DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 10, 2000

Dr. Dorothea Wilson
Vice President for Research
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Suite 6.606 Administration Building
301 University Blvd.
Galveston, TX 77555-0130

RE: Human Research Subject Protections Under the Multiple Project Assurance (MPA) M-1172
Research Projects Involving Prisoners as Subjects

Dear Dr. Wilson:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks, has reviewed your January 7, 2000 report concerning research involving prisoners as subjects at the University of Texas Medical Branch at Galveston (UTMB).

Based upon its review of your report, OHRP makes the following determinations:

(1) OHRP notes that as of January 7, 2000, UTMB has more than 220 active protocols approved for involvement of prisoners as subjects, of which more than 95 are supported by the Department of Health and Human Services (HHS).

(a) OHRP finds scant evidence that the UTMB Institutional Review Board (IRB) has made the findings required by HHS regulations at 45 CFR 46.305(a) when it reviewed and approved research involving prisoners as subjects.

(b) OHRP finds that UTMB has failed to certify to OHRP, acting on behalf of the Secretary of Health and Human Services, that the IRB has fulfilled it duties stipulated under 45.305(a) for all active HHS-supported research approved for involvement of prisoners as subjects, as required by HHS regulations at 45 CFR 46.305(c) and 46.306(a)(1).

(c) OHRP acknowledges that UTMB has recently written guidelines concerning research involving prisoners. The UTMB guidelines require that the IRB (i) review and approve research in accordance with the requirements of HHS regulations at 45 CFR 46.305 and 46.306; and (ii) for each protocol approved for involvement of prisoners as subjects, certify by letter to the OHRP that the duties of the IRB under HHS regulations at 45 CFR 46.305(a) were fulfilled.

OHRP further acknowledges receipt of such certifications from UTMB for some research approved for involvement of prisoners as subjects. OHRP notes that the certification letters submitted to OHRP fail to provide sufficient documentation that the IRB fulfilled all of its required duties under HHS regulations at 45 CFR 46.305(a) (see May 19, 2000 Guidelines at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/prison.htm).

Required Action 1: UTMB must suspend immediately involvement of prisoners in any Federally supported research projects that have not satisfied all requirements of HHS regulations at 45 CFR Part 46, Subpart C. For any project affected by this suspension action, enrollment of new prisoner subjects must cease immediately except in extraordinary cases approved in advance by OHRP (OHRP would expect approval requests for such cases to be rare). Furthermore, research activities involving previously enrolled subjects may continue only where it is in the best interests of individual subjects. This suspension must remain in effect for each affected protocol until the protocol has been reviewed, approved, and certified in accordance with all requirements of HHS regulations at 45 CFR Part 46, Subpart C.

Required Action 2: By July 31, 2000, UTMB must provide OHRP with a list of all research protocols affected by this suspension. This list should identify those research projects where research activities involving previously enrolled prisoner subjects are allowed to continue because UTMB judged it to be in the best interests of individual subjects.

Recommended Action 3: Where HHS regulations require specific findings on the part of the IRB, such as approving research involving prisoners (see 45 CFR 46.305-306), the IRB should document such findings. OHRP strongly recommends that these findings be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding.

OHRP has the following additional questions and concerns concerning research involving prisoners as subjects at UTMB:

(2) OHRP notes that a convened quorum of the IRB (including the presence of a prisoner or prisoner representative) must make the findings required by HHS regulations at 45 CFR 46.305(a). OHRP is concerned that UTMB has implemented a procedure under which the responsibilities of the convened IRB for review and approval of research involving prisoners as subjects is inappropriately delegated to an Ad Hoc Committee on Prisoners. Please respond. In your response, please describe (i) the membership, functions, and procedures of the Ad Hoc Committee on Prisoners; (ii) the nature of the interactions between this committee and the IRB for protocols undergoing either initial or continuing review; and (iii) the procedures followed by the convened IRB for making and documenting the findings required under 45 CFR 46.305(a).

(3) Biomedical or behavioral research conducted or supported by HHS may involve prisoners as subjects only if the IRB and the Secretary of Health and Human Services determines that the research represents one of the categories of research permissible under HHS regulations at 45 CFR 46.306(a)(2). OHRP is concerned that many of the active HHS-supported research projects approved for involvement of prisoners as subjects at UTMB either (i) may not represent any of the categories of research permissible at 45 CFR 46. 306(a)(2) or (ii) may require that the Secretary consult with appropriate experts, including experts in penology, medicine, and ethics, and publish notice, in the **Federal Register**, of the intent to approve such research [see 45 CFR 46.306(a)(2)(C) and (D)]. For example, OHRP notes the following:

> (a) There are several active NIH-sponsored phase II (and perhaps phase I) clinical oncology (e.g., GOG #76-X, IRB #96-231; SWOG 9451, IRB #96-234; GOG #159, IRB #96-269; GOG #160, IRB #96-311; GOG #26-LL, IRB # 96-314; GOG #168, IRB #97-193; GOG #76-Z, IRB #97-285; SWOG 9618, IRB #97-360; SWOG 9149; IRB #97-402, GOG #146-H, IRB #98-057; GOG #180, IRB #99-280; and GOG #126-K, IRB #99-412) approved for the involvement of prisoners as subjects. Given the nature of phase II clinical trials, it appears unlikely that such research has a *reasonable probability* of improving the health or well-being of the subject, as would be required for protocols representing the category of research permissible under 45 CFR 46.306(a)(2)(D).
>
> (b) There is an active research protocol involving placebo groups, RTOG 98-09, IRB #99-458, approved for the involvement of prisoners as subjects.

Please respond.

(4) OHRP is concerned that there are many other non-HHS-supported protocols approved for involvement of prisoners as subjects that may not represent one of the categories of research permissible under 45 CFR 46.306(a)(2) (e.g., IRB #96-177, IRB #97-115; IRB #97-186, IRB #97-298; IRB #97-312; IRB #97-340; IRB #97-374; IRB #98-124; IRB #98-136; IRB #98-188; IRB #98-191; IRB #98-354; IRB #98-402; IRB #98-420; IRB #98-458; IRB #98-505; IRB #99-003; IRB #99-218; IRB #99-265; IRB #99-320; IRB #99-403). Please respond.

(5) HHS regulations at 45 CFR 46.304(b) require that for the review of research involving prisoners as subjects at least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. OHRP is concerned that the background and experience of the current (as well as previous) prisoner representative on the IRB appears to be insufficient for representing the perspective of prisoners. Please respond.

(6) HHS regulations at 45 CFR 46.305 (a)(7) require that where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, the research must include adequate provision for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact. OHRP is concerned that the IRB is not taking this requirement into consideration in the review of research proposing involvement of prisoners as subjects.

For example, the informed consent document for protocol # 99-412 (GOG #0126-K: Phase II Evaluation of Oxaliplatin in Recurrent, Platinum-Resistant and Refractory Ovarian Cancer) states that the subject, or her insurance company, will be responsible for the cost of all procedures and medications in the study; and the informed consent document for protocol #99-458 (RTOG Protocol 98-09: Phase III Study of Pentosanpolysulfate (PPS) in Treatment of GI Tract Sequelae of Radiotherapy) states that UTMB is not able to absorb the costs of medical treatment in the event the subject is injured. Furthermore, many of the protocols approved for involvement of prisoners appear to expose the subjects to interventions that may have long-term medical complications, thus necessitating follow-up examination and care of the prisoner subjects after the end of their participation. As it is unlikely that prisoners will have medical insurance after serving their sentences, it is unclear how such individuals will be able to receive such follow-up care. Please respond.

OHRP has the following additional concerns and questions regarding UTMB's overall system for protecting human subjects:

(7) OHRP notes that, unless research is eligible for review by the IRB under an expedited review procedure, a convened quorum of the IRB must make the findings required by HHS regulations at 45 CFR 46.111, as well as the additional findings required under 45 CFR Part 46, Subparts B and D, for research involving fetuses, pregnant women, and human in vitro fertilization or research involving children, respectively.

OHRP is concerned that UTMB has implemented a procedure under which the responsibilities of the convened IRB for making these required findings is delegated to Study Sections of the Subcommittee on Human Research. Furthermore, the minutes of IRB meetings provided to OHRP suggest that little, if any, substantive review takes place at convened meetings for many protocols requiring review by the convened IRB. It appears that most protocols undergoing review are neither individually presented, discussed, nor acted and voted upon at a convened meeting by the IRB as a group.

Please respond. In your response, please describe (i) the membership, functions, and procedures of the Study Sections and the Subcommittee on Human Research; (ii) the nature of the interactions between this subcommittee and the IRB; (iii) the procedures followed by the convened IRB for making and documenting the findings required under HHS regulations; and (iv) the protocol documents received and reviewed by all IRB members prior to convened IRB meetings.

(8) Continuing IRB review of research must be substantive and meaningful. In conducting continuing review of research not eligible for expedited review, all IRB members should at least receive and review a protocol summary and a status report on the progress of the research, including (i) the number of subjects accrued; (ii) a description of any adverse events or unanticipated problems involving risks to subjects or others and of any withdrawal of subjects from the research or complaints about the research; (iii) a summary of any recent literature, findings obtained thus far, amendments or modifications to the research since the last review, reports on multi-center trials and any other relevant information, especially information about risks associated with the research; and (iv) a copy of the current informed consent document. Primary reviewer systems may be employed, so long as the full IRB receives the above information. Primary reviewers should also receive a copy of the complete protocol including any modifications previously approved by the IRB (see OPRR Reports 95-01). Furthermore, the minutes of IRB meetings should document separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB.

When conducting research under an expedited review procedure, the IRB Chair (or designated IRB member(s)) should receive and review all of the above referenced documentation.

Based upon its review of minutes of IRB meetings and UTMB's written IRB policies and procedures, OHRP is concerned that continuing review of research by the IRB regularly fails to satisfy these requirements. Please respond.

(9) HHS regulations at 45 CFR 46.404-407 require specific findings on the part of the IRB for approval of research involving children. Based on its review of minutes of IRB meetings, OHRP is concerned that the IRB fails to make the required findings when reviewing research involving children. Please respond.

Where HHS regulations require specific findings on the part of the IRB, such as (i) approving a procedure which alters or waives the requirements for informed consent [see 45 CFR 46.116(d)]; (ii) approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)]; (iii) approving research involving prisoners (see 45 CFR 46.305-306); or (iv) approving research involving children (see 45 CFR 46.404-407), OHRP strongly recommends that all required findings be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding.

(10) OHRP notes that IRBs frequently approves research contingent upon substantive modifications or clarifications without requiring additional review by the convened IRB. OPRR recommends the following guidelines in such cases:

> (a) When the convened IRB requests substantive clarifications, protocol modifications, or informed consent document revisions, IRB approval of the proposed research must be **deferred**, pending subsequent review by the convened IRB of responsive material.
>
> (b) Only when the convened IRB stipulates specific revisions requiring simple concurrence by the investigator may the IRB Chair or another IRB member designated by the Chair subsequently approve the revised research protocol on behalf of the IRB under an expedited review procedure.

Please clarify the IRB's procedure for reviewing and approving specific revisions requiring simple concurrence by the investigator. Please indicate the person(s) conducting this review in your clarification.

(11) HHS regulations at 45 CFR 46.115(a)(2) require that the minutes of IRB meetings document the vote on all IRB actions including the number of members voting for, against, and abstaining. OHRP notes that simply recording votes as unanimous, as is the case for the minutes of UTMB IRB meetings, is not satisfactory.

In order to document the continued existence of a quorum, OHRP strongly recommends that votes be recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1 (NAME).

(12) Regarding the UTMB IRB Policies and Procedures, OHRP has the following questions, concerns, and comments:

(a) Please provide the current membership rosters, as well as the prior rosters dating back to January 1, 1999, for the two Study Sections, the permanent Subcommittee for the Protection of Human Subjects, and the permanent Subcommittee on Continuing Review for the Protection of Human Subjects that are referenced in Section 3.5. Furthermore, please provide documentation of attendance at all meetings of these Study Sections and Subcommittees for the past 12 months.

(b) Section 3.6 defines a quorum of the IRB as a majority of the total membership duly appointed to conduct the business. Please note that HHS regulations at 45 CFR 46.108(b) require that, except when an expedited review procedure is used, research be reviewed at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in a nonscientific area. The definition of a quorum in Section 3.6 should be revised to include the presence of a non-scientist. OHRP emphasizes that should the quorum fail during a meeting (e.g. those with conflicts being excused, early departures, loss of a non-scientist), the meeting must be terminated from further votes unless the quorum can be restored.

(c) HHS regulations at 45 CFR 46.111(a)(1) require that the IRB determine that risk to subjects are minimized as a condition for approval of research. OHRP recommends that this criteria for approval of research be added to Section 5.2, paragraph B.

(d) Section 5.2, paragraph C(1), contains the following statement:

> "In general, those projects which involve more than minimal risk or physical or psychological injury require prior written informed consent of the research subject."

Please be aware that for all nonexempt research involving human subjects, regardless of the degree of risk, HHS regulations at 45 CFR 46.116 require that the investigators obtain the informed consent of the subjects, unless the IRB waives this requirement in accordance with HHS regulations at 45 CFR 46.116(d). Furthermore, such informed consent is to be documented in writing unless the requirement for the investigator to obtain a signed consent form is waived in accordance with HHS regulations at 45 CFR 46.117(c).

(e) Section 5.2, paragraph C(3), concerns research involving organs, tissues, body fluids and other materials obtained in the course of the routine performance of medical services. OHRP is concerned that the last sentence in this paragraph appears to imply that informed consent may only be required when such research involves risk to the subjects. Such a policy may not be consistent with the requirements of HHS regulations at 45 CFR 46.116.

Furthermore, OHRP notes that standard clinical and surgical consent documents rarely include all the elements required under HHS regulations at 45 CFR 46.116. Reliance on such documents for research generally requires formal waiver of consent requirements in accordance with Section 46.116(d), which requires that the IRB find and document four specific conditions.

(f) Section 6.2 lists the documents required for initial IRB review. HHS regulations at 45 CFR 46.103(f) require that an institution with an approved assurance shall certify that each application for research has been reviewed and approved by the IRB. It is unclear whether the items listed in Section 6.2 include a copy of any Federal grant application, if applicable. Please respond. In your response, please clarify whether the IRB receives and reviews complete copies of Federal grant applications proposing human subject research.

(g) Section 6.3 states that "Minimal risk protocols may be submitted at any time and will receive 'Expedited' review." OHRP is concerned the IRB inappropriately confounds the concepts of minimal risk and expedited review. Please respond.

HHS regulations at 45 CFR 46.110 stipulate that the IRB may conduct review of research using an expedited review procedure only for certain categories of research involving no more than minimal risk (see 63 FR 60364, copy enclosed), and for minor changes in approved research. Minimal risk research involving activities not listed at 63 FR 60364 may not be reviewed by the IRB using an expedited review procedure.

(h) Section 6.4, paragraph (1), describes the responsibilities of the IRB Study Section Primary Reviewer for the review of a research protocol. It is unclear whether the Primary Reviewer is required to attend the convened IRB meeting and provide a presentation to other IRB members. Please clarify.

(i) Section 6.4, paragraph (4) indicates that Study Section reports are prepared and presented at a convened meeting of the entire IRB on the Wednesday following the Study Section meetings.

In conducting the initial review of proposed research, IRBs must obtain information in sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111. Materials should include the full protocol, a proposed informed consent document, any relevant grant applications, the investigator's brochure (if one exists), and any advertising intended to be seen or heard by potential subjects. Unless a primary reviewer system is used, all members should receive a copy of the complete documentation. These materials should be received by members sufficiently in advance of the meeting date to allow review of this material.

If the IRB uses a primary reviewer system, the primary reviewer(s) should do an in-depth review of all pertinent documentation (as listed above). All other IRB members should at least receive and review a protocol summary (of sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111), the proposed informed consent document, and any advertising material. In addition, the complete documentation should be available to all members for review.

Please clarify what documents are received and reviewed by the Study Section Primary Reviewer, and what documents are provided to all members of the IRB prior to its meetings.

(j) Regarding the procedure for continuing review described in Section 7.1, please clarify what documents are received and reviewed by the Study Section Primary Reviewer, and what documents are provided to all members of the IRB prior to its meetings.

(k) OHRP is concerned that UTMB does not have written IRB policies and procedures that adequately describe the following activities, as required by HHS regulations at 45 CFR 46.103(b)(4) and (5):

(i) The procedures which the IRB will follow for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review.

(ii) The procedures for ensuring prompt reporting to the appropriate institutional officials, Department or Agency head, and OHRP of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

Please respond. Please note that IRBs must determine which protocols require continuing review more often than annually, as appropriate to the degree of risk [see 45 CFR 46.109(e)]. OHRP recommends that the minutes of IRB meetings clearly reflect these determinations regarding risk and approval period (review interval).

(l) Appendix A-6, APPLICABILITY section, list "language barrier" as one of several conditions where adult subjects may not be able to execute a legally effective informed consent. Language barrier should not be a condition which precludes legally effective informed consent.

The regulations require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing (see 45 CFR 46.116 and 46.117). Where informed consent is documented in accordance with HHS regulations at 45 CFR 46.117(b)(1), the written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with an informed consent document written in a language understandable to them. OPRR strongly encourages the use of this procedure whenever possible. Alternatively, HHS regulations at 45 CFR 46.117(b)(2) permit oral presentation of informed consent information in conjunction with a short form written informed consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written informed consent document should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject.

(m) Regarding Appendix A-16, paragraph B.2.a, OHRP notes the following boiler- plate language for informed consent documents related to genetic testing research:

> "By participating in this study, I agree to relinquish any claim to the work or results of the researchers or their sponsors and any property rights I might have in any tissue or fluid of mine that is given in the process."

HHS regulations at 45 CFR 46.116 state that no informed consent may include exculpatory language through which the subject or the subject's representative is made to waive or appear to waive any of the subject's legal rights. OHRP finds the above statement to be exculpatory. Please respond. In your response, please include revised boiler-plate language.

(n) HHS regulations at 45 CFR 46.117 require that a copy of the informed consent document be given to the person signing the form. OHRP finds that the policy described in Appendix A-19, paragraph 6, that a copy of the signed consent form should not be given to the inmate subjects fails to comply with this HHS requirement. Please respond.

(o) Regarding Appendix C-1, INITIAL IRB REVIEW FLOW CHART, OHRP has the following concerns:

> (i) According to the pathway depicting expedited review, if a principal investigator does not meet the conditions asked for by the reviewer, the research is not approved. However, please note that HHS regulations at 45 CFR 46.110 (b)(2) stipulate that reviewers may not disapprove research under an expedited review procedure. A research activity may be disapproved only after review by the convened IRB under procedures set forth at 45 CFR 46.108(b).
>
> (ii) According to the pathway depicting non-expedited review, research can be approved without ever being reviewed by the convened IRB.

Please respond.

(p) Regarding Appendix C-2, CONTINUING IRB REVIEW, OHRP is concerned that the pathway depicting continuing review of research does not include review by the convened IRB. Please respond.

Regarding IRB protocol #99-412 (GOG #0126-K: Phase II Evaluation of Oxaliplatin in Recurrent, Platinum-Resistant and Refractory Ovarian Cancer), OHRP has the following concern:

(13) HHS regulations at 45 CFR 46.116(a)(3) require that the informed consent process include a description of any benefits to the subject or others that may *reasonably* be expected from the research. OHRP is concerned that given the nature of phase II trials, the informed consent document approved for this research protocol appeared to overstate the reasonably foreseeable benefit to the subjects (i.e., "I understand that the potential benefit of my participation in this study is the control of my disease").

It appears that it would have been more appropriate simply to state that the subjects are unlikely to benefit from this research. Please respond.

Notification of OHRP Site Visit:

OHRP will conduct an on-site evaluation of the UTMB system for protecting human research subjects on September 12-14, 2000. During this evaluation, OHRP will meet with institutional administrators, the IRB Chairperson, IRB members, IRB staff, investigators who conduct HHS-supported human subjects research, and others, as necessary. OHRP will also review a large number of IRB files.

OHRP will need to meet with you, the Authorized Institutional Official on the MPA, for approximately 30 minutes on Tuesday, September 12 , 2000 to discuss systemic human subject protections at your institution and for one hour on the morning of Thursday, September 14, 2000 to describe OHRP's findings.

A draft agenda for this site visit is enclosed. Please notify OHRP as soon as possible if you require any modifications to this agenda. Also, unless notified otherwise, OHRP will work directly with you on all logistical matters for this site visit.

In order to assist OHRP in preparing for this site visit, please provide the following no later than August 15, 2000:

(1) A written response to all findings, concerns, and questions described above.

(2) A current, detailed organizational chart for UTMB.

(3) A copy of the current IRB membership roster.

(4) A copy of the agenda and minutes for all IRB meetings convened during the past 12 months.

(5) A list of all active IRB-approved protocols. For each protocol, please indicate the following: title, principal investigator name, type of IRB review (expedited or convened review), the source of support, the date of initial IRB approval, and the date of the most recent IRB continuing review and approval.

(6) A list of all IRB administrative support staff, including a description of duties and percentage of time devoted to IRB functions.

(7) Copies of any written IRB policies and procedures, IRB guidelines for investigators, and any IRB application and protocol forms, **if revised since your submission of January 7, 2000.**

Please feel free to contact us should you have any questions.

OPRR appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Michael A. Carome, M.D.
Chief, Compliance Oversight Branch
Division of Human Subject Protections

Sanford Leikin, M.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

Enclosures: (1) OPRR Reports 95-01
(2) Categories of Research Eligible for Expedited IRB Review
(3) Draft OHRP Site Visit Agenda

cc: Dr. John D. Stobo, President, UTMB
Dr. George M. Bernier, Jr., Vice President for Education, UTMB
Dr. Wayne Patterson, IRB Director, UTMB
Dr. Frank C. Schmalstieg, Chairperson, IRB, UTMB
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Melody H. Lin, OHRP
Dr. J. Thomas Puglisi, OHRP
Ms Michele Russell-Einhorn, OHRP
Dr. Michael A. Carome, OHRP
Dr. Clifford C. Scharke, OHRP

Dr. Katherine Duncan, OHRP
Ms Carol J. Weil, OHRP
Ms Elyse I. Summers, OHRP