

EXECUTIVE SUMMARY DETAILING CONCERNS WITH THE ABILITY TO PERFORM PATHOGEN RESEARCH AT UF

IMPORTANCE OF PATHOGEN RESEARCH:

We are experiencing the third pandemic caused by a coronavirus in two decades (SARS-CoV, MERS-CoV, SARS-CoV-2) and have witnessed the recent emergence of several clinically relevant arboviruses (e.g., Chikungunya virus, Zika virus) which threaten the health of the people of the State of Florida. In fact, more than 50 new viruses have emerged since 1988 and the pace of emergence is only expected to climb in response to large-scale changes in virus ecology introduced by people. Today's funding climate in the midst of the COVID-19 pandemic is ripe for multi-investigator virology grants including P01s, U01s and multi-investigator R01s. Equally important is the study of pathogenic bacteria and parasites that continue to garner direct interest from the NIH and entities within the Department of Defense. As a top public university, UF should be leading the way in researching the pathogenesis of emerging pathogens, including development of novel therapeutics and vaccines. According to US News and World Report 2021 rankings, **UF ranks as the 22nd best U.S. university for infectious disease research compared to top 5 institutions like University of North Carolina, Chapel Hill, University of Michigan, and University of California, Los Angeles who rank 6th, 7th, and 10th respectively.** This ranking is based on reputation and research in the field. In the quest for the top 5, increased investment and productivity in this field would be highly beneficial given the current global environment.

SCOPE OF THE PROBLEM:

There have been long-standing difficulties in the ability of researchers at UF to successfully carry out research programs focused on high-containment pathogens, detailed below. This hinders our success in attaining research funding, has prevented us from recruiting and retaining numerous highly successful PIs in recent years, and has affected the reputation of UF.

- Length of time for approval to perform research at biosafety levels 2 and 3. Multiple PIs have been waiting 10 months to be given access to an ABSL3 suite to perform SARS-CoV-2 infections in a rodent model; as of Aug. 27, 2021, they still have not been granted access*. This is a devastating setback for their research projects in a fast-paced and highly competitive area of research. Moreover, the average time for EH&S to approve biosafety projects **has increased from 10 days to 90 days over the past decade.** The biosafety staff works incredibly hard but the increase in EH&S staff is not proportional to the increase in research at UF over this time period.
- Annual closure of ABSL3: BSL3 facilities require periodic shutdowns for the purpose of inspections and equipment repairs. At UF, these occur annually and generally take 1 month at the EPI for non-animal BSL3 space and 3+ months in our ABSL3 facility. This is substantially longer than at peer institutions. For example, Colorado State which has much larger BSL3/ABSL3 facilities than UF has annual 1-week shutdowns. The lost research time for UF PIs that rely heavily on high-containment research is unsustainable and has led to the departure of successful faculty.
- Inability to perform ABSL3 experiments in non-rodent models: UF has a reputation among faculty, both within and outside our campus, of being overly risk averse, particularly with regard to high-containment research. It is perceived that this is responsible for the systemic barriers to the approval and conduct of this research that do not exist at our peer institutions and which go beyond State and Federal regulations and guidance. This is an impediment to hiring and retaining faculty in this area. For example, UF has attempted to hire several world-renowned influenza virus

researchers over the past decade but each has declined our offer because of the university's resistance to allowing them to do experiments in ferrets. Likewise, requests by PIs on campus to perform anthrax studies in rabbits and SARS-CoV-2 studies in cats were denied.

- **Capacity:** While BSL2 non-animal research can be carried out in any lab with an appropriate biosafety cabinet, more ABSL2 space is desperately needed on campus. We are also at capacity in non-animal BSL3 space in the EPI.
- **Cost:** Operation of ABSL3 space can be expensive but should be considered an essential and ongoing investment in research infrastructure. The idea that ACS can turn a profit from per diem research costs is not the norm for these types of facilities across the country yet has been stated explicitly to be an expectation at UF. Because of this, our ABSL3 per diems are astronomically high (\$11.91 per cage) compared to those at peer institutions (e.g., \$3.61 at U.M).

SUMMARY OF SYSTEMIC BARRIERS AND PROPOSED SOLUTIONS:

1. Unacceptably slow approval process of BSL3 protocols and SOPs at Biosafety Office (EH&S) as well as ABSL3 in Animal Care Services.

Proposed Solutions: Form a special committee to review Approval Processes in both offices to identify unnecessary steps and opportunities for increased efficiencies and recommend appropriate staffing levels. Increase staffing levels proportional to the increase in research on campus over the past decade. As a model of what success would look like in terms of EH&S staffing, we recommend University of Wisconsin-Madison: <https://ehs.wisc.edu/staff-directory/>. Note they have 23 staff members compared to 5 staff at UF covering the same activities, with multiple specialists in the areas of certifications and facilities as well as high-containment (select agent and BSL3) procedures.

2. Inability to perform ABSL3 studies in non-rodent animal models (e.g., ferrets, rabbits, guinea pigs, and cats) puts UF infectious disease research at a huge disadvantage to our peer institutions and is a missed opportunity to hire world class faculty and garner increased NIH funding.

Proposed solution: Executive level review is needed (with input from stakeholders) to identify how ABSL3 capability can be expanded to facilitate research on these non-rodent models.

3. Severely limited BSL2 and 3 space in the animal facilities that needs to be expanded.

Proposed solution: Additional vivariums and BSL3 non-animal space should be planned for in new research building(s) and/or new self-standing auxiliary animal facilities.

4. Need for changing public perception that UF's research regulatory enterprise is overly risk adverse and overburdened with outdated approval processes.

Proposed solution: The proposed solution in item 1 should identify the extent to which these barriers are real or perceived.

Overall, UF should embrace high-containment research as an institutional strength and asset rather than a perceived risky endeavor.