INDIANA UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB)

DOCUMENTATION OF REVIEW AND APPROVAL (DRA)

Reviewing IRB (please choose one): IRB STUDY NUMBER: 1210009754

Biomedical: ☐ IRB-02 ☐ IRB-03 ☐ IRB-04 ☐ IRB-05
Behavioral: ☒ IRB-01 ☐ IUB IRB

Please type only in the gray boxes. To mark a box as checked, double-click the box, select "checked", and click "OK".

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator (advisor in the case of student/fellow/resident research):
Name *(Last, First, Middle Initial)*: **Scott Goebel, MD**
Department: Ped Hem/Onc Phone: 944-8784 E-Mail: sgoebel2@iupui.edu
Fax: 948-0616 Address: RI 4340

Co-Principal Investigator (for student/fellow/resident research):
Name: Kerry Hege, MD Phone: 944-8784 E-Mail: kmfitzpa@iupui.edu

☐ Student: ☒ Fellow ☐ Resident
☐ Undergraduate
☐ Graduate

Additional Study Contact:
Name: Anne Bubnick Phone: 948-0101 E-Mail: abubnick@iupui.edu

Project Title: Recovery of Human Peripheral Blood Hematopoietic Stem Cells Following Long-term Cryopreservation with Transplantation into NOD/SCID/ILγ^{null} Mice
Anticipated Project Completion Date: 10-9-2013

Sponsor/Funding Agency: _____ PI on Grant: _____
Sponsor Protocol #/Grant #: _____ Period: from: _____ to _____
Sponsor Type: ☐ Federal ☐ State ☐ Industry ☐ Not-for-Profit ☒ Unfunded ☐ Internally Funded
Funding Status: ☐ Pending ☐ Funded ☐ N/A
Grant Title (if different from project title): _____

SECTION II: TYPE OF REVIEW

☒ Exempt Review
☐ Expedited Review
☐ Full Board Review (*Choose One*) → ☐ Behavioral: ☐ IRB-01 ☐ IU Bloomington IRB
☐ Biomedical: ☐ IRB-02 ☐ IRB-03 ☐ IRB-04 ☐ IRB-05

SECTION III: DOCUMENTS INCLUDED WITH RESEARCH SUBMISSION

☐ Assent, dated: _____
Number of assent documents: _____
☐ Authorization, dated: _____
Number of authorizations: _____
☐ Clinical Investigator's Brochure, dated: _____
☐ Expedited Research Checklist, dated: _____
☒ Exempt Research Checklist, dated: 10-8-12
☐ HIPAA & Recruitment Checklist, dated: _____
☐ Informed Consent, dated: _____
Number of consent documents: _____
☒ Investigator List, dated: 10-9-12
☐ Protocol, dated: _____
☐ Recruitment materials (please list and date): _____
☐ Request form(s) for vulnerable population(s) (please list and date); _____
☐ Surveys, questionnaires (please list and date): _____
☐ Summary Safeguard Statement or HUD Form, dated: _____
☐ Study Information Sheet, dated _____
☐ Other (please list and date): _____

SECTION IV: INVESTIGATOR STATEMENT OF COMPLIANCE

By submitting this form, the Principal Investigator assures that all information provided is accurate. He/she assures that procedures performed under this project will be conducted in strict accordance with federal regulations and Indiana University policies and procedures that govern research involving human subjects. He/she acknowledges that he/she has the resources required to conduct research in a way that will protect the rights and welfare of participants, and that he/she will employ sound study design which minimizes risks to subjects. He/she agrees to submit *any* change to the project (e.g. change in principal investigator, research methodology, subject recruitment procedures, etc.) to the Board in the form of an amendment for IRB approval prior to implementation.

SECTION V: IRB APPROVAL

This research project, including all documents included with the submission (e.g., informed consent statement, authorization, and/or waiver of authorization) has been reviewed and approved by the Indiana University IRB for a maximum of a one year period unless otherwise indicated as follows:_____

☒ Exempt Category(ies), if applicable: 4
☐ Expedited Category(ies), if applicable: _____

Authorized IRB Signature: Kenneth Mumaw Digitally signed by Kenneth Mumaw DN: cn=Kenneth Mumaw, o=ORA, ou=Human Subjects Office, email=kmumaw@indiana.edu, c=US Date: 2012.10.18 13:12:20 -04'00' IRB Approval Date: 10/18/2012

Printed Name of IRB Member: _____

For IU Human Subjects Office use only.

Recorded in the Minutes of: _____