LSUHSC Clinical Research Project

Education, Training, and Mentoring Focus Group

The LSUHSC Clinician-Researcher Programs

Chairman: Warren R. Summer MD

Members: John Burgess, James Diaz, Connie Romain, Judd Shellito, Warren Summer, Kurt Varner

Objectives: (1) To promote clinical research at LSUHSC. (2) To identify potential clinician-researchers at LSUHSC. (3) To attract potential clinician-researchers to convenient educational programs that further define careers and opportunities in clinical research. (4) To design an optional core educational curriculum in clinical research for potential clinician researchers. (5) To supplement the core curriculum in clinical research for committed clinician-researchers with a rigorous, didactic degree-granting program in the experimental design and analysis of clinical investigations. (6) To provide on-going administrative, physical, and fiscal support of newly trained clinician-researchers and their mentors. (7) To provide on-going mentoring of newly trained clinician-researchers.

Meeting the Objectives

(1) Promoting Clinical Research. Define the benefits of clinical research at LSUHSC through several mechanisms including (a) stressing the needs and advantages of clinician researchers in academic programs; ease of appointments, promotions in rank, quality of life, etc.; (b) frequently recognizing research heroes (Boyd Professors) and inviting them to train new research mentors; (c) inviting distinguished clinician-researchers and healthcare and biotechnology industry executives to extol the scientific and contractual benefits of strong clinical research programs; (d) recognizing and rewarding potential young clinician-researchers who actively participate in clinical research presentations, formal research day events, clinical case presentations, clinical and experimental trials, and scientific publications.

(2) Identifying Potential Clinician-Researchers. Medical and dental students are early in their LSU Health Science Center careers and already have opportunities to earn the MPH degree jointly with their professional degrees. Target group for potential clinician-researchers should include senior (chief) level residents, subspecialty fellows, and junior faculty at the rank of Instructor or Assistant Professor. Major Senior Faculty, with interest in career redirection would also be encouraged.
(3) **Attracting Potential Clinician Researchers.** Using both the existing GCRC (Methods in Clinical Research I and II) and the existing UNC SPH Models (Web-based Certificate Programs in the field of Epidemiology), design an optional, convenient, and informal lunch hour (12-1 PM with lunch) and/or early evening hour (4-5 PM with refreshments) 2-semester educational program in clinical research aimed at the target group. Award AMA PRA Category I CME hours at no charge for faculty. The program would feature lectures by ethicists, established clinician-researchers, study evaluators, epidemiologists, evaluators, grant specialists, and biostatisticians, grant writing specialist in a broad introductory curriculum.

(4) **Designing an Optional Core Curriculum.** For target group members who attend or complete the informal “Methods in Clinical Research” activities, or other interested individuals offer a more rigorous, one-year (2 semesters, maximum of 2 courses per semester), Internet-based scientific program in Clinical Research that awards both a **Certificate in Clinical Research** and 9-12 graduate credit hours that may be applied to an advanced degree at LSUHSC, either through the LSUHSC School of Public Health (the MPH in Clinical Research-45 credit hours), or through the LSUHSC School of Graduate Studies (the MS in Experimental Design and Analysis-38 credit hours). Internet-based courses are expensive to design and produce initially, especially if streaming video is added to create a virtual classroom. To meet the time and expense constraints, the web-based certificate program could begin with 3 courses (9 credit hours: Introductory Biostatistics, Introductory Epidemiology, and Responsible Conduct of Research for example) with a virtual classroom, and be expanded to 4 courses (12 credit hours) by adding a more robust methods course with a real classroom at a later date. It is possible that the “right program” is better taught or available elsewhere as ours is developed over time. An available LSU program should not delay the process in “growing” our clinical research faculty.

(5) **Supplementing the informal conference and web-based certificate programs.** Although some highly motivated graduates of the informal and certificate programs may begin clinical research activities at LSUHSC without further training, most target group members will still be trying to further identify their roles as clinician-researchers and will seek further education and training. Such individuals may enroll in unique degree-granting programs in clinical research at LSUHSC and may apply any credit hours earned in the LSUHSC Certificate Program in Clinical Research (9-12 credit hours) towards an advanced degree, such as the MS (38 credit hours) or the MPH (45 credit hours). With fewer credit hours required (38 hrs) and an emphasis on experimental design and analysis (and not public health practice), the MS will be more attractive to young clinician-researchers than the MPH, unless the researcher plans to enter government or the military. The program in Biostatistics in the LSUHSC SPH currently offers a SACS-approved MS in Biostatistics, which could be easily re-configured to an **MS degree in Experimental Design and Analysis** by adding more research design and conduct of clinical trials courses. The **MPH in Clinical Research**, a more rigorous 45-credit hour program, would require completion of the core curriculum in public health, the 9-12 certificate hours if earned, and further coursework in experimental design and analysis, including significant community service work and thesis/capstone.
Time Table for initiation of training process: ASAP

Providing on-going administrative, physical, and fiscal support to newly minted clinician researchers and their mentors. Newly graduated clinician-researchers may be offered postdoctoral-like positions as Assistant Professors in both a basic science and a clinical science department, such as pulmonary physiology and pulmonology/critical care, microbiology and infectious disease, genetics and obstetrics/gynecology. Both departments would be required to contribute administrative, physical, and fiscal support to the clinician-researcher, thus sharing the financial burden while jointly benefiting from the clinician-researcher’s activities. These new salaries are likely to require new support for the LSUHSC since current clinicians and basic research salary support is tight. Further advancement of the clinician-researcher after a 2-year period would be based on the researcher’s clinical research activities, external contracts, patents, grant awards, and scientific presentations and publications. The clinical programs should provide the opportunity to supplement income with private or public patient activity.

Providing on-going mentoring of clinician-researchers. Faculty who serve as instructors, supervisors, and mentors of new clinician-researchers must be recognized and rewarded for their extra time and effort spent developing the Methods in Clinical Research Core Curriculum, the Certificate Program in Clinical Research, and the MS in Experimental Design and Analysis and the MPH in Clinical Research degree programs. This can be accomplished at relatively low cost by combining with and augmenting the existing GCRC program. For example, LSUHSC could offer lunch hour lectures in clinical research methods that do not duplicate the GCRC evening lecture series. Attendance at both lecture series would constitute LSUHSC’s informal “Methods in Clinical Research” program, a more robust course for potential LSUHSC clinician-researchers than what the GCRC offers now. Each clinical department needs to recruit one outstanding GCRC clinical researcher. This will be expensive but will pay dividends in future mentoring and GCRC renewal applications as well as speeding the initiation of the clinical research process.

Jump starting and maintenance of program. The concept of the LSUHSC Clinician-Researcher Programs will need to be jump-started by an immediate financial infusion and nurtured by continuing financial infusions until the program becomes self-sufficient, running on its own grant and contract-generated income in 5-10 years. The acute infusions could come from indirect or other taxes on current large grant awards to departments and Centers of Excellence, which will need to rely on fresh clinician-researchers for current and future translational research. Alternatively, the LSUHSC Clinician-Researcher concept could be re-packaged as a grant proposal to the Board of Regents seeking seed-funding for 5 years from the Health Education Fund (HEF) to create the LSUHSC Center for Clinical Research. This is how the LSU Hurricane Center and many other LSU Centers were created. Continuing infusions could come from new grant awards for the training of clinician researchers, such as KO8 grants, K-30 awards, RO grants, CAP awards, FIPSE grants from the Department of Education, Fulbright grant awards, etc. Developing private and public clinics for clinical practice which attract
patients for possible future clinical research investigation is critical to the success of the clinical investigator.

(10) **Managing resistance to change.** There will be significant resistance among some faculty, department heads, administrators, and middle managers to the Clinician-Researcher Programs for many valid reasons including unwillingness to change and to accept additional responsibilities, unwillingness to recognize newly graduated clinical researchers as well trained and experienced scientifically and clinically, insufficient physical office and laboratory space, insufficient funding for teachers and mentors, and a personal bias and focus either on pure basic science research or on pure clinical practice. Techniques to manage such resistance might include combinations of: (1) organizing the early adopters and supporters into their own Center of Excellence for Clinical Research and seeking HEF funding from the BoR for such a Center, as indicated; (2) removing the road blockers and non-team players by allowing them to concentrate only on their own focused goals in basic science research or clinical practice; and (3) converting the road blockers and non-team players by significant rewards of more space and funds for resident and faculty expansion.

**Conclusions**

This focus group has presented one concept for establishing and nurturing clinical research at LSUHSC. This concept is based on the theory of relevant incrementalism, incentives, and the career ladder approach to advancement. This proposed program has the potential to produce capable clinician-researchers in a few years at several levels depending on the intelligence, ingenuity and self-motivation of the individual. Competent and prolific investigators may be produced at the informal Clinical Methods level, the Certificate Program level, or the Masters Degree level.