

Study Section business and for the study section to consider safety and occupational health-related grant applications.

For Further Information Contact: Nina Turner, Ph.D., Scientific Review Officer, NIOSH, 1095 Willowdale Road, Morgantown, WV 26506, (304) 285-5976; nturner@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC); Notice of Charter Renewal; Correction

Notice is hereby given of a change in the Charter Renewal of the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC), Notice of Charter Renewal which was published in the **Federal Register** on November 24, 2017, Volume 82, Number 225, page 55843.

The name of the committee should read as follows: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC) and the Summary section should read as follows:

SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 5, 2019.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F-63, Atlanta, GA 30341, Telephone (770) 488-1430. Email address: GCattledge@cdc.gov.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Invitation to Manufacturers of Pertussis Serological Kits

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces an opportunity for commercial manufacturers to work with CDC's National Center for Immunization and Respiratory Diseases (NCIRD) on the validation of pertussis serological kits prior to submission to the Food and Drug Administration (FDA) for marketing authorization. CDC is interested in the development of an assay that is an Immunoglobulin G (IgG) anti-pertussis toxin (PT) enzyme-linked immunosorbent assay (ELISA), calibrated to an international reference standard (such as FDA Reference Standard Lot #3, World Health Organization (WHO) International Standard 06/140, or equivalents). The ELISA will be used for *in vitro* serological diagnosis of pertussis in clinical cases of selected age groups. CDC will be able to provide guidance, materials, and evaluation support for the manufacturer; however, the manufacturer will be responsible for submitting a premarket submission to FDA with adequate information, including any analytical or clinical data needed to support the submission, to demonstrate to FDA that FDA can grant marketing authorization to the product.

DATES: CDC is accepting information through June 18, 2018.

ADDRESSES: You may submit information by any of the following methods:

- *Email:* PertussisDL@cdc.gov.
- *Mail:* Lucia Tondella, National Center for Immunization and

Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop D-11, Atlanta, GA 30329.

FOR FURTHER INFORMATION CONTACT:

For Technical Questions: Lucia Tondella, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop D-11, Atlanta, GA 30329. Phone: 404-639-1239, Email: PertussisDL@cdc.gov.

For Business Questions: Jason Cloward, Technology Transfer Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop E-51, Atlanta, GA 30329. Phone: 404-639-2679, Email: wvn3@cdc.gov.

SUPPLEMENTARY INFORMATION: CDC's National Center for Immunization and Respiratory Diseases (NCIRD), Division of Bacterial Diseases (DBD), Meningitis and Vaccine Preventable Diseases Branch (MVPDB) has lead technical responsibility for research, development and evaluation of diagnostic assays for their application in epidemiologic studies of pertussis. CDC uses epidemiologic, laboratory, clinical, and biostatistical sciences to control and prevent bacterial infectious disease such as pertussis. CDC also conducts applied research in a variety of settings, and translates the findings of this research into public health practice.

CDC is working closely with the Council of State and Territorial Epidemiologists (CSTE) to consider including serology as an appropriate diagnostic tool for confirming a pertussis case. Serology can be very useful for diagnosing pertussis in adolescents and adults during the later phases of disease when the current accepted diagnostic methods, culture and PCR, are no longer reliable. Sensitive and specific quantitative seroassays have been developed and are routinely used for diagnosis of pertussis world-wide; however, FDA marketing authorization is necessary before these seroassays can be made commercially available as *in vitro* diagnostics in the United States. To date, no quantitative pertussis serology kits are commercially available in the United States for diagnostic use.

Interested manufacturers that may have candidate products are invited to contact CDC to discuss potential opportunities for collaboration. At a minimum, discussions with CDC should include the following information for each candidate product:

- a. Product package insert or detailed instructions for use.