



Academic Senate

MEMORANDUM

TO: Laurie L. Clabo, Interim Provost

FROM: Academic Senate Policy Committee

IN RE: Temporary Charter for the Center for Emerging and Infectious Diseases

Date: June 30, 2021

The Wayne State University Academic Senate Policy Committee has reviewed the documents related to the planned Center for Emerging and Infectious Diseases in accordance with your request for an expedited review given the possibility of an external funding source. We consider admirable the idea of aggregating the university's expertise from pharmacology, medicine, nursing and other areas to create a new synergy that allows increased ability to garner grants and conduct research and education around the topic of pandemic diseases, and we recognize the timeliness of the topic given the current experience with the global COVID-19 pandemic.

Nonetheless, we are deeply concerned about multiple aspects of this proposal, including the lack of clear focus and operational expectations, over-use of administrative positions, and unclear expectations for internal and external educational and training opportunities. Further, we find the lack of a more detailed and work-specific budget for the first year concerning, along with the lack of any description or detail regarding expected operational costs in the first few startup years. We believe that these concerns should be addressed before the center is approved for a temporary charter.

These concerns are outlined in more detail in the following sections.

**I. Broad and Vague Description of Center Activities.**

One issue of substantial concern is the lack of detail in the proposal regarding the broad range of activities apparently intended to be undertaken in the proposed center. For example, the executive summary describes the center as a "leader in controlling and responding to emerging and pandemic diseases" but it is not clear in what way it will "control" or "respond". The proposal mentions disaster preparedness but also clinical care, training, research, innovation, raising revenue from laboratory services, providing guidance to healthcare workers, providing education to campus personnel and externally, and engaging in various collaborative activities with both internal and external constituencies. This list does not seem adequately tied to a definitive and clear mission, unless being the be-all and end-all of pandemic preparedness is the mission of this center. The proposal includes establishment of the campus's only BSL3 laboratory for dealing with highly contagious organisms, but it confuses the reader by at one time indicating that research will be the priority and in other places indicating that the lab (only one-fifth the size of the lab proposed in the original Bold Moves proposal) will be used for training, for research and for profit-making, with no clear description of how these various functions will be directed, prioritized, and coordinated. The proposal provides no measures by which its success during a temporary charter year could be (or should be) measured.

**II. Administrative Staff Overload.**

A second major concern expressed by Policy Committee members relates to the various administrative staffing proposals for the Center. While the proposal suggests three staff members for each of the types of clinical trial activities (a total of 9 FTE), the “organogram” indicates *multiple center administrators*—a “center administrator”, “center laboratory director” and “center program manager”—with *additional staffing in each of the clinical trial areas*. Duties and responsibilities of these administrative roles are unclear regarding the particular areas of clinical trials.

The proposal also indicates that the *three founding members will all serve as “co-directors”* of the center in addition to an unclear number of “*assistant directors*” of the center. This proposal for three co-directors seems particularly worrisome. There is no indication of the specific duties of each of the co-directors or how decisions will be made when the co-directors disagree or when the co-directors and center administrator disagree. Members of the Policy Committee are generally most knowledgeable about centers with a single director whose vision and expertise drive the direction of the center, and with NIH requirements when there are co-PIs for a *specified leadership plan* to delineate duties, interactions, chains of command, and what happens if one of the co-PIs is unavailable. Here, the proposal is for three co-directors without specification of duties and a “center administrator” whose duties are also not specified. The Policy Committee views this administrative overload likely to be fatal to efficient operation of the center.

Complicating the administrative situation still further, the three proposed directors have appointments at various university affiliates. Nothing in the proposal makes clear how those appointments will relate to their appointments and roles in the proposed center.

### **III. Unclear Training and Educational Activity Proposals.**

The various discussions of training and educational activities appear to have little relationship with the specific research and clinical trials to be conducted in the new laboratory. It is unclear whether these are primarily roles already being conducted by the three proposed co-directors in their existing roles and just to be subsumed under the center as work of the center, or whether indeed a new program of internal and external training and educational opportunities is expected to be created. The vagueness of this discussion is worrisome, since training/educational use of the laboratory entails significant scheduling, safety, and skill-level concerns.

A significant concern in this regard is the mention of education for “medical students”. The clinical delivery of research trials requires individuals who have completed their medical degrees as well (i.e., residents/fellows in infectious disease, psychology, etc.), since medical students are not able to independently deliver care through clinical research. This is not addressed with any evaluable detail in the documents for the proposal. In what way does the center hope to reach students who have not completed their medical degrees, and how does the center expect to interface with postgraduate trainees who are affiliated with the university or with residents in university programs?

Any educational outreach by the center to the community at large requires both marketing and material development as well as presentation. The relationship with community organizations generally is unspecific and vague. There does not appear to have been any budget developed for the marketing and educational outreach activities.

None of these training and educational activities has been articulated in understandable detail, and budgetary resources to support these training and educational activities are not described in the document.

#### **IV. Budget Concerns.**

The fourth issue of substantial concern to Policy Committee members is whether the proposed budget is adequate to the tasks planned and what will be the ultimate sources for both start-up funding and operational funding. The proposal includes only its startup budget needs for establishing the BSL3 laboratory (space and equipment) and personnel. The proposal suggests that some of these startup costs will be (or already are) funded by unnamed “external sources” (presumably grants, foundations, or corporations). That is, of course, the expectation for centers—all of their funding should come from external sources, since the synergy of the center is designed to draw such external funding so that the center itself is not just another cost drain on the university’s finances.

Nonetheless, there are a number of concerning aspects about the budgetary considerations here. One of the documents suggests that the proposers are confident of acquiring space in the iBio building. The proposal does not include *any* information about ongoing operational costs, yet the operation of a BSL3 laboratory will require considerable expenditures. Since the “external sources” of funding to support the creation of the BSL3 laboratory are not named, that raises further concerns.

Furthermore, the proposal includes a statement that the center will be part of the School of Medicine’s annual budgetary process. That suggests that the founding directors expect some unstated amount of funding through the School of Medicine budgetary process. Such a funding source seems entirely inappropriate at a time, as some Policy Committee members noted, when the School’s Dean has suggested stark changes in clinical and research faculty compensation due to concerns about financing.

The proposal suggests that it will generate revenues by conducting laboratory evaluations for outside users. These revenue-generating uses of the laboratory will need to work efficiently in conjunction with the training and research activities that the proposal says are primary, but it is not clear that there is an appropriate organizational structure that will allow that to happen, as noted in the prior section on administration of the center.

Policy members considered the budget justification for the clinical trial programs section both too broad and too vague, which tends to result in poor evaluation by grant review committees. Each of the clinical trial programs is stated to have the same three positions—apparently separate personnel for each program, based on the budget FTE statements. But those same position titles are reflected in the “center” staff, along with a statistician, so it remains somewhat unclear.

It is not clear why the indirect revenue is indicated at 25% when the rate for the NIH is twice that. Does that mean that the center directors are assuming industry grants rather than NIH funding?

The budget shows only 1 FTE for center director. Does that mean that each of the three “co-directors” are intended to occupy only one-third of a full-time director role rather than having a center administrator who is full time? If the three are each intending to occupy a part-time role, this heightens the concerns raised in the section on administrative overload about the means of making decisions and ensuring continuity of management. As noted in that section, this proposal seems to be a recipe for inefficient management and issues that fall through the cracks.

The overall budget is presented in such a sketchy manner that it is hard to evaluate. One expects a budget justification for each line item, with the name of the person to occupy each position and salary stated. Here, the medical director budget is listed as 90k for year 1 and 180k for year 2 though in both cases it is for 1 FTE. Further, the salaries for clinical research nurses seem extraordinarily low—about half of what is typically paid for research nurses. That is especially true if fringes are included. (There is no discussion of fringes in the salary section so, again, hard to evaluate.)

**V. Conclusion.**

In conclusion, the Policy Committee appreciates the overall stated mission of this center proposal and the timeliness of the university's development of a substantial center around a theme of pandemic preparedness, but we find this proposal as currently stated needful of more specific development before it is given approval of a temporary charter.