

APPROVAL FORM

THESES/DISSERTATION and INSTITUTIONAL REVIEW BOARD APPROVAL

This is to certify that the dissertation entitled:

Pain and Pain Management in a Medicaid Waiver Program

presented by Elizabeth Annette Byma

has been accepted towards fulfillment of the requirements for the

doctoral degree in Nursing

University and federal policies and procedures require that all research involving human or animal subjects receive **prior approval** from the appropriate review board. (See Faculty Handbook (<http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/index.htm>) and the Academic Programs book (<http://www.reg.msu.edu/AcademicPrograms/>).

HUMAN SUBJECTS

Does the thesis or dissertation you are submitting include research involving human subjects or materials of human origin? (Research involving human subjects includes surveys and telephone interviews used for research; materials of human origin include human blood and /or tissue.)

☒ Yes IRB Log Number: X08-742

☐ No

If **yes**, indicate Institutional Review Board (IRB) log number for the **approved** protocol and attach the Institutional Review Board **approval** letter for that protocol to this form.

ANIMAL SUBJECTS

Does the thesis or dissertation you are submitting include research involving vertebrate animals in any way?

☐ Yes AUF Number: _____

☒ No

If **yes**, and an animal use form was submitted to the Institutional Animal Care & Use Committee (IACUC), please list the **approval** number above and attach a copy of the IACUC **approval** letter to this form.

If **yes**, but your project did not need an animal use form, provide a copy of the letter from the IACUC which cites the relevant exclusionary policy.

Thesis/Dissertation approved by professor

☒ Yes

☐ No

IRB documentation approved by professor

☒ Yes

☐ No

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Office Use Only: _____ Semester Submitted: _____ Degree List: _____

MICHIGAN STATE
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Initial IRB
Application
Determination
Exempt

August 26, 2008

To: Charles GIVEN
B510 W. Fee Hall
MSU

Re: IRB# X08-742 Category: EXEMPT 4
Approval Date: August 26, 2008

Title: Pain management in a Medicaid waiver program: A comparison to nursing home care

The Institutional Review Board has completed their review of your project. I am pleased to advise you that your project has been deemed as exempt in accordance with federal regulations.

Additional investigator to include Elizabeth Byma.

The IRB has found that your research project meets the criteria for exempt status and the criteria for the protection of human subjects in exempt research. Under our exempt policy the Principal Investigator assumes the responsibilities for the protection of human subjects in this project as outlined in the assurance letter and exempt educational material. The IRB office has received your signed assurance for exempt research. A copy of this signed agreement is appended for your information and records.

Renewals: Exempt protocols do not need to be renewed. If the project is completed, please submit an *Application for Permanent Closure*.

Revisions: Exempt protocols do not require revisions. However, if changes are made to a protocol that may no longer meet the exempt criteria, a new initial application will be required.

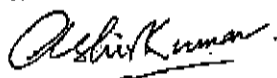
Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events, or any problem that may increase the risk to the human subjects and change the category of review, notify the IRB office promptly. Any complaints from participants regarding the risk and benefits of the project must be reported to the IRB.

Follow-up: If your exempt project is not completed and closed after three years, the IRB office will contact you regarding the status of the project and to verify that no changes have occurred that may affect exempt status.

Please use the IRB number listed above on any forms submitted which relate to this project, or on any correspondence with the IRB office.

Good luck in your research. If we can be of further assistance, please contact us at 517-355-2180 or via email at IRB@msu.edu. Thank you for your cooperation.

Sincerely,



Ashir Kumar, M.D.
BIRB Chair

c: Barbara A. GIVEN
B510 W. Fee Hall
MSU



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