REVISED 4/15/14

PURPOSE

The CTRC follows an investigator "charge-back" system in order for the CTRC to be able to maintain a level of service with the potential of expanding current services available to investigators. This policy is subject to change depending upon changes in the NIH budget to the CTSA program and other economic factors.

POLICY

The CTRC Resources committee approves all CTRC charges which investigators will be expected to pay for CTRC services. Investigators are notified to contact the CTRC Administrator at the time of external grant submissions to receive guidance in preparing for charges for CTRC services. At the time of CTRC new protocol review, the CTRC Resource Committee may waive or reduce the standard CTRC service charges in accordance with the policies below. The CTRC Resource Committee and Core Directors must review and approve each request to ensure the volume of services requested are feasible.

The CTRC maintains its commitment to active studies already approved and will not alter pricing on these studies per the new protocol as long as the scope and estimated time frame of the study does not change and the CTRC does not experience any major new financial constraints.

PROCEDURES

1) For investigator-initiated studies, CTRC will waive or reduce charges for certain studies acquiring pilot or preliminary data based on the following criteria. The study must show high potential of securing external grant funds and must be for the purpose of the investigator gathering data for future external grant applications. Criteria for selection/approval are based on the scientific merit of the proposal, potential for future funding, or trainee study with high potential. (Industry initiated studies will be charged standard CTRC fees for industry studies without any charges waived).

   Pilot or preliminary studies are designed to generate early data that will help in powering and designing the future definitive study. A pilot study is unpowered and generally includes a small sample size. It is acceptable if the applicant then includes an analysis demonstrating how the chosen sample size will demonstrate differences, but the primary outcome does not hinge on this. As an alternative, the term "preliminary" could be used for investigations powered for sample size that do not meet the criteria for a pilot study. It is advised that applicants consult with a statistician. Applications should state how the data will help the investigator plan the future more definitive study and demonstrate the feasibility of recruitment and study procedures

a. Unfunded fellow/instructor studies: CTRC requires a mentor's letter of support. The fellow and mentor should detail their plan to use the data from the study to obtain external funding and to build a research career for the junior investigator. If the fellow does not plan a long-term research career, it is expected that the study will lead to publication in a peer-review journal, and will have significant impact upon the field. Priority will be given to funding studies with the best scientific score as rated by the CTRC scientific reviewers. The number of subjects the CTRC will support will be dependent on availability of resources, and CTRC statistician input as to an appropriate sample size to meet the aims and objectives of the study. Support will be given over a maximum of 3 years or the length of the fellowship.

b. Unfunded studies by investigators above the level of fellow or instructor: Limited free support for pilot studies or preliminary data studies (that may yield definitive, publishable results, but are nevertheless small studies needed to acquire preliminary data for extramural grants) will be available. The CTRC will, whenever possible, provide free CTRC services for: (i) A maximum of 20 subjects, (ii) All subjects must be studied within 12 months from enrollment of the first subject. Consideration may be given for additional resources only if the request is very well-justified (e.g., a recommendation from a study section for a set amount of further data).

c. K12, K08, K23 and other equivalent career development and mentored awards: Awards where at least 50% salary support to the trainee is given and significant financial support to the study. CTRC will waive the charge for these "K" awards. Free support to these studies will only be for the duration of the NIH "K" award. (Note: PI must pay expenses for lab kits when using the CTRC Core Lab).

2) For NIH approved studies, CTRC may reduce charges for funded studies if the investigator's extramural grant award is cut after submitted and the investigator is not able to compensate for the difference. The CTRC charge may be reduced proportionate to the NIH grant. CTRC will be as flexible as possible to work within the NIH budget. Decreases in charges are dependent on CTRC Budget Committee's review of grant vs award and conclusion that the reduced charges are appropriate in relation to grant funding amount, the scientific merit of the grant, and the ability of the CTRC to provide all Core requests at this cost reduction without jeopardizing the availability of resources for other projects.

3) Inpatient research stays: Charges to investigators are instituted for inpatient stays at the CTRC rate of $800/night (plus incidentals charged by the hospital). For unfunded studies (as detailed above) a detailed justification of the need for inpatient beds to be paid for by the CTRC must be provided.

4) Studies requesting that the CTRC waive or reduce charges may be required to have some or all services performed at the 3550 Market Street site rather than Main campus whenever possible as expenses of the CTRC are considerably lower at this location.

5) If CTRC resources are inadequate to support all proposals, the scientific score awarded during the CTRC review process will be used to prioritize use of resources.

6) Investigators are required to budget a 3% annual increase to CTRC prices for external grant applications.

7) Investigators receiving CTRC support may be required to serve as a CTRC/IRB joint reviewer.

8) The CTRC is responsible for communicating with investigators as to the CTRC Resources Committee decision on charges, and ensuring that the appropriate category is reflected on the Budget/Billing Plan and in the EPIC Revenue Location for the CTRC.

Approved By: Contributors:

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