DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
General Medical Sciences
Bethesda, Maryland 20892-6200

http://www.nigms.nih.gov

APR 14 2005

James A. Glazier, Ph.D.
717 East Third St, SW 159
Bloomington, IN 47405

Re: 1 R01 GM076692-01 B270LP MAY 2005 Council

Dear Dr. Glazier:

I am enclosing a copy of the summary statement prepared by the scientific review administrator of the initial review group (IRG) that evaluated your application. Also enclosed is an information sheet (NIGMS Staff Actions on Applications after Initial Review) explaining the actions that NIGMS staff may take with regard to applications. The actions or rank that may be recommended by an IRG are underlined. Please consult this sheet to ascertain which NIGMS staff action pertains to your application. If your application received a rating that makes it unlikely for funding, please be assured that this will in no way prejudice the independent consideration of any applications (revised or new) that you may submit in the future. The third enclosure describes the appeal process.

REMINDER for Required, Countersigned Information: If your application, with the exception of T32 or R25 applications, received a percentile ranking between 0.1 and 20.0, or if a percentile ranking is not specified and the priority score is between 100 and 250, please submit Other Support information within two weeks of receipt of the Summary Statement. Further, if your research involves human subjects, you must submit information on required education in the protection of human research participants for all key personnel. Please refer to the enclosed NIGMS Staff Actions sheet for instructions.

This letter is not intended to imply anything about the ultimate funding status of your application. If you have questions about the peer review process or concerns about the scientific review of your application, I encourage you to discuss them with me, your program director, as soon as possible. For information about the business aspects of your application, you may contact the grants management officer identified below.

Sincerely yours,

Peter Lyster, Ph.D.
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The Grants Management Officer is:
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Enclosures (3)
Business Official (Letter only)

SUMMARY STATEMENT
(Privileged Communication)

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Release Date: 04/11/2005

Application Number: 1 R01 GM076692-01
Formerly: 1R01EB005815-01

GLAZIER, JAMES A PHD
717 EAST THIRD ST, SW 159
BLOOMINGTON, IN 47405

Review Group: ZEB1 OSR-A (M1)
National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel

Meeting Date: 01/31/2005
Council: MAY 2005
Requested Start: 07/01/2005

RFA/PA: EB05-501
PCC: B000LP

Project Title: MSM - Multiscale Studies of Segmentation in Vertebrate *

SRG Action: Priority Score: 145
Human Subjects: 10-No human subjects involved
Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested	Estimated Total Cost
1	250,000	377,869
2	250,000	377,869
3	250,000	377,869
TOTAL	750,000	1,133,607

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1 R01 GM076692-01 GLAZIER, JAMES

RESUME AND SUMMARY OF DISCUSSION:
The proposed work will test the hypothesis that during segmentation, physical forces and biomaterial properties must coordinate with a moving biological oscillator—the segmentation clock—for somitogenesis to succeed. This question is of fundamental importance for understanding the somitogenesis process and would have significant impact on the field as well as the community. Understanding the precursor mechanisms of tissue development would lead to insight into a wide variety of medical topics. The investigators are highly qualified and have excellent track-records in this area. There are both junior and senior personnel on this project. There is a plan for connecting the modeling and experimentation. Some aspects have already been validated. They have developed models at each scale of the molecular, cellular and tissue level and provide a method of parameter estimation, validation and testing. There is a definitive algorithm for carrying out the work. No current biological simulation system covers the range of scales and techniques that are being studied in this proposal. The scientific development is grounded in a very well-formulated hypothesis driven research. The research methodology described in this proposal has four major components: 1) Identifying (discovering) mechanisms and relevant models to use at each score; 2) Determining the parameters for each level of the model; 3) Validating model results; and 4) Testing model predictions of normal and abnormal behaviors. This proposal will develop a multiscale model of somitogenesis within a Tissue Simulation Toolkit (TST) environment. The TST software will be open source and distributed via SourceForge, and the Notre Dame and Indiana University websites.

DESCRIPTION (provided by applicant):
In vertebrates, segmentation during early embryogenesis forms somites, recurring tissue modules, distributed along the anterior-posterior axis. Segmental structures give rise to the ribs, vertebrae, limbs, associated muscles, and central and peripheral nervous system. Failures in segmentation can be lethal or cause serious developmental abnormalities. Somitogenesis relies on a molecular clock, growth factor gradients and the expression of cell-adhesion and extracellular matrix (ECM) molecules. Segmentation requires complex, large-scale (millimeter) coordinated movement of cells and ECM. Despite increasing knowledge of the molecular mechanisms underlying segmentation, the interplay of molecular-, cell- and tissue-level mechanisms during somitogenesis remains obscure. Because of the tight feedback between subcellular and large-scale processes, no single-scale model can simulate somitogenesis. Current models address only the subcellular or macroscopic levels and do so separately. A successful multiscale model will answer one of developmental biology's great open problems: how do the molecular mechanisms of fate determination couple to large-scale tissue deformations? The proposed work will test the hypothesis that during segmentation, physical forces and biomaterial properties must coordinate with a moving biological oscillator, the segmentation clock, for successful somitogenesis. We will both model and conduct experiments on key developmental mechanisms ranging from local regulation of cell adhesion proteins (micrometers) to global tissue deformations (millimeters). We will develop novel theories and modeling approaches to bridge these scales. Our methodology has four major components: 1) Identifying (discovering) mechanisms and relevant models at each scale. 2) Determining the parameters for each level of model. 3) Validating model results. 4) Testing model predictions of normal and abnormal behaviors, e.g. inhibition or overproduction of adhesion molecules. The techniques and insights the research will produce will apply to other developmental processes. The software we develop will form the core of an open-source, multiscale and general purpose Tissue Simulation Toolkit, which other researchers can apply to this and other developmental problems. The proposed research contributes to public health by addressing the causes of a significant subset of the developmental malformations which occur in approximately 150,000 infants born each year in the USA (1 out of 28 births). Disturbing somite formation results in Klippel-Feil syndrome.spondylocostal dysostosis.Jarcho-Levin syndrome, congenital scoliosis and kyphosis, Goldenhar syndrome, and spina bifida, among others disorders. Studying the developmental mechanisms in vertebral patterning will aid in the identification of protective or potentially disruptive factors for normal somitogenesis and could potentially impact treatments for the prevention of vertebral patterning disorders.

CRITIQUE 1

SIGNIFICANCE:
The proposed work will test the hypothesis that during segmentation, physical forces and biomaterial properties must coordinate with a moving biological oscillator, the segmentation clock, for somitogenesis to succeed. This question is of fundamental importance for the understanding of the somitogenesis process. The proposed work to develop a Tissue Simulation Toolkit capable of modeling multiscale aspects of tissue development is excellent. The research plan is very good and the work should have very positive impacts on other areas of mathematical biology.

INVESTIGATOR:
The investigators are very well-established researchers. They have excellent track records and have already released a widely used and available modeling system. The group of investigators is of very high caliber, they are well positioned to carry out the proposed work and have interdisciplinary research experience. They are well versed in modern multiscale techniques and have been successful on smaller similar projects. The investigators have clearly thought about how to interface between different scales and models. All the investigators have excellent track records in supporting undergraduate research.

INNOVATION:
No current biological simulation system covers the range of scales and techniques that are being studied in this proposal. The scientific development is grounded in very well-formulated hypothesis driven research.

APPROACH:
The research methodology described in this proposal has four major components: 1) Identifying (discovering) mechanisms ad relevant models to use at each score; 2) Determining the parameters for each level of the model; 3) Validating model results; and 4) Testing model predictions of normal and abnormal behaviors, e.g. inhibition or overproduction of adhesion molecules. This is a new collaboration between modeling experts at Indiana University and University of Notre Dame who have traditionally focused their models on the same system, but at different scales. Experimentalists at the Kansas University Medical Center, currently working on a single experimental scale, but who wish to employ a multiscale approach will also collaborate. Together this proposal will develop a multiscale model of somitogenesis within a Tissue Simulation Toolkit (TST) environment. The software should be a welcome addition to the public domain. Clearly this research and software will be very valuable to other areas of research. The work will provide interdisciplinary education of undergraduates and graduate students.

ENVIRONMENT:
The environment is excellent and adequate for the research.

What are the broader impacts of the proposed activity?
The work proposed will contribute considerably to understanding somitogenesis and of related diseases. The integration of experiments with multiscale modeling will provide a powerful predictive mechanism for the consolidation of current findings and the generation of new hypotheses regarding gastrulation. In the long term, these findings will reveal new avenues for therapeutic intervention. This project will produce important and novel tools for research on basic biological problems and the biomedical community at large. Future contributions of students trained in this unique interdisciplinary environment will heighten that impact. This proposal will increase the amount of interdisciplinary research and provide new foci for the education of undergraduate, graduate and postdoctoral students. The software development and dissemination plan is well thought-out and the team has excellent past-experience.

OVERALL EVALUATION:

This is an excellent proposal with very clear research plan and software development and dissemination strategy.

CRITIQUE 2:

SIGNIFICANCE:
The proposed activities are important to understanding not only the described field but also allied and related fields. This proposal focuses on developmental biology, specifically what is the interaction between molecules and tissue. Their work could have significant impact on their field as well as the medical community. Being able to connect the molecular cues to the final result would be a great breakthrough. Their algorithm does not seem to be to innovative but does seem to suggest a high probability for success. The focus is mostly on software development with some proposed model analysis.

INVESTIGATORS:
The investigators are accomplished, with track records for collaboration, especially in regard to the scope of the stated project. The team is excellent and the methodology is well planned. The investigators are well qualified to carry out their plan. The collaborators are at other institutions but the distance should not be a factor in limiting their working together.

INNOVATION:
The creation of a tissue simulation tool kit, intending to perform multiscale modeling of cell interactions and tissue level models is innovative and appropriate.

APPROACH:
Although the background section is rather extensive, unfortunately, a detailed research plan with an explicit description of the study arms have not been included.

ENVIRONMENT:
The software they propose to develop and make available would significantly impact many researchers in their field. The software would be of importance in related areas such as wound healing and pattern formation. The working group is made up of both senior and junior faculty and they propose to hire postdoctoral students and graduate students to assist, however there is no apparent plan of using this to address diversity. This reviewer does not believe it would enhance infrastructure or education at IU as their environment is already top notch.

The environment is supportive of the described research, with sufficient access to resources. The investigators are cognizant of diversity issues and have stated their strong documented support for diversity.

What are the broader impacts of the proposed activity?
The described project builds on an existing long-term collaboration, rather than introducing new collaborators as part of the intended novel cross-disciplinary pollination. The project is clearly multi-scale, although the distribution scheme could be more ambitious.

OVERALL EVALUATION:
The project is of great value in promoting an improved and increased understanding of somitogenesis and embryogenesis, and could be strengthened by improved distribution scheme and more specific descriptions of the research arms. Understanding the precursor mechanisms of tissue development would lead to insight into a wide variety of medical topics. This proposal has a chance of significantly impacting their field and closely related fields. Any success in connecting the molecular mechanism to tissue would be a breakthrough and would lead to more advances. Hence, this is a good proposal that addresses an important scientific question through multiscale modeling. The PI is a leader in this field and the team has a plan for model validation through-out the experimentation. Success depends on the development of the TST software.

THE FOLLOWING RESUME SECTION WAS PREPARED BY THE SCIENTIFIC REVIEW

ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

COMMITTEE BUDGET RECOMMENDATIONS: The budget is recommended as requested.

ADMINISTRATIVE NOTES:
The Resume and Summary of Discussion is essentially identical to the NSF panel summary written for this application, with minor modifications. The roster contains the names of all of the reviewers participating in all five of the MSM sub-panel meetings.

NOTICE: The NIH has modified its policy regarding the receipt of amended applications. Detailed information can be found by accessing the following URL address: http://grants.nih.gov/grants/policy/amendedapps.htm

NIH announced implementation of Modular Research Grants in the December 18, 1998 issue of the NIH Guide to Grants and Contracts. The main feature of this concept is that grant applications (R01, R03, R21, R15) will request direct costs in $25,000 modules, without budget detail for individual categories. Further information can be obtained from the Modular Grants Web site at http://grants.nih.gov/grants/funding/modular/modular.htm

MEETING ROSTER

National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel
NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING
ZEB1 OSR-A (M1) R
January 31, 2005 - February 01, 2005

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

NIGMS STAFF ACTIONS ON APPLICATIONS AFTER INITIAL REVIEW *

REMINDER: If you have not done so and if your application, **with the exception of T32 or R25 applications**, received a percentile ranking between 0.1 and 20.0 or a priority score alone between 100 and 250, please forward the information requested below as soon as possible to the Grants Management Officer named in the accompanying letter at FAX number 301-451-5601. **The request for this information is not intended to imply anything about the ultimate funding status of your application.**

- Up-to-date information on active and pending support for key personnel, submitted as instructed in the PHS Form 398 guidelines on Other Support. A cover letter signed by both the Principal Investigator and an official authorized to sign for the applicant organization must accompany the information.

- For research involving human subjects, please provide the OHRP (Office for Human Research Protections) Assurance Type and number and the Certification of Institutional Review Board Approval and refer to the following URL: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. This site details the information that must be provided for all key personnel. Key personnel include all individuals responsible for the design and conduct of the study.

Priority Score and Percentile:

- ***If your application received a percentile ranking between 0.1 and 30.9***: At this time, you should come to no conclusions concerning the probability of funding, since the rank accorded your application is only one of the factors that is considered in making funding decisions. We will notify you specifically no later than 30 days after the National Advisory General Medical Sciences Council (NAGMS) meeting of May 19-20, 2005, if the Council makes a recommendation that differs from or alters that of the initial review group. Your application will remain active until the automatic withdrawal date of March 31, 2006.

- ***If your application received a percentile ranking between 31.0 and 65.9***: Staff has determined that your application may not be competitive for funding. We will notify you specifically no later than 30 days after the National Advisory General Medical Sciences Council meeting of May 19-20, 2005, if the Council makes a recommendation that differs from or alters that of the initial review group. In the absence of such a Council recommendation, your application will be administratively withdrawn immediately following the Council meeting.

- ***If your application received a percentile ranking greater than 65.9***: Staff has determined that your application will not be competitive for funding and therefore will administratively withdraw it. Applications in this category usually are not reviewed by the Council.

Priority Score Alone (No Percentile):

- ***If your application received a priority score between 100 and 300***: At this time, you should come to no conclusions concerning the probability of funding, since the priority score accorded your application is only one of the factors that is considered in making funding decisions. We will notify you specifically no later than 30 days after the National Advisory General Medical Sciences Council meeting of May 19-20, 2005, if the Council makes a recommendation that differs from or alters that of the initial review group. Your application will remain active until the automatic withdrawal date of March 31, 2006.

- ***If your application received a priority score greater than 300***: Staff has determined that your application will not be competitive for funding and therefore will administratively withdraw it. Applications in this category usually are not reviewed by the Council.

Unscored:

- ***If your application did not receive a score***: Your application is unscored because the initial review group believed that its scientific merit placed it approximately in the bottom half of the applications that they reviewed. Staff has determined that your application will not be competitive for funding and therefore will administratively withdraw it. Applications in this category usually are not reviewed by the Council.

- ***If your application*** was not recommended for further consideration (NRFC), it will be administratively withdrawn by staff. Applications in this category usually are not reviewed by the Council.

*** NOTE TO R13 APPLICANTS: R13 applications do not receive Council review. However, you will be notified of NIGMS staff actions after the NAGMS Council meeting.**