

**A Memorandum of Understanding  
between  
V.A. Pittsburgh Healthcare System and University of Pittsburgh  
concerning  
Jurisdiction and Collaboration between the  
Institutional Review Boards of the Two Institutions**

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**Effective Date: May 13, 2005**

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This Memorandum of Understanding sets forth the express agreement between V.A. Pittsburgh Healthcare System (“VAPHS”) and the University of Pittsburgh – Of the Commonwealth System of Higher Education (“University”) concerning the utilization and jurisdiction of their respective Institutional Review Boards (“IRBs”) over the conduct of human subject research involving investigators who have appointments at one or both of these institutions, or involving the facilities, records or patients of these or other institutions. This Memorandum of Understanding supercedes and replaces any previous Memorandum of Understanding between the VAPHS and University.

**VAPHS and University hereby agree to each of the following provisions:**

**General Procedures**

1. Both the VAPHS and the University will maintain separate IRBs. The following criteria will determine which IRB will serve as the IRB-of-record with respect to a particular protocol:
  - (a) The VAPHS IRB shall be the IRB-of-record for all human subject research studies in which: (1) a VAPHS staff member or University faculty member is the principal investigator or a co-investigator of the study; (2) the research is conducted using only VAPHS records and/or research subjects recruited through the VAPHS; (3) no University or UPMC facilities are engaged in the conduct of the research<sup>1</sup>; and (4) no University funds are expended in direct support of the research.
  - (b) The University IRB shall be the IRB-of-record for all human research studies in which: (1) a VAPHS staff member is the principal investigator or a co-investigator of the study; (2) the conduct of the research does not involve VAPHS records, patients, and/or other resources; (3) no VAPHS facilities are engaged in the conduct of the research; and (4) either the research is funded in whole or in part by or through the University, or the

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<sup>1</sup>“Engaged in the conduct of the research”, as used throughout this Agreement, shall be defined in accordance with current Office of Human Research Protection (OHRP) guidance.

research involves the records of the University or UPMC or research subjects recruited through the University or UPMC, or University or UPMC facilities are engaged in the conduct of the research.

- (c) Approval of both the VAPHS IRB and University IRB is required for all other cases wherein the research study is jointly subject to oversight by these committees.

Each institution reserves the right to insist on review by its own IRB with respect to any specific protocol, regardless of this Memorandum of Understanding, so long as that preference is expressed in writing and is provided to the chair or designee of both IRBs. Neither institution may administratively overrule disapprovals by an IRB. The decision of the reviewing IRB with respect to disapproval is final. In cases where there is a question regarding which IRB should be the IRB-of-record, the issue will be determined by discussion between the IRB Chairs of the VAPHS and the University and the decision will be memorialized in writing by the Chair of the IRB of the institution that has been determined to be the IRB-of-record.

### **Documentation**

- 2. The University's IRB Office shall maintain all documents and database information associated with the review, approval and oversight of human subject research for which the University IRB is the IRB-of-record in accordance with this Memorandum of Understanding, and shall make such documents available to the VAPHS R&D Office upon request.
- 3. The VAPHS R&D Office shall maintain all documents and database information associated with the review, approval and oversight of human subject research for which the VAPHS IRB is the IRB-of record in accordance with this Memorandum of Understanding, and shall make such documents available to the University IRB upon request.

### **Reporting**

- 4. The University IRB Office and the VAPHS R&D Office shall immediately report, in writing, to the reciprocal office any noncompliance issues (including but not limited to human subject protection violations) involving VAPHS staff and/or research involving VAPHS patients, facilities or records of which it becomes aware. Each Office should notify the reciprocal Office, in writing, if and when the respective IRB or an external oversight agency or organization initiates any action regarding such noncompliance.

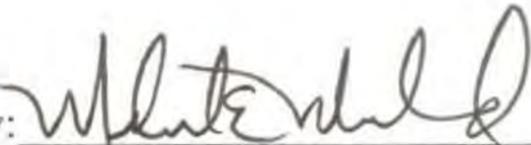
### **Oversight**

5. The VAPHS Research Compliance Committee will be the initial committee that oversees compliance issues related to human research for all studies that fall exclusively under the jurisdiction of the VAPHS IRB as defined in Paragraph 1 (a) above. The VAPHS Research Compliance Committee will receive, review and act upon audit reports and investigator responses for these studies. The VAPHS Research Compliance Committee will report its findings and actions to the University IRB Executive Committee when such studies involve the University faculty.
6. The University IRB Executive Committee will be the initial committee that oversees compliance issues related to human research for all studies that fall under the jurisdiction of the University IRB or are jointly reviewed by the VAPHS IRB and University IRB as defined in Paragraphs 1 (b) and (c). above. The University IRB Executive Committee will receive, review and act upon audit reports and investigator responses for these studies. The University IRB Executive Committee will report its findings and actions to the VAPHS Research Compliance Committee when such studies involve VAPHS staff, patients, facilities, records or funding.
7. Each institution will cooperate fully with the other institution and make appropriate records available to regulatory and accrediting entities, upon request, whenever the human research protection program of either institution is under review.
8. Each institution shall be responsible for making appropriate filings with the Office for Human Research Protections or other relevant federal agencies to effect the designation of IRB-of-record as set forth in Paragraph 1, above.

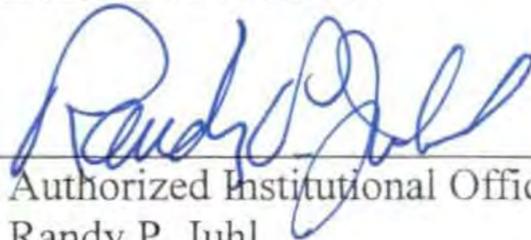
The undersigned have read and agreed to all of the terms above. Full concurrence is required for this Memorandum of Understanding to have legal effect. This Memorandum of Understanding shall remain in effect until such time as authorized agents of both the VAPHS and the University mutually agree to terminate or modify this Memorandum of Understanding.

[remainder of page intentionally left blank]

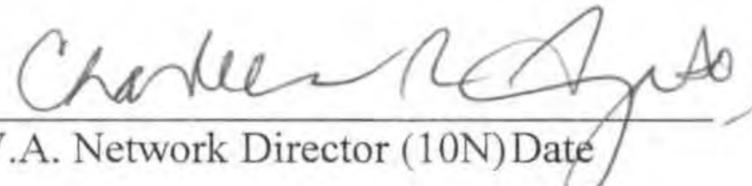
V.A. PITTSBURGH HEALTHCARE SYSTEM

By:   
Authorized Institutional Official  
Name: Michael E. Moreland  
Title: Director  
Date: 5/26/05

UNIVERSITY OF PITTSBURGH – OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION

By:   
Authorized Institutional Official  
Name: Randy P. Juhl  
Title: Vice Chancellor for Research Conduct and Compliance  
Date: 5/12/05

Approved by:

 ~~7/22/05~~  
V.A. Network Director (10N) Date 6/10/05