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Subject: **Special Approval Requirements for Research Undergoing IRB Review**

APPROVAL REQUIREMENTS

UAB Radioisotope and Radiation Safety Committee

UAB holds a license through the State of Alabama to implement requirements related to use of radioisotopes and radiation in humans generally and, in particular, human research activities. The Department of Occupational Health and Safety (OH&S) is responsible for the maintenance and implementation of these licensing requirements. The UAB Radioisotope and Radiation Safety Committee reviews all projects included in the scope of the State licensing agreement. The UAB Radioisotope and Radiation Safety Committee is composed of faculty members, research personnel, and OH&S staff. Members of this committee are appointed by the UAB President through the Vice President for Research and the Vice President for Financial Affairs and Administration. The Radioisotope and Radiation Subcommittee for Human Use is responsible for reviewing and approving proposed research involving radioisotopes and radiation in humans. In addition, the Radioactive Drug Research Subcommittee, a separate subcommittee, is responsible for maintaining licenses and approvals for radioactive research drugs and devices. See their web site for more details: SUP427

http://www.healthsafe.uab.edu/pages/radiationsafety/rm_human_use_studies_submissions.pdf

Institutional Biosafety Committee (IBC)

The UAB IBC is one of several safety committees with membership appointed by UAB's President via the Vice President for Research and operates out of the UAB Department of Occupational Health and Safety (OH&S). The IBC has been in operation for more than 20 years and is responsible for assessing risks and potential environmental impacts associated with campus activities involving biological agents and recombinant DNA/RNA, including human gene therapy and making recommendations for safe conduct of such activities. The membership is composed of 14-20 researchers and/or faculty, UAB administrators and OH&S staff. The Chair, who is a member of the UAB faculty, is also appointed by UAB's President via the Vice President for Research. Cross-membership with other institutional committees is emphasized to

reduce paperwork for researchers and provide coordinated comprehensive review and reporting of research activities (e.g., Institutional Animal Care and Use Committee [IACUC]; Institutional Review Board for Human Use [IRB]; UAB Systems Infection Control [IC] which includes University Hospital; and Research Compliance Committee). IBC meetings are held monthly. A formal letter, signed by the IBC Chair, is sent directly to researchers detailing the results of the review and recommendations, with copies forwarded to IACUC, the IRB, and IC, as appropriate. The IBC operates administratively out of the Biosafety Program.

The Pittman General Clinical Research Center (GCRC)

The GCRC Guidelines require that all applications (regardless of funding source) be reviewed by the GCRC Scientific Advisory Committee (SAC) for scientific merit and need for Center services. Applications are reviewed by an independent reviewer and a member of the SAC for scientific merit and are presented at the monthly SAC meeting. See the GCRC web site for more details: SUP428 http://www.gcrc.uab.edu/docs/forms/20050405complete.doc

The Comprehensive Cancer Center Clinical Trials Review Committee (CTRC)

The CTRC reviews UAB Cancer Center-related applications—except for Cooperative Group protocols and retrospective chart reviews—for scientific merit, safety, study design, and feasibility to ensure there are no competing studies that would prevent the trial from reaching its targeted accrual goal. Following review by the CTRC, the trial is assigned a priority score based on clinical and scientific merit. When the CTRC reviews a protocol, this will serve as the Protocol Oversight Review for the study.

Gene Therapy Project Review Panel

A standing project review panel has been established for protocols involving gene therapy. Investigators preparing for initial review should select and contact three panel members from the gene therapy panel member list early in the protocol preparation process. Gene therapy protocols require IBC and RAC review prior to submission to the IRB. Applications are reviewed for scientific merit and safety and are submitted for continuing review on a quarterly basis.

Vaccine Trials Project Review Panel

A standing project review panel has been established for protocols involving vaccines. The panel will review the applications for scientific merit and safety and will confirm the trial

meets the criteria for exemption from RAC review. All protocols are required to have IBC review prior to submission to the IRB. These studies will be submitted for continuing review on an annual basis unless the IRB determines the protocol requires a more frequent review based on an unusual level of type of risk to participants.

Jefferson County Department of Health (JCDH)

A special project review panel, which includes employees of the health department, must review all studies conducted at the health department. The purpose of the application review is to make the health department aware of the planned research and to confirm their support and approval of the research request. This signed confirmation will be submitted to the UAB IRB by the health department.