

October 6, 2004

Johns Hopkins School of Medicine (JHUSOM) and National Institutes of Health,
National Institute on Drug Abuse IRB (NIDA) Review Agreement (the "Agreement")

- I. **Recitals.** JHUSOM faculty must submit all human subjects research protocols for review by a designated JHM IRB before a research project may be initiated. National Institutes of Health, National Institute on Drug Abuse (referred to from this point forward as NIDA) staff must submit all human subjects research protocols for review by the NIDA IRB before research may be initiated. JHUSOM faculty and NIDA staff who conduct collaborative research have been required to have a project reviewed and approved by both a JHM IRB and the NIDA IRB. In order to minimize burdens on both parties, this document outlines a review agreement between JHUSOM and NIDA IRB to delegate IRB review authority and remove the requirement for dual review under the following terms.

- II. **Research conducted by NIDA staff members using only participants, facilities, substances, and/or records of NIDA and on which a Hopkins' faculty member is a co-investigator.** The IRB of record for such projects is the NIDA IRB. JHUSOM faculty who participate as a co-investigator on such projects do not have to submit the NIDA IRB approved protocol for JHM IRB review. As the IRB of record, the NIDA IRB shall conduct all review and oversight activities in accordance with applicable NIH regulatory requirements including the human subjects protection requirements of NIH -approved Federal Wide Assurances (FWAs) and will assure that the required NIH and NIDA ancillary reviews will be conducted as appropriate to the protocol; e.g., Resource, Statistical, Medical Safety, Radiation Safety, and any other relevant NIH or NIDA reviews. The NIDA IRB Administrator will promptly notify the JHUSOM Office of Human Subjects Research (OHSR) when action is taken on such protocols. The individuals to be notified are: 1) The Director of the Office of Human Subjects Research and 2) The Assistant Dean for Human Subjects Research Compliance. For approved projects the NIDA IRB Administrator will promptly report to JHUSOM officials:
 - any serious continuing investigator noncompliance with the IRB requirements related to the approved research,
 - any suspension or termination for cause of IRB approval,
 - any injuries to human subjects related to the approved research which are reported to the NIDA IRB,
 - any unanticipated problems involving risks to subjects or others related to the approved research which are reported to the NIDA IRB and,
 - any other substantive matter related to the conduct of the study, such as notification of an FDA audit or a participant complaint associated with a NIDA protocol approved under this agreement.

- III. **Research conducted by JHUSOM faculty not using NIDA participants, facilities, records and/or other resources and on which a NIDA staff member is a co-**

investigator. The IRBs of record for such projects are the designated JHM IRBs. NIDA staff who participate as a co-investigator on such projects do not have to submit the JHM IRB approved protocol for NIDA IRB review. As the IRBs of record, the JHM IRBs shall conduct all review and oversight activities in accordance with applicable regulatory requirements including the human subjects protection requirements of JHUSOM-approved FWA and will assure that the following required JHUSOM ancillary reviews will be conducted as appropriate to the protocol: Pharmacy & Therapeutics Committee, Institutional Biosafety Committee, and Radiation Safety Committee. The JHUSOM Office of Human Subjects Research (OHSR) will promptly notify NIDA officials through the NIDA IRB office when action is taken on such protocols. The individual to be notified is the IRB Administrator, Clinical Programs Specialist, NIDA IRP. For approved projects the JHUSOM Assistant Dean for Human Subjects Research Compliance or (Director of the Office of Human Subjects Research) will promptly report to NIDA officials:

- any serious continuing investigator noncompliance with the JHM IRB requirements related to the approved research,
- any suspension or termination for cause of JHM IRB approval,
- any injuries to human subjects related to the approved research which are reported to the JHM IRB,
- any unanticipated problems involving risks to subjects or others related to the approved research which are reported to the JHM IRB and,
- any other substantive matter related to the conduct of the study, such as notification of an FDA audit or a participant complaint associated with a NIDA protocol approved under this agreement.

IV. Research conducted by NIDA staff members using participants, facilities, substances, and/or records of NIDA and on which a Hopkins' faculty member is a co-investigator and a subset of research procedures will be performed at a JHMI facility (e.g., the PET facility or MRI facilities). There are two possible review processes.

a. Projects for which a JHUSOM faculty member is not the physician sponsor of an IND for administration of a FDA regulated product in the research : The IRB of record for such projects is the NIDA IRB. JHUSOM faculty who participate as a co-investigator on such projects do not have to submit the NIDA IRB approved protocol for JHM IRB review. As the IRB of record, the NIDA IRB shall conduct all review and oversight activities in accordance with applicable regulatory requirements including the human subjects protection requirements of the NIH-approved FWA and will assure that the following required NIH and NIDA ancillary reviews will be conducted as appropriate to the protocol; e.g., Resource, Statistical, Medical Safety, Radiation Safety, and any other relevant NIH or NIDA reviews.

The consent form approved by the NIDA IRB is the only research consent form of record. The JHUSOM faculty member is responsible for assuring research participants enrolled using the NIDA IRB approved research consent form sign a HIPAA

authorization form upon arrival at a JHM facility prior to study testing and sign an appropriate Hospital procedure consent form (when applicable to the study procedures.)

The NIDA IRB Administrator will promptly notify the JHUSOM Office of Human Subjects Research (OHSR) when action is taken on such protocols. For approved projects the NIDA IRB Administrator will promptly report to JHUSOM Office of Human Subjects Research:

- any serious continuing investigator noncompliance with the NIDA IRB requirements related to the approved research,
- any suspension or termination for cause of NIDA IRB approval,
- any injuries to human subjects related to the approved research which are reported to the NIDA IRB,
- any unanticipated problems involving risks to subjects or others related to the approved research which are reported to the NIDA IRB and,
- any other substantive matter related to the conduct of the study, such as notification of an FDA audit or a participant complaint associated with a NIDA protocol approved under this agreement.

b. Projects for which a JHUSOM faculty member is the physician-sponsor of an IND for administration of a FDA regulated product in the research procedures conducted at Hopkins' facilities. The IRB of record for the research conducted using the NIDA participants/facilities, etc. is the NIDA IRB and the IRBs of record for the administration of the federally regulated product in a Hopkins' facility are the JHM IRBs. The NIDA IRB will review the complete protocol submitted by the NIDA staff member. The JHM IRBs will review the portion of the protocol applicable to the administration of the regulated product. The NIDA IRB consent form describing the procedures associated with administration of the regulated product will be approved by the JHM IRBs for use at the Hopkins' facility. The JHM IRBs will notify the NIDA IRB of action taken on the portion of the protocol with the regulated product and provide a copy of the consent form, if approved.

Final approval to initiate the project will be provided by the NIDA IRB upon confirmation of approval by the JHM IRBs. The JHUSOM faculty member is responsible for assuring research participants enrolled using the NIDA IRB approved consent form also sign upon arrival at a JHM facility (i) the JHM IRB approved consent form for procedures conducted at Hopkins' involving administration of the regulated product and (ii) the JHM HIPAA authorization form.

V. Record Retention and Production. Relevant minutes of IRB meetings will be made available to the requesting party to this Agreement upon request. This Agreement must be kept on file at both institutions and provided to OHRP upon request.


VI. Term and Termination. The initial term of this Agreement shall be from the 1st day of November 2004 and shall continue until the 30th day of November 2005 unless otherwise terminated by either party as provided herein. Unless earlier terminated, this

Agreement shall continue for successive one year terms. Either party may terminate this Agreement upon 30 days written notice to the other party or may immediately terminate this Agreement upon filing written notice of any material breach of its terms with the other party.

VII. Miscellaneous. JHUSOM and NIH agree to amend their FWA on file with the OHRP to reflect the Agreement terms under which they will permit each institution to utilize one IRB review. Any future changes in the Agreement will be provided to OHRP.

Endorsement of JHUSOM:

Authorized Institutional Official:


Signature:

Date: 10/11/04

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Endorsement of NIDA IRP:


Signature:

Date:

Barry Hoffer, M.D.

Scientific Director, NIDA


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Authorized Institutional Official:


Signature:

Date: 10/21/04

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