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UHHS

Center For Clinical
Research

Office of Research Compliance
(Coming Soon!)

UHC IRB

UHC Grants and Contracts

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Obtaining Laboratory Reference Ranges for Regulatory Binders

Study Regulatory Binders should contain a list of normal laboratory values and reference ranges that is obtained from Laboratory Services. For your convenience, a copy of the current reference list is attached [here](#). Please be informed that the list of reference ranges is updated every three months. Therefore, you should contact Laboratory Services or the Center for Clinical Research every three months to ensure that your list of references ranges is current.

Update: Clinical Trials Brochure Available Online

Investigators from the Clinical Departments were recently invited to submit listings of Clinical Trials that are actively enrolling research participants for the Summer 2006 "Enrolling in Clinical Trials" publication. In addition, the listings have been added to the UHHS website. The brochure is now available on-line [Clinical Trials Brochure](#) and Departments may print [PDF](#) copies from the UHHS [About Clinical Trials](#) web site for distribution. As the new UH Brand is rolled out, we will work with the Marketing Department to initiate additional recruitment venues for the promotion of clinical trial enrollment.

Revisions to the UHC IRB Policies and Procedures

Last month, the research community was updated regarding revisions to the IRB Policies and Procedures resulting from UH seeking accreditation of the Human Research Protection Program with AAHRPP and to continue to improve the overall excellence of the program. The [Protocol Submission Requirements](#) policy, [Informed Consent](#) policy, and the [Investigator Checklist "N"](#) for new submissions provide additional guidance related to the Informed Consent Process, Data and Safety Monitoring Plan, and Privacy and Confidentiality.

All new research proposals are now required to use the revised Investigator Checklist (except for chart review and discarded tissue studies) and to include the information indicated in the revised policies.

Protocol Summary at Continuing Review

All Continuing Review (CR) submissions are required to include a protocol activity summary. The summary consists of the protocol abstract and a status report. The protocol abstract needs to briefly describe the research, including the study purpose and the aims and objectives; and the status report needs to address research activity since last CR: number of participants accrued; a summary of adverse events and other unanticipated problems, involving risks to participants or others; participant withdrawals and the reasons for withdrawals; complaints about the research; participant benefits; amendments or modifications; protocol deviations; relevant recent literature; interim findings; relevant multi-center trial reports; and a current risk-benefit assessment based on study results. A more detailed description of the status report can be found in the [Continuing Review](#) policy.

Certification Pursuit Program (CPP)

The new CPP rewards eligible UHHS employees who voluntarily further their skills by earning certifications or registries that are not required in their position. The Center for Clinical Research recommended the following certifications for qualification under the program: Certified Clinical Research Coordinator (CCRC), Certified IRB Professional (CIP), and Certified Research Administrator (CRA). Employees should input the certification information into Oracle Employee Self Service and provide proof of the certification to their Manager. More information is located on UHHS Connect under *Current Initiatives*, [Certification Pursuit Program](#).