OMB#: 0925-0593
EXPIRATION DATE: 07/31/2013

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

2500 North State Street
Jackson, Mississippi 39216-4505

Institutional Review Board
Telephone (601) 984-2815
Facsimile (601) 984-2961

DHHS FWA #00003630
IORG #0000043
IRB 1 Registration #00000061
IRB 2 Registration #00005033

Approval Notice
Amendment

May 12, 2011

Omar Abdul-Rahman, MD
School of Nursing
University Of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216-4505

RE: IRB File # 2010-0292
DEVELOPMENT OF A VISIT ASSESSMENT TOOL TO ADDRESS BIRTH DEFECTS AND DYSMORPHOLOGY FOR THE NATIONAL CHILDREN'S STUDY

Dear Dr. Abdul-Rahman:

Your Amendment was reviewed and approved by the Expedited review process on May 12, 2011. You may implement the amendment.

Please note the following information about your approved research protocol:

- Protocol Approval period: May 12, 2011 - January 18, 2012
- Parental Permission Document: Spanish version, Version 4-4-11
- Recruitment/Retention Material: Permission to Contact Form, Version 4-4-11
- Sponsor: National Institute of Child Health and Human Development (NICHD)
- Approved Enrollment #: 50
- Participant Population: Minors < 18
- Performance Sites: UMMC
- Amendment Description: Spanish translation of Parental Permission Document and Permission to Contact Form

Amendment Review History:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
05/09/2011	Amendment	Expedited	05/12/2011	Approved

Please remember to:

→ Use **the IRB file number** (2010-0292) on all documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure, UMMC Investigator Responsibilities, Protection of Human Research Participants.

A copy of the approved, date-stamped consent/assent/parental permission document(s) to use when obtaining consent/assent/parental permission will be available online at, http://irbweb.umc.edu/WebKit/. The IRB has the prerogative and authority to ask additional questions, request further information, require additional revisions, and monitor the conduct of your research and the consent process.

Please note, if this study involves an intervention of any sort (whether or not it involves a drug or device) you (or the "responsible party") must register the study before enrollment begins and report results within 12 months of study closure through Clinicaltrials.gov http://www.clinicaltrials.gov/. For additional information please go to http://irb.umc.edu/GuidanceInfo/ClinTrialRegistry.htm.

Penalties for responsible parties who fail to register applicable clinical studies are significant and include civil monetary penalties and, for federally-funded studies, withholding or recovery of grant funds.

We wish you the best as you conduct your research. If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815.

Sincerely,

Gailen D. Marshall, Jr., M.D., Ph.D.
Chairman, Institutional Review Board 2

GDM/kc

Enclosure(s): (1) Investigator Responsibilities, Protection of Human Research Participants
(2) Recruitment Material – Permission to Contact Form

OMB#: 0925-0593
EXPIRATION DATE: 07/31/2013

UMMC Investigator Responsibilities
Protection of Human Research Participants

The IRB reviews research to ensure that the federal regulations for protecting human research participants outlined in UMMC policy, the Department of Health and Human Services (DHHS) regulations (45 CFR 46) and the Food and Drug Administration (FDA) regulations (21 CFR Parts 50 & 56), as well as other requirements, are met. The University of Mississippi Medical Center's Federalwide Assurance (FWA), FWA# 00003630, awarded by the Office for Human Research Protections (OHRP) at DHHS, is a written pledge to follow federal guidelines for protecting human research participants in accordance with the principles of the Belmont Report. **All investigators must read both the Belmont Report and the UMMC FWA to understand their responsibilities in conducting research involving human participants**. Both documents are available on the Human Research Office webpage, http://irb.umc.edu/ , and in hard copy by request from the Human Research Office. Some of the responsibilities investigators have when conducting research involving human participants are listed below.

1. Conducting the Research: You are responsible for making sure that the research is conducted according to the IRB approved research protocol. **You are also responsible for the actions of the study's co-investigators and research staff**.

2. Participant Enrollment: You may not recruit or enroll participants prior to the IRB approval date or after the expiration date of IRB approval. All recruitment materials for any form of distribution or media use must be approved by the IRB prior to their use. If you need to recruit more participants than was noted in your IRB approval letter, you must submit an amendment requesting an increase in the number of participants.

3. Informed Consent: Informed consent is a process that begins with the initial contact and ends at some point after the study is complete. You are responsible for the conduct of the consent process, ensuring that effective informed consent is obtained and documented using **only** the IRB-approved and stamped consent document(s), and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Whoever is presenting the consent document to the potential participant and conducting the consent discussion must have all pertinent information at hand, be knowledgeable about the study and the disease or condition involved, if any, and have the ability and experience to answer questions regarding the study and any treatment involved. Please give all participants a signed copy of each consent or assent document they sign, and keep the originals in your secured research files for at least six (6) years. When appropriate, you should place a copy of the consent document in the participant's medical record.

4. Continuing Review: The IRB must review and approve all IRB-approved research protocols at intervals appropriate to the degree of risk, but not less than once per year. **There is no grace period.** Prior to the date on which IRB approval of the research expires, the IRB will send you three reminders to submit a Continuing Review, 90, 60 and 30 days prior to expiration. Although reminders are sent, **it is ultimately your responsibility to submit the renewal in a timely fashion to ensure that a lapse in IRB approval does not occur.** If IRB approval of your research lapses, you must stop new participant enrollment, and contact the IRB immediately.

5. Amendments and Revisions: If you wish to amend or change any aspect of your research, including research design, interventions or procedures, number of participants, participant population, consent document, instruments, surveys or recruitment and retention material, you must submit the amendment or revisions to the IRB for review with a Request for Change. You **may not initiate** any amendments or changes to your research without first obtaining IRB review and written approval. The **only exception** is when the change is necessary to eliminate apparent immediate hazard to participants. In that case the IRB should be immediately informed of this necessity, but the change may be implemented before obtaining IRB approval.

6. Unanticipated Events: All adverse events that are unanticipated **(unanticipated means that the event is serious, unexpected, related or possibly related to participation in the study and places participants at greater risk of harm than previously recognized)** and serious protocol deviations, must be reported to the IRB **within ten (10) business days** of discovery. The only exception to this policy is death - **the death of a UMMC research participant must be reported within 48 hours of discovery.** Reportable events should be submitted to the IRB with the Adverse Event/Unanticipated Problem Report form.

Events that do not meet the definition of an unanticipated problem involving risk to participants or others, including research related injury occurring at a UMMC performance site or to a UMMC study participant, participant complaints, problems, minor protocol deviations and non-compliance with the IRB's requirements for protecting human research participants should be reported as follows: Minor deviations and problems should be submitted at the time of continuing review, as instructed on the form. All other events should be reported in writing via letter or email to the IRB with sufficient detail to allow the reviewer to understand the problem and any actions taken to prevent it from happening again.

7. Research Record Keeping: At a minimum, you must keep the following research related records in a secure location for at least six years: the IRB approved research protocol and all amendments; all versions of the investigator's brochure; all informed consent documents; all recruiting materials; all renewal applications; all adverse or unanticipated event reports; all correspondence to and from the IRB; and all raw data.

8. Reports to FDA and Sponsor: When you submit the required annual report to the FDA or you submit required reports to your sponsor, you **must** provide a copy of that report to the IRB. You may submit the report with your IRB continuing review application.

9. Provision of Emergency Medical Care: When a physician provides emergency medical care to a participant without prior IRB review and approval, to the extent permitted by law, such activities will not be recognized as research and the data cannot be used in support of the research.

10. Final Reports: When you have completed the study, (no further participant enrollment, interactions, interventions or data analysis) or stopped work on it, you must submit a Final Report to the IRB using the Final Report form.

11. On-Site Evaluations, FDA Inspections, or Audits: If you are notified that your research will be reviewed or audited by the FDA, OHRP, the sponsor, any other external agency, or any internal group, you **must** inform the IRB immediately and submit all audit reports received as a result of the audit to the IRB.

If you have questions or need assistance, please contact the Human Research Office at 601 984-2815.

OMB#: 0925-0593
EXPIRATION DATE: 07/31/2013

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DHHS FWA #00003630
IORG #0000043
IRB 1 Registration #00000061
IRB 2 Registration #00005033

Approval Notice
Amendment

March 2, 2011

Omar Abdul-Rahman, MD
School of Nursing
University Of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216-4505

RE: IRB File # 2010-0292
DEVELOPMENT OF A VISIT ASSESSMENT TOOL TO ADDRESS BIRTH DEFECTS AND DYSMORPHOLOGY FOR THE NATIONAL CHILDREN'S STUDY

Dear Dr. Abdul-Rahman:

Your Amendment was reviewed and approved by the Expedited review process on March 2, 2011. You may implement the amendment.

Please note the following information about your approved research protocol:

- Protocol Approval period: March 2, 2011 - January 18, 2012
- Consent Document: Version 02/18/2011
- Sponsor: National Institute of Child Health and Human Development (NICHD)
- Approved Enrollment #: 50
- Participant Population: Minors < 18
- Performance Sites: UMMC
- Amendment Description: Update consent document
  Change Dr. Omar Abdul Rahman to Principal Investigator and change Dr. Sharon Wyatt to Co-Investigator

Amendment Review History:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
02/28/2011	Amendment	Expedited	03/02/2011	Approved

Please remember to:

→ Use **the IRB file number** (2010-0292) on all documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure, UMMC Investigator Responsibilities, Protection of Human Research Participants.

A copy of the approved, date-stamped consent/assent/parental permission document(s) to use when obtaining consent/assent/parental permission will be available online at, http://irbweb.umc.edu/WebKit/. The IRB has the prerogative and authority to ask additional questions, request further information, require additional revisions, and monitor the conduct of your research and the consent process.

Please note, as a condition for publication of study results, the International Committee of Medical Journal Editors (ICMJE) requires all clinical research studies that began enrolling participants on or after July 1, 2005, to be entered in a public registry **before enrollment begins**. Additionally, Public Law 110-85, Title VIII, enacted September 27, 2007, requires registration of clinical trials and submission of results data through ClinicalTrials.gov. For additional information please go to http://irb.umc.edu/GuidanceInfo/ClinTrialRegistry.htm

Penalties for responsible parties who fail to register applicable clinical studies are significant and may include civil monetary penalties and, for federally-funded studies, withholding or recovery of grant funds.

We wish you the best as you conduct your research. If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815.

Sincerely,

Gailen D. Marshall, Jr., M.D., Ph.D.
Chairman, Institutional Review Board 2

GDM/dr

Enclosure(s): (1) Investigator Responsibilities, Protection of Human Research Participants

OMB#: 0925-0593
EXPIRATION DATE: 07/31/2013

UMMC Investigator Responsibilities
Protection of Human Research Participants

The IRB reviews research to ensure that the federal regulations for protecting human research participants outlined in UMMC policy, the Department of Health and Human Services (DHHS) regulations (45 CFR 46) and the Food and Drug Administration (FDA) regulations (21 CFR Parts 50 & 56), as well as other requirements, are met. The University of Mississippi Medical Center's Federalwide Assurance (FWA), FWA# 00003630, awarded by the Office for Human Research Protections (OHRP) at DHHS, is a written pledge to follow federal guidelines for protecting human research participants in accordance with the principles of the Belmont Report. **All investigators must read both the Belmont Report and the UMMC FWA to understand their responsibilities in conducting research involving human participants**. Both documents are available on the Human Research Office webpage, http://irb.umc.edu/ , and in hard copy by request from the Human Research Office. Some of the responsibilities investigators have when conducting research involving human participants are listed below.

1. Conducting the Research: You are responsible for making sure that the research is conducted according to the IRB approved research protocol. **You are also responsible for the actions of the study's co-investigators and research staff**.

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3. Informed Consent: Informed consent is a process that begins with the initial contact and ends at some point after the study is complete. You are responsible for the conduct of the consent process, ensuring that effective informed consent is obtained and documented using **only** the IRB-approved and stamped consent document(s), and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Whoever is presenting the consent document to the potential participant and conducting the consent discussion must have all pertinent information at hand, be knowledgeable about the study and the disease or condition involved, if any, and have the ability and experience to answer questions regarding the study and any treatment involved. Please give all participants a signed copy of each consent or assent document they sign, and keep the originals in your secured research files for at least six (6) years. When appropriate, you should place a copy of the consent document in the participant's medical record.

4. Continuing Review: The IRB must review and approve all IRB-approved research protocols at intervals appropriate to the degree of risk, but not less than once per year. **There is no grace period.** Prior to the date on which IRB approval of the research expires, the IRB will send you three reminders to submit a Continuing Review, 90, 60 and 30 days prior to expiration. Although reminders are sent, **it is ultimately your responsibility to submit the renewal in a timely fashion to ensure that a lapse in IRB approval does not occur.** If IRB approval of your research lapses, you must stop new participant enrollment, and contact the IRB immediately.

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Events that do not meet the definition of an unanticipated problem involving risk to participants or others, including research related injury occurring at a UMMC performance site or to a UMMC study participant, participant complaints, problems, minor protocol deviations and non-compliance with the IRB's requirements for protecting human research participants should be reported as follows: Minor deviations and problems should be submitted at the time of continuing review, as instructed on the form. All other events should be reported in writing via letter or email to the IRB with sufficient detail to allow the reviewer to understand the problem and any actions taken to prevent it from happening again.

7. Research Record Keeping: At a minimum, you must keep the following research related records in a secure location for at least six years: the IRB approved research protocol and all amendments; all versions of the investigator's brochure; all informed consent documents; all recruiting materials; all renewal applications; all adverse or unanticipated event reports; all correspondence to and from the IRB; and all raw data.

8. Reports to FDA and Sponsor: When you submit the required annual report to the FDA or you submit required reports to your sponsor, you **must** provide a copy of that report to the IRB. You may submit the report with your IRB continuing review application.

9. Provision of Emergency Medical Care: When a physician provides emergency medical care to a participant without prior IRB review and approval, to the extent permitted by law, such activities will not be recognized as research and the data cannot be used in support of the research.

10. Final Reports: When you have completed the study, (no further participant enrollment, interactions, interventions or data analysis) or stopped work on it, you must submit a Final Report to the IRB using the Final Report form.

11. On-Site Evaluations, FDA Inspections, or Audits: If you are notified that your research will be reviewed or audited by the FDA, OHRP, the sponsor, any other external agency, or any internal group, you **must** inform the IRB immediately and submit all audit reports received as a result of the audit to the IRB.

If you have questions or need assistance, please contact the Human Research Office at 601 984-2815.

OMB#: 0925-0593
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DHHS FWA #00003630
IORG #0000043
IRB 1 Registration #00000061
IRB 2 Registration #00005033

Approval Notice
Initial Review (Response To Revisions)

January 19, 2011

Sharon B. Wyatt, RN, CS, PhD
School of Nursing
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216-4505

RE: IRB File # 2010-0292
DEVELOPMENT OF A VISIT ASSESSMENT TOOL TO ADDRESS BIRTH DEFECTS AND DYSMORPHOLOGY FOR THE NATIONAL CHILDREN'S STUDY

Dear Dr. Wyatt:

Your Initial Review (Response To Revisions) was reviewed and approved by the Expedited review process on January 19, 2011. You may begin this research.

Please note that you may not enroll non-English speaking participants until you submit a Request for Change with the translated document and certification of translation, or translated and back-translated documents with the qualifications of each translator.

Please note the following information about your approved research protocol:

- Protocol Approval period: January 19, 2011 - January 18, 2012
- Parental Permission Document: Version date 1-19-11
- Recruitment/Retention Material: Permission to Contact form
- Research Protocol: Version 12-6-10
- Sponsor: National Institute of Child Health and Human Development (NICHD)
- Approved Enrollment #: 50
- Participant Population: Minors < 18
- Performance Sites: UMMC
- Expedited Category(ies): 45 CFR 46.110(b) and/or 21 CFR 56.110(b)

(4) - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
(6) - Collection of data from voice, video, digital, or image recordings made for research purposes.

Initial Review (Response To Revisions) Review History:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
12/10/2010	Initial Review	Expedited	12/16/2010	Revisions Required
01/05/2011 – 01/19/2011	Response To Revisions	Expedited	01/19/2011	Approved

Please remember to:

→ Use **the IRB file number** (2010-0292) on all documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure, UMMC Investigator Responsibilities, Protection of Human Research Participants.

A copy of the approved, date-stamped consent/assent/parental permission document(s) to use when obtaining consent/assent/parental permission will be available online at, http://irbweb.umc.edu/WebKit/. The IRB has the prerogative and authority to ask additional questions, request further information, require additional revisions, and monitor the conduct of your research and the consent process.

Please note, as a condition for publication of study results, the International Committee of Medical Journal Editors (ICMJE) requires all clinical research studies that began enrolling participants on or after July 1, 2005, to be entered in a public registry **before enrollment begins**. Additionally, Public Law 110-85, Title VIII, enacted September 27, 2007, requires registration of clinical trials and submission of results data through ClinicalTrials.gov. For additional information please go to http://irb.umc.edu/GuidanceInfo/ClinTrialRegistry.htm

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We wish you the best as you conduct your research. If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815.

Sincerely,

Gailen D. Marshall, Jr., M.D., Ph.D.
Chairman, Institutional Review Board 2

GDM/kc

Enclosure(s): (1) Investigator Responsibilities, Protection of Human Research Participants
(2) Recruitment Material – Permission to Contact form

cc: Kimberly W. Hoover, Ph.D., R.N., Dean, School of Nursing
Vice Chancellor for Health Affairs
Office of Integrity and Compliance

OMB#: 0925-0593
EXPIRATION DATE: 07/31/2013

UMMC Investigator Responsibilities
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If you have questions or need assistance, please contact the Human Research Office at 601 984-2815.

South Dakota State University

Office of Research/Human Subjects Committee
SAD Room 124
Box 2201 SDSU
Brookings, SD 57007

To: Bonny Specker, National Children's Study/E.A. Martin Program

Date: September 15, 2010

Project Title: Development of a Visit Assessment Tool to Address Birth Defects & Dysmorphology

Approval #: IRB-1009004-EXP

The committee approved your project using expedited procedures as described in 45 CFR 46.110. The activity was deemed to be no greater than minimal risk, and the following expedited categories from 63 FR 60364-60367 were found to be applicable to your activity:

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
and
(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

Please note the following special conditions:

- Because a photograph of the infant is taken at/near the time of birth, if that photo is used, no additional information needs to be conveyed to the mother.
- If a separate photo is taken or taken at a time not explained through a VIS, please prepare a VIS that explains this procedure and submit it to the IRB.
- If/when protocol 2 (e.g., measurements) is implemented, please prepare the necessary VIS as needed and submit it to the IRB.

One-year approval of your project will be dated starting 9/15/10. If you require additional time to complete your project, please submit a request for extension before 9/14/11. Protocol changes must be approved by the Committee prior to implementation. Forms may be found on the Human Subjects web page. If there are any unanticipated problems involving risks to

subjects or others, please contact the SDSU Research Compliance Coordinator. At the end of the project please inform the committee that your project is complete.

If I can be of further assistance, don't hesitate to let me know.

Sincerely,

Norm

Norman O. Braaten
SDSU Research Compliance Coordinator