

INSTITUTIONAL REVIEW BOARD AUTHORIZATION AGREEMENT
USC Medical Cancer Physicians on Hoag Medical Staff

This Institutional Review Board Authorization Agreement (this "Agreement"), by and between the **University of Southern California**, a California nonprofit public benefit corporation (the "University"), USC Divisions of Oncology, Hematology, Surgical Oncology, Urology and other Cancer-related physicians as agreed upon in writing, on Hoag Medical Staff (Investigator") and Hoag Memorial Hospital Presbyterian ("**HOAG HOSPITAL**"), and is effective as of the 16 day of February **2016** (the "Effective Date"). University, Hoag Hospital and Investigator may be referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, the University has established several institutional review boards (each, an "IRB") to oversee the human subjects research conducted by the University;

WHEREAS, Hoag Hospital conducts human subjects research and desires to rely on the Designated IRB (as defined below); and

NOW, THEREFORE, for and in consideration of the agreements, covenants, representations and warranties herein contained, and intending to be legally bound, the Parties agree as follows:

1. Designated IRB. The following IRB shall be the "Designated IRB" for purposes of this Agreement:

U of Southern California Hlth Sci Ctr Los Angeles (LAC+USC) IRB #1 (IRB00000484)

U of Southern California Los Angeles (LAC+USC) IRB #2 (IRB00002880)

U of Southern California Los Angeles (LAC+USC) IRB #3 (IRB00002881)

FWA Number (if applicable): 00005906

2. Reliance on the Designated IRB. The University hereby authorizes Hoag Hospital to rely on the Designated IRB for review and continuing oversight, as more specifically described below, of the human subjects research described in this Section 2 (the "Research") (select one):

XX Agreed upon Oncology, Hematology, Surgical Oncology, Urology and other Cancer-related physicians, human subjects research covered by the Hoag Hospital's Federalwide Assurance ("FWA"). For the sake of clarity, the Parties expressly agree that this Agreement does not require Hoag Hospital to submit any research projects to the Designated IRB for review, but rather merely permits Hoag Hospital to do so.

OR

_____ The specific protocols described below (include the title and the IRB # of the research project, name of the principal investigator, sponsor or funding agency, and award number, if any):

OR

_____ Other (Please describe here):

3. **FWA Designation.** If Hoag Hospital has filed an FWA with the U.S. Department of Health and Human Services, Office of Human Research Protections (OHRP), it is the sole responsibility of the Hoag Hospital to identify the Designated IRB on its FWA approved by the OHRP, if required by applicable regulations or OHRP guidance.

4. **Protection of Human Subjects.**

(a) The Designated IRB is responsible for adopting and implementing institutional policies and procedures for protecting human subjects with respect to the Research in compliance with its FWA. The Designated IRB is authorized to review, oversee and monitor the Hoag Hospital's compliance with the policies and procedures of the Designated IRB, relevant ethical principles, and applicable state and federal laws, regulations, guidance, and rulings relating to the protection of human subjects (collectively, the "Standards"), with respect to the Research.

(b) Hoag Hospital and the Investigator on each research project submitted to the Designated IRB are responsible for complying with all determinations of the Designated IRB and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities or requirements to participate in any education training required by the Designated IRB or University. Notwithstanding the above, Hoag Hospital or Investigator may, in either's sole discretion, decide not to conduct research that the Designated IRB approves.

(c) Each research project Investigator is responsible for ensuring that the researchers promptly report any proposed changes in the research conducted under this Agreement and will not initiate changes in research without prior approval by the Designated IRB, except where necessary to eliminate apparent immediate hazards to subjects.

(d) Hoag Hospital and Investigator, as appropriate, are also responsible for ensuring that its respective researchers:

(1) Comply with this Agreement and abide by all determinations of the designated IRB, including but not limited to directives to terminate participation in designated research activities;

(2) Not enroll subjects in research covered by this Agreement prior to its review and approval by the designated IRB.

(3) Accept primary responsibility for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research;

(4) Adhere to sponsor requirements, the University's applicable policies and procedures, and applicable laws and regulations, including but not limited to: (i) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internally recognized equivalent); (ii) the relevant provisions of Title 45, Part 46 of the Code of Federal Regulations (the Common Rule); (iii) the relevant statutes, rules, regulations, and policies of the U.S. Food and Drug Administration; and (iv) all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in

research conducted under this Agreement.

(5) Complete any educational training required by the University or the Designated IRB prior to initiating research;

(6) Report promptly to the Designated IRB any proposed changes in the research conducted under this Agreement;

(7) Report promptly to the Designated IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement; and

(8) Obtain, document, and maintain records of informed consent for each subject or each subject's legally authorized representative as required under 45 CFR Part 46 (or any other intentional or national procedural standards selected on the FWA for the Designated IRB) and stipulated by the Designated IRB.

(e) Each Party shall promptly notify the others if it becomes aware at any time of a breach by any person conducting the Research of any Standard.

(f) University shall allow Hoag Hospital or its designee(s) to conduct audits, upon reasonable notice and during normal business hours, of the Designated IRB's compliance with this Agreement and the Standards. No-cause audits shall occur no more frequently than once every twenty-four months.

(g) University shall promptly inform Hoag Hospital if any state or federal agency with competent jurisdiction makes a final determination that the Designated IRB is in violation of any Standard, if the Designated IRB loses its AAHRPP accreditation, or the Designated IRB has such accreditation downgraded.

5. Compliance with FWA Requirements. If Hoag Hospital has filed an FWA, the University agrees that the review and continuing oversight performed by the Designated IRB will meet the human subjects protection requirements of Hoag Hospital's FWA (the "FWA Requirements"); provided, however, that Hoag Hospital shall not modify the FWA Requirements without the prior notice to the University. Hoag Hospital shall provide a copy, upon request, of its FWA to the University, if it has an FWA.

6. Term and Termination.

(a) This Agreement shall be effective as of the date first above written, and shall continue for an initial term of one (1) year. Thereafter, this Agreement shall renew automatically for successive one (1) year terms on the same terms and conditions as specified in this agreement, unless terminated in accordance with this section 6.

(b) Any Party may terminate this Agreement at any time upon thirty (30) days prior written notice in the event another Party breaches an obligation hereunder, provided such breach is not cured within said thirty (30) day period to the reasonable satisfaction of the non-breaching Party. Any Party may terminate this Agreement without cause upon sixty (60) days written notice. Upon termination of this Agreement, University shall cause the Designated IRB to cooperate with Hoag

Hospital and the Investigator for each research project then under supervision of the Designated IRB in transferring the Research to the supervision of another institutional review board selected by Hoag Hospital and Investigator in their sole discretion, and, notwithstanding the above, termination of this Agreement shall not occur until that new institutional review board has reviewed the Research. The provisions of this paragraph shall survive termination of this Agreement.

7. Access to Records and Confidentiality.

(a) Hoag Hospital and the Investigator for each research project submitted to the Designated IRB shall make available to the University, and shall cause their employees and agents to make available to the University, documentation required by the Designated IRB to perform the services hereunder. The University shall protect the confidentiality of all such documentation in accordance with relevant federal and state laws and regulations.

(b) The Designated IRB shall prepare and maintain documentation relating to the Research as required by the Standards and other requirements made known in writing by Hoag Hospital to the Designated IRB, and shall cooperate fully with Hoag Hospital's reasonable requests to inspect and copy, at its sole cost, such documentation relating to the Research.

(c) In connection with the performance of the services set forth herein, the Parties may have access to certain oral and written information concerning each other that is non-public, confidential and/or proprietary in nature. The Parties acknowledge the confidential or proprietary nature of such information and agree to, at all times, hold such information in strict confidence, refrain from delivering or disclosing any part of the information to any third party, and refrain from making any copies or reproductions of any of such information, each unless previously authorized to do so in writing by the other Party. The Parties also agree to limit access and use of such information to those employees and agents to whom such information is necessary in order to fulfill their respective obligations under this Agreement.

(d) Each Party shall use its reasonable efforts to preserve the confidentiality of Protected Health Information (as defined by law) it receives from another Party, and shall be permitted only to use and disclose such information to the extent permitted pursuant to the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-1329d-8; 42 U.S.C. 1320d-2) ("HIPAA"), regulations promulgated thereunder ("HIPAA Regulations") and applicable state law, including those provisions that relate to Business Associates.

8. **Non-Exclusivity.** Nothing in this Agreement is intended to limit the right of the University, through the Designated IRB or any other University IRB, to provide review and continuing oversight of human subjects research conducted by or on behalf of any other person or entity.

9. **Notices.** Any and all notices or other communications required or permitted to be given under any of the provisions of this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or mailed by first class registered mail, return receipt requested, or via overnight delivery addressed to the parties at the addresses set forth below:

If to the University:

Institutional Review Board
University of Southern California

If to Hoag Hospital:

Hoag Memorial Hospital Presbyterian
Hoag Institute for Research & Education

LAC+USC Medical Center
General Hospital
1200 North State Street Suite 4700
Los Angeles, CA 90033

One Hoag Drive, Bldg 44, Ste 210
Newport Beach, CA 92663
Attn: Cynthia Handen

If to Investigator:

Refer to Investigators listed as Party to this Agreement

10. Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their heirs, successors, assigns and representatives. This Agreement may not be assigned, nor the duties hereunder delegated, by any party without the other Parties' written consent.

11. Amendment. This Agreement may be amended only by the written agreement of the Parties. Investigators may be added to this Agreement upon written approval by USC and Hoag Hospital without amending this agreement.

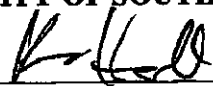
12. Governing Law. This Agreement shall be governed and construed in accordance with the laws of the State of California.

13. Severability. Should any provisions of this Agreement or application thereof be held invalid or unenforceable, the remainder of this Agreement shall continue to be valid and enforceable to the fullest extent permitted by law unless its continued validity and enforcement would defeat the purpose of this Agreement. Notwithstanding the foregoing, the Parties agree to modify this Agreement if any Party reasonably determines that such modification is required in order to comply with any change in applicable laws or regulations or the official interpretation thereof. If the Parties are unable to agree upon a modification, any Party may terminate this Agreement upon thirty (30) days advance written notice to the other.


14. Waiver. The failure by a Party at any time to require performance of any provision of this Agreement shall not constitute a waiver of such provision and shall not affect the right of such Party to require performance at a later time. Any waiver of the breach of any term or condition of this Agreement by any Party shall not be a continuing waiver and shall not operate to bar the waiving Party from claiming a breach of this Agreement for any subsequent breach hereunder.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

UNIVERSITY OF SOUTHERN CALIFORNIA

Signature: 
By: Randolph W. Hall, PhD
Its: Vice President of Research
Date: 2/25/16

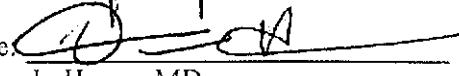
Hoag Memorial Hospital Presbyterian

Signature: 
By: Michael Brant-Zawadzki, MD
Its: Senior Physician Executive
Date: 3/7/16

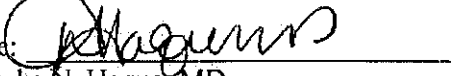
Investigator

Signature: 
By: Greg R. Angstreich, MD

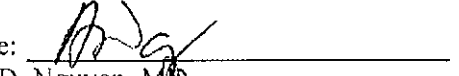
Its: Investigator
Date: 3/8/16

Signature: 
By: Diana L. Hanna, MD

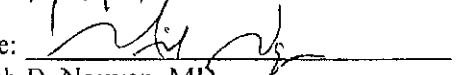
Its: Investigator
Date: 3/10/16

Signature: 
By: Dilruba N. Haque, MD


Its: Investigator
Date: 3/10/14

Signature: 
By: An D. Nguyen, MD

Its: Investigator
Date: 3/9/14

Signature: 
By: Minh D. Nguyen, MD

Its: Investigator
Date: 3/9/16

Signature: 
By: George B. Semeniuk III, MD

Its: Investigator
Date: 3/8/16

Burton Eisenberg

Signature: _____

By: Burton L. Eisenberg, MD

Its: Investigator

Date: *3/11/16* _____
[Signature]

Signature: _____

By: Jeffrey S. Yoshida, MD

Its: Investigator *3/11/2016*

Date: _____
Robert Torrey

Signature: _____

By: Robert R. Torrey, MD

Its: Investigator *3/11/16*

Date: _____
[Signature]

Signature: _____

By: Moses M. Kim, MD

Its: Investigator

Date: *3/11/16* _____