

**ATTACHMENT J**

**IRB APPROVAL**

DATE: 9/7/2006

FROM: IRB Administrator  
Human Research Protection Office  
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Amendment to Protocol #1955, "Metropolitan Atlanta Congenital Defects Program (MACDP)" (Expedited)

TO: JAMES KUCIK [EZK9]  
NCBDDD/DBDDD

CDC's IRB B has reviewed and approved your request to amend protocol #1955 by using the expedited review process outlined in 45 CFR 46.110(b)(2), minor changes in previously reviewed research during the period (of one year or less) for which approval is authorized.

The proposed changes involve the following:

- Modify the Atlanta Surveillance for Stillbirths' Project to reflect the purpose for implementing a pilot test survey instrument;
- Add a survey of Knowledge, Attitudes, and Practice Management Patterns Regarding Stillbirth Pregnancy Outcomes;
- Add to the case definition of MACDP to reflect the addition of the Atlanta Surveillance for Stillbirths Project;
- Add minor changes to reflect census updates; and
- Add minor wording and grammatical changes throughout the protocol.

Reminder: IRB approval of protocol #1955 will still expire on 3/26/2007. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any other proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639 4721 or e-mail: [huma@cdc.gov](mailto:huma@cdc.gov).

Connie Nakano

cc:  
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Kate Shaw  
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