The University of South Alabama, hereinafter known as the “institution” (see Appendix A), hereby gives assurance, as specified below, that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human subjects [45 CFR Part 46].

PART 1 – PRINCIPLES, POLICIES AND APPLICABILITY

1. All of the institution’s human subject activities, and all human subject activities of the Institutional Review Boards (IRBs) designated under the Assurance, regardless of funding source, will be guided by the ethical principles of *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

2. The following terms apply whenever (a) IRBs operated by the institution provide review and oversight of Federally-supported human subject research, regardless of where the research takes place or by whom it is conducted; or (b) the institution becomes engaged in Federally-supported human subject research. The institution becomes so engaged whenever (a) the institution’s employees or agents intervene or interact with living individuals for purposes of Federally-supported research; (b) the institution’s employees or agents obtain, release, or access individually identifiable private information for purposes of Federally-supported research; or (c) the institution receives a direct Federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

3. Federally-supported human subject research for which the IRB provides review and oversight will comply with the Federal Policy* (Common Rule) for the Protection of Human Subjects. All human subject research supported by the Department of Health and Human Services (HHS) will comply with all Subparts of HHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46). All Federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All Federally supported human subject research will comply with any human subject regulations and policies of any relevant regulatory Department or Agency.
4. Except for research exempted or waived under Sections 101(b) or 101(i) of the Federal Policy, all human subject research will be reviewed, prospectively approved, and subject to continuing oversight by the designated IRBs. The IRBs will have authority to approve, require modifications in, or disapprove the covered human subject research.

5. Except where specifically waived or altered by the IRB under Sections 101(i), 116(c) and (d), or 117(c) of the Federal Policy, all human subject research will require written informed consent, in nonexculpatory language understandable to the subject (or the subject’s legally authorized representative), including the following basic elements per Section 116(a) and (b) of the Federal Policy: (a) Identification as research; purposes, duration, and procedures; procedures which are experimental; (b) Reasonably foreseeable risks or discomforts; (c) Reasonably expected benefits to the subject or others; (d) Alternative procedures or treatments, if any, that might be advantageous to the subject; (e) Extent of confidentiality to be maintained; (f) Whether compensation or medical treatment are available if injury occurs (if more than minimal risk); (g) Whom to contact for answers to questions about the research, subjects’ rights, and research-related injury; (h) Participation is voluntary; refusal to participate, or discontinuation of participation, will involve no penalty or loss of benefits to which subject is entitled; and (i) When appropriate, additional elements per Section 116(b) of the Federal Policy.

6. The institution and the designated IRBs have established (or will establish within 90 days), and will provide to OHRP upon request, written procedures for (a) verifying whether proposed activities qualify for exemption from, or waiver of, IRB review; (b) conducting IRB initial and continuing review, approving research, and reporting IRB findings to the investigator and the institution; (c) determining which projects require review more often than annually, and which projects need verification from sources other than the investigator that no material changes have occurred; (d) ensuring that changes in approved research are reported promptly and are
not initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject; and (e) ensuring prompt reporting to the IRB, institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any (i) unanticipated problems involving risks to subjects or others in any covered research; (ii) serious or continuing noncompliance with Federal, institutional, or IRB requirement; and (iii) suspension or termination of IRB approval for Federally-supported research.

7. The Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), Manager, Office of Research Compliance and Assurance, and the IRB Chairperson(s) will personally complete the relevant OHRP basic educational modules, or comparable training approved by OHRP, prior to submitting the Assurance. Members and staff of the IRBs will complete relevant training before reviewing human subject research. All new IRB members are also required to complete and a orientation session prior to reviewing human subjects protocols. Research investigators and key study personnel must complete appropriate institutional training before conducting human subject research.

8. The institution and the designated IRBs have established and will provide to OHRP upon request, education and oversight mechanisms (appropriate to the nature and volume of its research) to verify that research investigators, IRB members and staff, and other relevant personnel maintain continuing knowledge of, and comply with, relevant Federal policies for the protection of human subjects. The institution and the designated IRBs will require documentation of such training from research investigators and key study personnel as a condition for conducting HHS-supported human subject research.

9. The institution is responsible for verifying that IRBs designated under the Assurance agree to comply with items (1) through (8) above and that the IRB possess appropriate knowledge of the local context in which research for which they are responsible will be conducted.

10. This institution is responsible for ensuring that all institutions and investigators collaborating in its Federally-supported human subject research operate under an appropriate Assurance of Protection for Human Subjects. All institutions engaged in such research, including subcontractors and subgrantees, must hold their own Assurance.

11. The institution will exercise appropriate administrative oversight to insure that institutional policies and procedures for protecting the rights and welfare of human subjects are effectively applied in compliance with this Assurance. The institution will provide the USA IRB with sufficient resources, professional staff, and support staff to carry out their responsibilities efficiently and effectively.

12. The activities of individual research investigators who are not employees or agents of the institution may be covered under the Assurance only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. (OHRP’s sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the institution may develop its own such commitment agreement). Institutions must maintain such commitment agreements on file and provide copies to OHRP upon request.
13. Information provided under this Assurance will be updated every 36 months, even if no changes have occurred, in order to maintain an Active Assurance. Failure to update this information may result in restriction, suspension, or termination of the institution’s Federalwide Assurance of Protection for Human Subjects.

Part 2 – RESPONSIBILITIES

Institutional responsibilities

1. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this Assurance, including complying with Federal, state or local laws as they may relate to such research.

2. This institution is responsible for acquiring appropriate Assurances or Amendments, when requested, and certifications of IRB review and approval for federally sponsored research from all its standing affiliates (see Appendix B) and Assurances or Agreements for all others, domestic or foreign, which may otherwise become affiliated on a limited basis in such research.

3. In accordance with the compositional requirements of Section 107, this institution has established the IRB listed in the attached roster (see Appendix C).

4. This institution is responsible for ensuring that it and all its affiliates comply fully with all applicable Federal policies and guidelines, including those concerning notification of seropositivity, counseling and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

5. This institution will require appropriate additional safeguards in research that involves: (1) fetuses, pregnant women {45CFR46 Subpart B}, (2) prisoners {45CFR46 Subpart C}, (3) minors {45CFR46 Subpart D}, (4) the cognitively impaired, or (5) other potentially vulnerable populations.

6. Legal consultation with University Counsel

Institutional Review Board (IRB): Administrative Functions

1. The IRB will receive from investigators all research protocols that involve human subjects, conduct a preliminary review of these materials to ensure completeness, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to investigators with a written explanation for all decisions to disapprove by the IRB.

2. The IRB is responsible for reviewing the preliminary determinations of exemption by investigators and for making the final determination based on Section 101 of the regulations. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator. All nonexempt research will be forwarded to the IRB for appropriate review.
3. The IRB will make the preliminary determination of eligibility for expedited review procedures in accordance with Section 110. Expedited review of research activities will not be permitted where full board review is required (e.g., provision of emergency care which also constitutes the conduct of more than minimal risk research).

4. The IRB will review all research (whether exempt or not) and decide, with advice from appropriate counsel as the IRB may request, whether the institution will permit the research. If not permitted by the IRB, the IRB will promptly convey notice to the investigator. No other office or individual of the institution may approve a research activity that has been disapproved by the IRB.

5. The IRB will forward certification of IRB approval of proposed research to the appropriate Federal department or agency only after all IRB-required modifications have been incorporated to the satisfaction of the IRB.

6. The IRB will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.

7. The IRB will maintain and arrange access for inspection of IRB records as provided in Section 115.

8. The IRB is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

9. The IRB will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of 45 CFR 46, regulations of other Federal departments or agencies as may apply, the Belmont Report, and all other pertinent Federal and state policies and guidelines related to the involvement of human subjects in research.

10. The IRB will report promptly to appropriate institutional officials, the Office for Human Research Protections (OHRP), and any other sponsoring Federal department or agency head: (i) any injuries to human subjects or other unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with the regulations or requirements of the IRB, and (iii) any suspension or termination of IRB approval for research.

11. The IRB will ensure (i) solicitation (or confirmation where applicable assurances to comply already exist), receipt and management of all assurances of compliance (whatever the appropriate format), and certifications of IRB review (where appropriate) for all performance sites to this institution (including those listed in Appendix B) and (ii) subsequent submission of new documents to the proper Federal department or agency authorities (e.g., OHRP for HHS) as a condition for involvement of each site in human subject research activities sponsored by HHS or any other Federal department or agency for which this Assurance applies.
12. The IRB will ensure that all affiliated performance sites that are not otherwise required to submit assurances of compliance with Federal regulations for the protection of research subjects at least document mechanisms to implement the equivalent ethical principles to which this institution is committed (see Part 1).

13. When an IRB of this institution accepts responsibility for review of research which is subject to this Assurance and conducted by any independent investigator who is not otherwise subject to the provisions of this Assurance, the IRB will either: (i) obtain and retain an Unaffiliated Investigator Agreement or (ii) obtain an Agreement for an Independent Investigator for review and approval by the appropriate Federal department or agency to document the investigator’s commitment to abide by the same requirements for the protection of human research subjects as does this institution and determinations of the IRB.

14. The IRB assumes responsibility for ensuring conformance with special reporting requirements for any OHRP-recognized Cooperative Protocol Research Programs (CPRP) in which the signatory institutions participate.

15. The IRB will be responsible for procedural and record keeping audits not less than once every year for the purpose of detecting, correcting and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by this institution.

16. The IRB will ensure compliance with the requirements set forth in this Assurance and Section 114 regarding cooperative research projects. In particular, where the IRB of another institution with a HHS MPA or FWA is relied upon, the IRB will ensure documentation of this reliance will be (i) in writing, (ii) approved and signed by the IRB, (iii) approved and signed by a contract officer for the institution, (iv) approved and signed by the correlative officials of each of the other cooperating institutions, and (v) retained by the IRB for at least three years past completion of the research project, if limited in scope to a specific research project or retained as a permanent addendum to the FWA if not restricted to a specific project. For all Cooperative Agreements (CAs), the IRB will forward a copy of the required signed understanding to the OHRP for approval and inclusion in this Assurance as an addendum.

17. The IRB will be responsible for drafting and sending all correspondence regarding IRB matters as directed by the IRB or IRB chair(s).

18. When human subjects protection issues arise that require clarification, the IRB and/or the Office of Research Compliance and Assurance will be responsible for directly contacting Federal, State, and local regulatory officials responsible for interpreting regulations. The Office of Research Compliance and Assurance is responsible for presenting this information to the IRB.

19. The Office of Research Compliance and Assurance will assist the IRB in conducting inquiries and investigations into allegations of noncompliance with applicable human subject regulations and policies. The Office of Research Compliance and Assurance will conduct regular reviews.
of research protocols to assure compliance in regulatory, protocol and informed consent requirements.

Institutional Review Board: Operational Functions

1. The IRB will review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research. For approved research, the IRB will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

2. IRB decisions and requirements for modifications will be promptly conveyed to investigators in writing. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator, in person or in writing.

3. Initial and continuing convened IRB reviews and approvals will occur in compliance with 45 CFR 46 and provisions of this Assurance for each project unless properly found to be exempt (section 101(b) and (i)) by the Institutional Review Board. Continuing reviews will be preceded by IRB receipt of appropriate progress reports from the investigator, including available study-wide findings.

4. The IRB will observe the quorum requirements of Section 108(b). This institution’s IRB has effective knowledge of subject populations, institutional constraints, differing legal requirements and other factors which can foreseeably contribute to a determination of risks and benefits to subjects and subjects’ informed consents and can properly judge the adequacy of information to be presented to subjects in accordance with requirements of Sections 103(d), 107(a), 111 and 116.

5. The IRB will determine, in accordance with the criteria found at 45 CFR 46.111 and Federal policies and guidelines for involvement of human subjects in HIV research, that protections for human research subjects are adequate.

6. The IRB will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of Sections 116 and 117. The IRB will have the authority to observe or have a third party observe the consent process.

7. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children as required by Subparts B, C, and D of 45 CFR 46. The IRB will notify OHRP promptly when IRB membership is modified to satisfy requirements of 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305(c).

8. Scheduled meetings of the IRB for review of each research activity will occur at least every 12 months and may be more frequent, if required by the IRB on the basis of degree of risk to subjects. The IRB may be called into an interim review session by the Chairperson at the
request of any IRB member or institutional official to consider any matter concerned with the rights and welfare of any subject.

9. The IRB will prepare and maintain adequate documentation of its activities in accordance with Section 46.115 and in conformance with IRB requirements.

10. In accordance with Section 109, the IRB will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects.

11. The IRB for this institution will ensure effective input (the use of consultants or voting or nonvoting members) for all initial and continuing reviews conducted on behalf of performance sites where there will be human research subjects. IRB minutes will document attendance of those other than regular voting members.

12. The IRB will act with reasonable dispatch, upon request, to provide full board review of protocols of OHRP-recognized Cooperative Protocol Research Programs (CPRP). The IRB will not employ expedited review procedures for CPRP protocols when they are to be entered into for the purpose of research.

Although emergency medical care based on such protocols is permitted without prior IRB approval, patients receiving emergency care under these conditions will not be counted as research subjects and resultant data will not be used for research purposes.

13. Certifications of IRB review and approval will be forwarded to the appropriate Federal department or agency for research sponsored by such departments or agencies.

14. The IRB, in conjunction with the Office of Research Compliance and Assurance, is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the rights and welfare of the subjects.

15. The IRB will support the educational activities conducted by the Office of Research Compliance and Assurance, alone or in conjunction with the IRB, as a means of maintaining a high level of awareness and compliance with this Assurance and other efforts for safeguarding the rights and welfare of research subjects.

16. The IRB is responsible for reviewing adverse events and determining what action, if any, is required.

Research Investigator

1. Research investigators acknowledge and accept their responsibilities for protecting the right and welfare of human research subjects and for complying with all applicable provisions of this Assurance.
2. Research investigators who intend to involve human research subjects will not make the final determination of exemption from applicable Federal regulations or provisions of this Assurance.

3. Research investigators are responsible for providing a copy of the IRB-approved, signed and date-stamped informed consent document and the Subject’s Bill of Rights (for medical research) to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the Institutional Review Board.

4. Research investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

5. Research investigators are responsible for reporting progress of approved research to the Institutional Review Board, as often as and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once per year.

6. Research investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to subjects and others.

7. No research investigator who is obligated by the provisions of this Assurance, any associated inter-institutional amendment, or non-institutional investigator agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see Section 116(f)). However, such activities will not be counted as research nor the data used in support of research.

8. Research investigators will maintain research records and arrange access for their inspection as required by applicable regulations and IRB policies. This responsibility continues even if the investigator leaves USA.

Affiliated Institutions and Investigators

1. Each performance site affiliated with this institution that is involved in federally sponsored research activities must provide to the IRB an appropriate written assurance of compliance with the Belmont Report and Federal Policy to include Subparts B, C and D or 45 CFR 46 where appropriate (or equivalent protections if a foreign site) for review and approval, as specified by the sponsoring Federal department of or agency (e.g., by OHRP for HHS), prior to involvement of human subjects or expenditure of funds or other support to do so.

2. Each legally separate entity needs its own Federalwide Assurance (FWA). However, any registered IRB can be designated under this institution’s FWA, as long as the IRB
Organization agrees to the designation and satisfies the guidelines for knowledge of the local research context.

3. Research investigators who are not acting as employees or agents of an FWA institution when they conduct Federally-supported human subject research are nevertheless subject to all of the usual human protection requirements. Such investigators may enter into an arrangement with this institution under which they agree to be bound by the human protection policies of this institution and its designated IRB. The “Unaffiliated Investigator Agreement” (see Appendix D, taken from the OHRP website) may be used for this purpose. Individual physicians operating in private practice settings that are not covered under an Assurance may follow the same procedure.

4. Performance sites that are not legally inseparable components of this institution (whether an institutional or non-institutional performance site) are not authorized to cite this Assurance.
Institutional Endorsements

The officials signing below assure that any research activity conducted, supported, or otherwise subject to HHS or other Federal departments or agencies that are authorized to rely on this Assurance (Parts 1, 2, 3 and Appendices) or any other sources provided for in this Assurance, will be reviewed and approved by the appropriate IRB in accordance with the requirements of all applicable Subparts of Part 46, Title 45 of the Code of Federal Regulations, with this Assurance, and the stipulations of the IRB.

1. PRIMARY SIGNATORY INSTITUTION

Authorized Institutional Official

Signature: __________________________  Date: ________
Name: Robert A. Kreisberg, M.D.
Title: Dean, College of Medicine, and Vice President for Medical Affairs
Address: University of South Alabama
170 CSAB
307 University Boulevard
Mobile, AL 36688-0002
Phone: 251-460-7189
Fax: 251-460-6073
E-mail: rkreisberg@usouthal.edu

2. Primary Contact

Signature: __________________________  Date: ________
Name: W. Kevin Green, M.D.
Title: Chairman, Institutional Review Board and Assistant Professor of Internal Medicine
Address: University of South Alabama
400G Mastin
2451 Fillingim Street
Mobile, AL 36617-2293
Phone: 251-471-7895
Fax: 251-471-7898
E-mail: wgreen@usouthal.edu
APPENDIX A

COMPONENTS WHICH ARE LEGALLY INSEPARABLE FROM THIS INSTITUTION AND PARTICIPATE IN HUMAN RESEARCH

UNIVERSITY OF SOUTH ALABAMA
FWA Signatory Institution

The University of South Alabama is a public body corporate, created by act of the legislature of the State of Alabama and is deemed to be an agency of the State of Alabama, as well as an institution of higher education in the State. It is governed by one Board of Trustees. The University of South Alabama is divided into various colleges for its academic components, as well as owns and operates three separately licensed hospitals, although all of those are under the corporate name of the University of South Alabama. For purposes of assuring clarity in referencing components, subdivisions of the University of South Alabama that may, for purposes of DHHS, be components, the following are listed:

University of South Alabama Baldwin County, Fairhope, AL
University of South Alabama Baldwin, County, Bay Minette, AL
University of South Alabama Medical Center, Mobile AL
University of South Alabama Children’s and Women’s Hospital, Mobile, AL
University of South Alabama Knollwood Park Hospital, Mobile, AL
University of South Alabama Springhill, Mobile, AL
University of South Alabama Stanton Road Ambulatory Care Center, Mobile, AL
University of South Alabama College of Allied Health Professions, Mobile, AL
University of South Alabama College of Arts and Sciences, Mobile, AL
University of South Alabama Mitchell College of Business, Mobile, AL
University of South Alabama College of Education, Mobile, AL
University of South Alabama College of Engineering, Mobile, AL
University of South Alabama College of Medicine, Mobile, AL
University of South Alabama College of Nursing, Mobile, AL
University of South Alabama School of Continuing Education and Special Programs, Mobile, AL
University of South Alabama Division of Computer and Information Sciences, Mobile, AL
University of South Alabama Department of Cooperative Education, Mobile, AL
and other University of South Alabama departments and divisions
APPENDIX B

STANDING AFFILIATES WHICH ARE LEGALLY SEPARATE FROM EACH DESIGNATED SIGNATORY INSTITUTION AND POSSESS OHRP-APPROVED INTER-INSTITUTIONAL AMENDMENTS

FWA Signatory Institution: University of South Alabama

Affiliate Institutions: No suitable standing affiliates (as of 11/19/04)
APPENDIX C

UNIVERSITY OF SOUTH ALABAMA IRB ROSTER
AS OF 11/12/2004

<table>
<thead>
<tr>
<th>IRB Chair</th>
<th>Gender</th>
<th>Affiliated</th>
<th>Status</th>
<th>Department</th>
</tr>
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<tbody>
<tr>
<td>Green, W. Kevin, M.D.</td>
<td>M</td>
<td>Yes</td>
<td>PS</td>
<td>Medicine</td>
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**Voting Members**

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<thead>
<tr>
<th>Name</th>
<th>Gender</th>
<th>Affiliated</th>
<th>Status</th>
<th>Department</th>
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<tbody>
<tr>
<td>Anderson, Susan, Ph.D.</td>
<td>F</td>
<td>Yes</td>
<td>SS</td>
<td>Psychology</td>
</tr>
<tr>
<td>Angell, Norman, MD, Ph.D.</td>
<td>M</td>
<td>Yes</td>
<td>PS</td>
<td>OB/Gyn</td>
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<tr>
<td>Chung, Allison, Pharm.D.</td>
<td>F</td>
<td>Yes</td>
<td>OS</td>
<td>Pediatrics</td>
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<tr>
<td>Cronis, Terry, Ed.D.</td>
<td>M</td>
<td>Yes</td>
<td>SS</td>
<td>Special Education</td>
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<tr>
<td>DeVillier, Becky, DSN</td>
<td>F</td>
<td>Yes</td>
<td>NS</td>
<td>Asst. Hospital Admin, CWH</td>
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<tr>
<td>Falkos, Sheryl, M.D.</td>
<td>F</td>
<td>Yes</td>
<td>PS</td>
<td>Pediatrics</td>
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<tr>
<td>Fouty, Brian, M.D.</td>
<td>M</td>
<td>Yes</td>
<td>PS</td>
<td>Medicine/Lung Biology</td>
</tr>
<tr>
<td>Greiner, Francis, M.D.</td>
<td>M</td>
<td>Yes</td>
<td>PS</td>
<td>Radiology</td>
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<tr>
<td>Halim-Kirolos, Afifa, M.D.</td>
<td>F</td>
<td>Yes</td>
<td>PS</td>
<td>Emergency Medicine</td>
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<tr>
<td>Henderson, James, Ph.D.</td>
<td>M</td>
<td>Yes</td>
<td>OS</td>
<td>Phys. Asst Program</td>
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<tr>
<td>Hodges, Juvonda, M.D.</td>
<td>F</td>
<td>Yes</td>
<td>PS</td>
<td>Surgery</td>
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<tr>
<td>Lee, Ron, M.D.</td>
<td>M</td>
<td>Yes</td>
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<tr>
<td>Luterman, Arnold, M.D.</td>
<td>M</td>
<td>Yes</td>
<td>PS</td>
<td>Surgery</td>
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<tr>
<td>Mahan, Howard, Ph.D.</td>
<td>M</td>
<td>No</td>
<td>NS</td>
<td>Lay Member</td>
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<tr>
<td>Matre, Marc, Ph.D.</td>
<td>M</td>
<td>Yes</td>
<td>SS</td>
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<tr>
<td>McCovey, Andretta, RN</td>
<td>F</td>
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<td>Millsap, Pam, JD</td>
<td>F</td>
<td>No</td>
<td>NS</td>
<td>Prisoner Representative*</td>
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<tr>
<td>Polski, Jacek, M.D.</td>
<td>M</td>
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<td>PS</td>
<td>Pathology</td>
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<tr>
<td>Ross, Candice, RN, Ph.D.</td>
<td>F</td>
<td>Yes</td>
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<td>Nursing</td>
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<td>Taylor, Dan, Ph.D.</td>
<td>M</td>
<td>No</td>
<td>NS</td>
<td>Lay Member</td>
</tr>
<tr>
<td>Teplick, Richard, M.D.</td>
<td>M</td>
<td>Yes</td>
<td>PS</td>
<td>Chief of Staff, USA hospitals</td>
</tr>
<tr>
<td>Townsend, Kara, Pharm.D.</td>
<td>F</td>
<td>Yes</td>
<td>OS</td>
<td>Family Practice</td>
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<tr>
<td>Williams, Larry, Ph.D.</td>
<td>M</td>
<td>Yes</td>
<td>OS</td>
<td>Comparative Medicine/Psychology</td>
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<td>Wilson, Glenn, Ph.D.</td>
<td>M</td>
<td>Yes</td>
<td>OS</td>
<td>Cell Biology and Neuroscience</td>
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<tr>
<td>Wade, Philip, M.D.</td>
<td>M</td>
<td>Yes</td>
<td>PS</td>
<td>Oncology</td>
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</tbody>
</table>

**Alternate Members**

None at this time

* Judge Pam Millsap will only be required to be present at IRB meetings when projects involving prisoner-related research are reviewed.
ORGANZATIONAL STRUCTURE

Institutional Signatory
Robert A. Kreisberg, M.D.
Vice President for Medical Affairs
Dean, College of Medicine

Institutional Review Board
W. Kevin Green, M.D.
Chair, IRB
Jacek Polski, M.D.
Vice Chair, IRB
Ms. Pamela Horner, BS
IRB Coordinator
Ms. Dusty Layton, BS
Research Compliance
Samuel J. Strada, Ph.D.
Senior Associate Dean
Ex-Officio, Dean’s Office
John Rothrock, M.D.
Associate Dean for Clinical Research
Jean Tucker, J.D.
University Attorney
Connie Knizley
Risk Management

Marion Leach
Assistant Director,
Office of Sponsored Programs
Research Office
College of Medicine

Robert Galbraith, MS
Senior Associate VP
for Research Administration
University Administration

Investigators
All components of the University
APPENDIX D

Unaffiliated Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): ______________________

Applicable FWA #: ______________________

Unaffiliated Investigator’s Name: ______________________

Specify Research Covered by This Agreement: ______________________

(1) The above-named Unaffiliated Investigator has reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internationally recognized equivalent; see B1 of FWA Terms for institutions outside the United States); 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46 (or other internationally recognized equivalent, see B3 of FWA Terms for institutions outside the United States); 3) the Federalwide Assurance (FWA) referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Unaffiliated Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Unaffiliated Investigator will comply with all other National, State, or local laws or regulations that may provide additional protection for human subjects.

(4) The Unaffiliated Investigator will abide by all determinations of the IRB designated under the above Assurance and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Unaffiliated Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(6) The Unaffiliated Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Unaffiliated Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
(8) The Unaffiliated Investigator will obtain, document, and maintain records of informed consent from each subject or the subject’s legally authorized representative as required under DHHS and FDA regulations (or other international or national equivalent) and stipulated by the IRB.

(9) The Unaffiliated Investigator acknowledges and agrees to cooperate in the IRB responsibility for initial and continuing review, record keeping, reporting, and certification. The Unaffiliated Investigator will provide all information requested by the IRB in a timely fashion.

(10) In conducting research involving FDA-regulated products, the Unaffiliated Investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 and 812.

(11) The Unaffiliated Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(12) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable Federal regulations and State law. However, data and information obtained as a result of emergency medical care may not be included as part of federally-supported or –conducted research.

(13) This Agreement does not preclude the Unaffiliated Investigator from taking part in research not covered by the Agreement.

(14) The Unaffiliated Investigator acknowledges that he/she is primarily responsible 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.

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