

**ARKANSAS CHILDREN'S HOSPITAL RESEARCH INSTITUTE
LITTLE ROCK, ARKANSAS**

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| SUBJECT: Unfunded/Under-funded Human Research Policy | DATE: 6/17/05 PAGE: 1 of 3 |
| | APPLICATION: ACHRI DISTRIBUTION: Interdepartmental Policy and Procedure |
| | APPROVED BY: |
| RECOMMENDED: Janet Storment, RN, CCRC, Clinical Trials Administrator | Supersedes: NONE |

1. Purpose: Arkansas Children's Hospital Research Institute (ACHRI) is committed to assisting our research community with investigator/sponsored projects, using human subjects, that have minimal funding and that could later develop into extramural funded studies and clinical investigations. This policy is for investigators who are requesting a waiver of fees that would hinder their ability to complete the research project. Investigator's seeking additional funding for a research project should consider submitting an application to one of the Institutional Intramural programs or other potential funding sources.

2. Applicability and Distribution: This Policy applies to Principal Investigators wanting to conduct clinical trial research on the ACH or ACHRI campus with minimal funding (funding that will not cover all expenses incurred by the proposed project) resources and are requesting a waiver of fees and/or reduced F&A cost recovery.

3. Definitions:

Research: is defined as any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge. Examples of research activity include clinical trials, surveys, interviews, behavioral investigations, retrospective reviews or medical information, experiments with blood and tissue.

Clinical Trial Research: the systematic investigation of the effects of materials (i.e., investigational drugs, devices, biologics) or methods (i.e., surgery, radiation) on a disease state conducted according to a formal study plan (protocol) that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

Human Research: is defined as any investigation involving human subjects that meets the definition of research

Human Subject: A living individual about whom data is obtained through intervention or interaction with the individual or collects identifiable private information 45CFR 46.102(f). An individual who is or becomes a participant in research, either as a recipient of a test article or as a control 21 CFR 56.102 (e).

Investigator/Sponsor: A term defined in the FDA regulations as an individual with responsibility for initiating and conducting a research study.

4. Responsibilities: The ACHRI Board of Directors will review all requests and provide the investigator with a letter granting approval or the reasons why the approval was not granted

5. Methods/Procedures: A request for support or services by ACHRI (which includes waivers for PCRU usage fees) **must** include the following information before the request will be reviewed.

1. Study Title:
2. Anticipated Start date and expected duration of project:
3. Expected number of subjects:
4. Documentation of compelling reason and benefits to the subject/patient
5. Description of the study protocol and the estimated cost of the study, contact ACHRI Clinical Trials Administrator for assistance, stormentjanets@uams.edu.
6. Resources needed (i.e. PCRU, Radiology, Lab, Pharmacy etc.): Complete the ACHRI Clinical Trials Study Summary Form, [Clinical Trial Study Summary Form](#)
7. Completed ACHRI Internal Budget form with all appropriate department signatures, [ACHRI Clinical Trial Submission Form](#).
8. Documentation of all services and support to be provided by the GCRC <http://www.uams.edu/gcrc/gcrc2/default.asp> , if this project has been approved by the GCRC
9. Documentation of *Funding sources: please include all 038, 0125, 02610 and 2630 account balances and how much of those balances' will be used for the research.
10. Documentation of alternative funding sources that have been applied for and the response (whether approved, disapproved or pending).
11. Documentation of resources that your home department will be willing to provide or why support is not forthcoming from the department.
12. Documentation of resources that your home section will be willing to provide or the reasons why support is not available from the section.
13. Documentation of departmental approved ACH support if other ancillary departments are involved (i.e. Pharmacy, Radiology, Lab. etc.).
14. Documentation of any residuals expected from this project if applicable.
15. Provide current C.V. for Principal Investigator

Each request that is submitted will be evaluated based on merit, section and departmental support, and the resources ACHRI has available at the time of request.

If waiver is granted, approval will be granted for that level of support, number of subjects and duration indicated in the application. Any additional subjects, prolonged time frame or additional support will require a new request with a progress report for the project to date.

*** - 038 General Research Accounts ;
2610 ACH Foundation Accounts; 2630 Research Foundation Accounts**