA) Update

The Office for Human Research Protections (OHRP) has approved the enclosed *update* to your Federal-Wide Assurance (FWA) recently submitted. The FWA approval has been extended for a three-year period from the approval of the update and should be renewed prior to its expiration. Any further update in the FWA should be submitted to OHRP by completing a new FWA form.

The **FWA identification number** is important and will be required in certain forms (e.g., PHS-2590) and for certification of IRB review to funding authorities. Under this Assurance, the designated Institutional Review Board(s) (IRBs) is/are recognized as the responsible IRB(s) for fulfilling, in part, the requirements of the Federal regulations at 45 CFR 46.

No human subject research for which this FWA applies may be initiated at your institution prior to approval by the OHRP-registered IRB(s) designated in this FWA. The principal investigator and the awardee institution are responsible for ensuring that every collaborating institution engaged in Federally conducted or supported research has appropriately assured compliance with 45 CFR 46 and complied with the IRB requirements prior to its involvement of human subjects. Failure to comply may result in fiscal sanctions by the supporting agency.

This Assurance defines the relationship of your institution with the supporting Federal Department or Agency. It sets out your responsibilities and the procedures that will be used by your institution to protect human research subjects. Among the most important elements of the assurance to comply are the prompt reporting requirements to the relevant Department of Agency head, any applicable regulatory body, as well as this office, and your agreement to ensure that the appropriate training and educational requirements as described in the terms of the FWA are fulfilled. **Your institution should consult with the supporting department or agency with regards to any additional requirements and/or guidance for human subjects research.**

The Federal regulations, policy, and guidance on the conduct of human subject research may be found at the OHRP website at http://ohrp.osophs.dhhs.gov.

Do not hesitate to contact OHRP should you have any questions.

JAN 28 2002

☐ **New Filing** X☐ **Update for Assurance Identifier:** FWA00001413

Department of Health and Human Services
Federalwide Assurance of Protection for Human Subjects

(1) Institution Name: **Centers for Disease Control and Prevention**
Address: **1600 Clifton Road, NE**
City, State, and zip code: (if USA) **Atlanta, GA 30333**
Country: (if outside USA): **USA**

HHS Institution Profile File (IPF) code, if known:

Federal Entity Identity Identification Number (EIN), if known:

assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the following document. (*indicate below*)

X☐ **Domestic Institutions**: (*choose one*)
X☐ ***The Belmont Report***
☐ ***Other*** *(please submit copy to OHRP with this Assurance)*

☐ **International Institutions**: (*choose one*)
☐ ***The Declaration of Helsinki***
☐ ***The Belmont Report***
☐ ***Other*** *(please submit copy to OHRP with this Assurance)*

(2) This institution assures that all of its activities related to Federally-supported human subject research will comply with the following procedural standards. (*indicate below*)

X☐ **Domestic Institutions**: X☐ **45 CFR 46 as Stipulated in the Terms of Assurance for Protection of Human Subjects Within the United States,** provided on this date at the OHRP website.
☐ ***Other*** *(please submit copy to OHRP with this Assurance)*

(*please check one of the following)*
X☐ This institution elects to assure compliance with the Terms of Assurance for all of its human subject research, regardless of funding source.
☐ This institution assures compliance with the Terms of Assurance only for Federally-supported research.

G Please check here if there are no such components or alternate names:

Name of Component	City	State (or Country if Outside US)
Agency for Toxic Substances & Disease Registry (ATSDR) Epidemiology Program Office (EPO) National center for Chronic Disease Prevention and Health Promotion (NCCDPHP) National Center for Environmental Health (NCEH) National Center for HIV, STD, and TB Prevention (NCHSTP) National Center for Infectious Disease (NCID) National Center for Injury Prevention and Control (NCIPC) National Immunization Program (NIP) Office for Global Health (OGH) Public Health Practice Program Office (PHPPO)	Atlanta	Georgia
National Institute for Occupational Health (NIOSH)	Cincinnati	Ohio
National Center for Health Statistics	Hyattsville	Maryland

(4) Operations, Procedures, and Oversight Mechanisms (a, b, c, e = optional)

(a) Institutional procedures for protecting human subjects were last updated on: 1/2001

(b) These procedures include formal mechanisms for monitoring compliance with human subject protection requirements. X☐Yes ☐ No

(c) The institution has established continuing programs to educate IRB members, IRB staff, and research investigators about human subject protection requirements. X☐Yes ☐ No

(d) For Domestic Institutions, the Signatory Official, Human Protections Administrator, and IRB Chairpersons of all designated IRBs have completed the relevant OHRP modules(s), and other staff are appropriately trained. For International Institutions, relevant personnel are required to complete appropriate comparable training. X☐Yes ☐ No

(e) Number of full time positions devoted solely to human subject education activities: 0

(f) If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number: M-1141

(5) Designation of Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs)

This institution designates the following IRB(s) for review of research on a regular basis* under this Assurance (if the IRB is not previously registered with HHS or has not provided a membership roster to HHS, please attach the necessary materials available elsewhere on this website).

*Institutions may, on an occasional or ad hoc basis, choose to rely on an IRB operating under another Institution's Assurance. Such occasional reliance must be documented in writing and provided to OHRP upon request, but need not be listed below. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the institutions may develop their own agreement.

HHS IRB Registration Identifier IORG0000112	**Name of IRB As Registered with HHS**	**Name and Signature of IRB Chairperson or IRB Organization Head Authorizing Designation of the IRB Under This Assurance**
IRB00000183	IRB #1/CDC IRB A	John R. Livengood
IRB00000184	IRB #2/CDC IRB B	John R. Livengood, MD, MPhil
IRB00000185	IRB #3/CDC IRB C	Deputy Associate Director for Science
IRB00000186	IRB #4/CDC NIOSH IRB, Cincinnati, OH	Centers for Disease Control and
IRB00000187	IRB #5/CDC NCHS IRB, Hyattsville, MD	Prevention (USERID: jrl1@cdc.gov)
IRB00000188	IRB #7/CDC IRB G	
IRB00000773	Biomedical Research Inst America IRB#1	

(6) Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person -- cannot be IRB Chairperson):

Signature John R Livengood Date: 11/06/01

First Name, Middle Initial, and Last Name: **John R. Livengood**
Degrees or Suffix (e.g., MD, PhD): **M.D., M.Phil.**
Institutional Title: **Deputy Associate Director for Science**

Human subject protection training last taken on: **5/23/01**

Telephone: (404) 639-7260
Fax: (404) 639-7341
E-mail: jrl1@cdc.gov

Address: 1600 Clifton Road, NE
City, State, and zip code: (if USA) Atlanta, GA 30333

(7) **Signatory Officials (i.e., Official Legally Authorized to Represent the Institution -- cannot be IRB Chairperson or IRB member):**

Acting officially and in an authorized capacity on behalf of this institution, I assure protections for human subjects as specified above. The IRBs above are designated to provide oversight for research under this Assurance. These IRBs will comply with the terms of the Assurance and possess appropriate knowledge of the local context in which this institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I have personally satisfied the education requirements referenced in the Terms of Assurance and will require that all other relevant personnel also do so. I will further require that all such personnel receive appropriate additional initial and continuing education about human subject protection requirements. (Note: False statements could be cause for invalidating this Assurance and may lead to administrative or legal action.)

I understand that all collaborating institutions engaged in Federally-supported human subject research must submit their own Assurance.

Signature Dixie E. Snider Jr. MD Date: 11/6/01

First Name, Middle Initial, & Last Name: **Dixie E. Snider, Jr.**
Degrees or Suffix (e.g., MD, PhD): **M.D., M.P.H.**
Institutional Title: **Assistant Surgeon General, Associate Director for Science**

Human subject protection training last taken on: **5/25/01**

Telephone: (404) 639-7240 Fax: (404) 639-7341 E-mail: des1@cdc.gov

Address: 1600 Clifton Road, NE
City, State, and zip code: (if USA): Atlanta, GA 30333

Signature John R. Livengood Date: 11/6/01

First Name, Middle Initial, and Last Name: **John R. Livengood**
Degrees or Suffix (e.g., MD, PhD): **M.D., M.Phil.**
Institutional Title: **Deputy Associate Director for Science**

Human subject protection training last taken on: **5/23/01**

Telephone: (404) 639-7260 Fax: (404) 639-7341 E-mail: jrl1@cdc.gov

Address: 1600 Clifton Road, NE
City, State, and zip code: (if USA) Atlanta, GA 30333

NOTE: Facilities operated by the US Government may require Department or Agency clearance. Please contact the relevant Department or Agency Human Protections Officer before forwarding to OHRP.

(8) HHS Approval

The Federalwide Assurance of Protection for Human Subjects submitted to HHS by the above institution is hereby approved for the conduct of Federally-supported research.

Signature of HHS Approving Official: Yvonne K Higgins Date: 28 December 2001

Name:

Address: Yvonne K. Higgins
Public Health Analyst
Office for Human Research Protections
OPHS/OS/DHHS
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Phone #: 3(Phone: 301-402-5034 FAX: 301-402-0527 ___@nih.gov

E-mail: yhiggins@osophs.dhhs.gov

Web: http://ohrp.osophs.dhhs.gov

Assurance Identifie