EXECUTIVE SUMMARY:

ADVISORY COMMITTEE REPORT

REGARDING *Burkholderia pseudomallei* INFECTIONS AT

TULANE NATIONAL PRIMATE RESEARCH CENTER

EXECUTIVE SUMMARY ISSUED: FEBRUARY 10, 2016

SITE VISIT: MAY 24 – 27, 2015
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I. INTRODUCTION

In late 2014, there were confirmed infections of non-human primates (“NHPs”) at the Tulane National Primate Research Center (“TNPRC”) with the Tier 1 Select Agent Burkholderia pseudomallei (the “Bp Incident”), which was being used by researchers for various research projects conducted at TNPRC.1 This resulted in a review of the Bp Incident by the Centers for Disease Control and Prevention (“CDC”) Division of Select Agents and Toxins and the United States Department of Agriculture (“USDA”) Animal and Plant Health Inspection Service (“APHIS”) Agriculture Select Agent Services (together, CDC and USDA head the Federal Select Agent Program or “FSAP”). In response to the Bp Incident, Tulane University (“Tulane”), of which TNPRC is a part, convened an expert advisory committee (the “Committee”) chaired by Paul Keim, Ph.D., Director of the Center for Microbial Genetics and Genomics at Northern Arizona University. The Committee, which is comprised of experts in the study of Bp and in the fields of biosafety, infectious disease, environmental health, and genetics and genomics, participated in a site visit at TNPRC from May 24 to May 27, 2015 (the “Site Visit”) and continued to meet via telephonic conference at various intervals between that time and the date of this report’s issuance.

The Committee reviewed numerous documents in advance of, during and after the Site Visit; interviewed TNPRC and Tulane employees, including, but not limited to, the TNPRC Director, faculty members and principal investigators, veterinary staff, animal care staff and facilities staff; and toured the TNPRC campus, including the veterinary hospital, regional biocontainment laboratory (“RBL”) and the breeding colony. The Committee’s goal was to review the Bp Incident, attempt to determine its cause(s), make recommendations for changes in procedures to prevent any recurrence, and to make recommendations regarding any future monitoring of Bp.

The Committee recognizes the efforts made by Tulane to address these unfortunate events. Tulane and TNPRC have mobilized resources—including this Committee—to (i) identify the possible causes of the release of this pathogen; (ii) protect the public, TNPRC staff and the NHPs; and (iii) institute remedial actions to prevent any similar incidents in the future. It is the Committee’s goal that its review of these events can assist Tulane in these efforts.

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1 Bp is a bacterium that is found in soil and water and causes the disease melioidosis in humans and animals. Bp is endemic in tropical regions of the world, including countries in East and South Asia, the Middle East, Africa, Latin America, the Caribbean and the Pacific, and it is especially common in Southeast Asia and Australia. See Bart J. Currie & Mirjam Kaestli, A Global Picture of Melioidosis, 529 Nature 290 (2016); Direk Limmathurotsakul et al., Predicted Global Distribution of Burkholderia pseudomallei and Burden of Melioidosis, 1 Nature Microbiology 1 (2016). Bp is categorized as a Tier 1 Select Agent by the United States Centers for Disease Control and Prevention and the United States Department of Agriculture Animal and Plant Health Inspection Service, the designation given to agents of the highest risk. See 42 C.F.R. § 73.4(b). It is considered an “overlap agent” because it has the potential to pose a severe threat to both (i) public health and safety, and (ii) animal health or animal products. See 42 C.F.R. § 73.4(a).
II. OVERVIEW OF TNPRC AND BRIEF SUMMARY OF MAJOR EVENTS

A. Overview of TNPRC

Established in 1964, TNPRC is a prominent infectious disease research center whose mission is to improve human and animal health through basic and applied biomedical research. Central to this mission is the ethical use of NHPs. More than 400 scientists from around the US use TNPRC’s resources, primarily for NIH-funded research, to examine the pathogenesis of infectious diseases. Knowledge gained through this work is used to develop vaccines, diagnostics and therapeutics to improve human and animal health. Research at TNPRC includes work with Select Agents, such as Bp, the use of which is overseen by FSAP through enforcement, inspection, investigation and guidance activities.

B. Brief Summary of Major Events

On November 7 and 9, 2014, respectively, two male adult NHPs (referred to herein, as Case 1 and Case 2) presented to TNPRC’s veterinary hospital with symptoms of lethargy and depression. Notably, these two animals had not been in the same field cage prior to admission to the veterinary hospital, and they had no known contact with one another prior to admission. On November 12, 2014, during a routine follow-up check, TNPRC veterinary staff discovered a large, firm caudal intra-abdominal mass on Case 1. Surgery revealed a large abscess in the pelvis from which cultures grew a “Pseudomonas species” subsequently identified by CDC as Bp, as discussed in more detail below. Then, on November 21, 2014, TNPRC veterinary staff discovered a similar intra-abdominal mass on Case 2. Urine and mass fluid samples from Case 2 were sent for culture and subsequently were identified by CDC as containing Bp. Case 2 was euthanized under anesthesia on November 26, 2014 due to poor health condition and extensive pelvic abscess found at laparotomy. Case 1 was placed on antibiotic treatment, but later relapsed when taken off such treatment, and subsequently was euthanized on February 19, 2015.

On December 6, 2014, at the request of TNPRC’s clinical laboratory supervisor, the principal investigator (the “PI”) conducting Bp research at TNPRC tested the samples taken from Case 1 and Case 2 using a Western blot with a monoclonal antibody specific for the Bp capsule. This test suggested the presence of Bp. A third NHP (referred to herein as Case 3) was found to have multiple pelvic abscesses in February 2015 that yielded Bp on culture. As of January 21, 2016 these are the only three (3) animals that have been culture-positive for Bp. Soon after receiving these findings, TNPRC notified CDC and sent isolates from Case 1 and Case 2 for further testing for Bp. On December 19, 2014, CDC confirmed these isolates as Bp. FSAP inspectors from CDC and USDA visited TNPRC to investigate the Bp incident from January 21-23, 2015, and again from February 5-13, 2015. On February 7, 2015, CDC suspended all research involving Select Agents at TNPRC and, as of the date of this executive summary, has not yet reinstated such research.

In February 2015, TNPRC began sending to CDC batches of NHP sera for indirect hemagglutination (“IHA”) testing, beginning with animals that were housed in the veterinary hospital at the same time as were Case 1 and Case 2, and then expanding to NHPs housed in
other areas of TNPRC (e.g., NHPs housed in the same field cages as had been Case 1 and Case 2). Those NHPs identified as seropositive for Bp were isolated within the veterinary hospital.

Testing via culture remains the “gold standard” for determining the presence of Bp, but Tulane has, understandably, taken the more cautious approach and has regarded certain animals as “positive” on the basis of serology, despite the fact that these animals had a negative culture result for Bp. There have been fourteen (14) animals that have had “positive” serology tests in addition to the three culture positive NHPs. Of these 14 animals, thirteen (13) have been regarded as “positive” due to the presence of a four-fold increase in their titer level, the benchmark that CDC suggests should be used to determine which animals are positive for Bp. The fourteenth animal has been regarded as “positive” due to having a titer in excess of 1:10,000. While CDC had classified this animal as “inconclusive” due to the lack of an earlier sample from the animal that could be used to measure an increase in titer, the extremely high titer level is suggestive of possible exposure to Bp. The fourteen (14) seropositive animals and the three (3) culture positive animals have all been euthanized.

The Committee notes that serology for Bp infection is an inexact science, particularly because “positive” results may actually reflect a response to bacteria other than Bp that cause cross-reactions. It cannot therefore be concluded that all fourteen (14) of these “positive” animals had actually been exposed to Bp, although the antibody titers in at least four (4) of these animals were greater than 1:10,000, which is unlikely to be the result of cross-reactions in the opinion of the Committee.

Also, in February 2015, representatives from the United States Environmental Protection Agency (“EPA”) designed a protocol and directed the collection of environmental samples at TNPRC, including soil, water and air samples, that CDC later confirmed were all negative for Bp. In March 2015, CDC issued a media statement indicating that it found no evidence to suggest that Bp was released into the surrounding environment and that CDC had completed its investigation of the Bp Incident. Later, in April 2015, Committee member Dr. David Wagner and his team collected 588 soil samples in and around the field cages in which Case 1 and Case 2 had been housed, all of which were tested and determined to be negative for Bp. In addition, to date, all wildlife captured and tested as part of the Wildlife Sampling Plan, further discussed below, have been culture-negative for Bp.

Since mid-December 2014, TNPRC has held many informational meetings regarding the Bp Incident—initially for those staff at highest risk of exposure and soon after for all staff—during which Bp/melioidosis materials were distributed and a risk assessment questionnaire was offered to each individual in attendance. In late December 2014 and January 2015, TNPRC began communicating regularly with various state and local agencies (including the Louisiana Department of Health and Hospitals, the Louisiana Department of Agriculture and Forestry and St. Tammany Parish), as well as entities with property bordering TNPRC (including surrounding homeowners’ associations and the Northlake School) and the TNPRC Community Advisory Board. Also, in February and March 2015, public meetings were held regarding the Bp Incident, with representatives from TNPRC and local, state and federal agencies in attendance to answer questions.
Finally, TNPRC is in the process of revising its policies and procedures, and has re-trained personnel with access to ABSL-3 and BSL-3 facilities on such policies and procedures that address (i) procedures for donning, doffing and disinfecting personal protective equipment (“PPE”); (ii) waste decontamination and disposal; (iii) proper entry and exit into laboratories, animal holding rooms and procedure rooms while in containment; and (iv) reporting biosafety violations through proper channels. These re-trainings first took place in March and April 2015, and further retraining was provided in September and October 2015 under the direction of the new Biosafety Officer. Going forward, in addition to the annually required biosafety trainings, the Biosafety Officer plans to initiate a quarterly training curriculum offering hands-on training on biosafety SOPs as well as ongoing agent-specific and research study-specific trainings at the start of new research projects.

III. SUMMARY OF FINDINGS AND RECOMMENDATIONS

A. Evidence Does Not Support Conclusively a Particular Theory of Infection

The Committee has not been able to find concrete evidence that supports conclusively any particular theory of infection. It is highly likely based on the genetic match of the organism recovered from the infected macaques to the strain previously used in rodent experiments conducted in a research building at TNPRC that the latter represented the source of the escape. Although some of the NHPs may have been exposed by cross-contamination inside the veterinary hospital, there also is significant concern that NHPs may have been exposed outside the veterinary hospital. How the organism was transferred from the research building remains uncertain and may never be identified conclusively.

The Committee examined (among others) the initial working hypothesis developed by TNPRC regarding the cause of infection in Case 1 and Case 2, which has been publicly supported by CDC statements—namely, that \( Bp \) was transferred from the research building, in which the PI conducted a \( Bp \) study in rodents in Fall 2014, to the veterinary hospital via a staff member’s contaminated clothing or an otherwise contaminated person or object, which then led to the contamination of a multi-use drug vial or other common source or object used in the care of NHPs housed in the veterinary hospital. Under this theory, Case 1 and Case 2 would have acquired their infections during their stay in the veterinary hospital, and not before entry into that facility. Yet the observed time course and clinical features in at least one of the NHPs do not align with typical observations of \( Bp \) infection in humans, at least following naturally acquired infection, in that lesions seen were larger than would be expected to have developed in such a short time. In addition, the time from hospital infection to acute signs of melioidosis in that animal was unexpectedly brief. In addition, some animals with very high serologic test results that are unlikely to have arisen other than by exposure to \( Bp \), had not been in the veterinary hospital beforehand. In sum, we find this initial theory of infection implausible and inadequate.

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2 For example, one animal had never been admitted to the veterinary hospital prior to having a serum draw that yielded a high IHA titer (1:10,240).

to explain all of the evidence based on the method of transfer from building to building, the timeline of events, and the clinical presentation of several of the NHPs. We also considered potential methods of transmission related to breaches of infection control procedures, but at this point, there are still insufficient data to validate fully any particular theory of transmission.

Recommendations: TNPRC should continue to investigate any newly identified exposed or infected animals with the goal of identifying a unifying hypothesis as to how all such animals might have been exposed to \( Bp \) (or unifying hypotheses, if later-discovered evidence indicates that infections occurred at different points in time). In continuing its investigation, TNPRC should (i) complete testing of all animals in the breeding colony that have yet to be tested as soon as practicable; (ii) continue to monitor animals serologically during semi-annual examinations conducted in the breeding colony, utilizing the breeding colony as a surveillance tool; (iii) ensure that all abscesses are cultured appropriately; and (iv) ensure that all oxidase positive Gram-negative bacilli from clinical samples are tested to exclude \( Bp \).

B. Improved Serologic Methods are Needed, Although Methods Now Employed by TNPRC are Adequate Given Current Constraints

CDC has been using IHA as the primary means of testing serologic samples taken from TNPRC NHPs. While IHA-based serologic analysis currently is the most widely used technique for diagnosis of human melioidosis within endemic areas, there also are limitations to the assay. High IHA titers were observed with two culture-positive animals (and the third culture-positive animal did not have serum available for testing), thus reinforcing the evidence that melioidosis induces a strong humoral immune response in macaques that IHA detects. However, moderate and even high titers have been observed in multiple NHPs that were asymptomatic and were never culture positive for \( Bp \).

Recommendations: TNPRC should continue to pursue improved, specific, rapid, high-volume and efficient alternative serologic testing methods. Because of the potential for low frequency “positive” titers from animals exposed to non-\( Bp \) bacteria (i.e., false positives), different tests should be used first to screen the colony (e.g., the polystyrene beads with multiple antigens) and then secondarily to confirm melioidosis (e.g., LAT or a \( Bp \)-specific antigen ELISA). At present, TNPRC is using the latex agglutination test ("LAT") as a screening test, with any positive and/or inconclusive samples sent to CDC for confirmatory testing via IHA. Use of the LAT has been acknowledged and approved by CDC, as indicated by email dated May 20, 2015 from CDC officer Alex Hoffmaster to Katie Portacci of USDA/APHIS, in which he explained the use of LAT as a screening tool at TNPRC. While the Committee has not reviewed specific methods and results of the LAT employed by TNPRC, based on the information received to date, this appears to be a reasonable approach to \( Bp \) testing while TNPRC continues to monitor and refine the testing process.

C. Wildlife Testing Results Are of Uncertain Meaning But Have Shown No Evidence of \( Bp \) Infection in Animals Tested

The Biosecurity Sciences Laboratory of the Queensland Department of Agriculture and Fisheries (the “Australian Lab”) has been conducting serological testing on wildlife captured on the
TNPRC campus, pursuant to the request of USDA/APHIS. In the absence of scientific literature supporting the utility of wildlife testing, we find such testing to be of limited value because (i) serology testing conducted on diverse wildlife is highly likely to yield many low-level “positive” test results, which may represent cross-reactivity with bacteria other than \( Bp \) (i.e., near neighbors or other common bacteria), rather than exposure to \( Bp \) itself; (ii) validation of serology testing in these diverse animals to estimate sensitivity and specificity is lacking and would be difficult to obtain; and (iii) it is problematic from an ethical standpoint to euthanize and test hundreds of wildlife without appropriately validated and reliable testing methods.

In support of our above concerns, Dr. Wagner recently sent blinded sera samples to the Australian Lab, via USDA/APHIS, for testing using the complement fixation test. These four serum samples were from the mice that had been infected with a Florida \( B. vietnamiensis \) strain, an Australian \( B. vietnamiensis \) strain, a Texas \( B. thailandensis \) strain, and control mice that had received saline injections with no bacteria. The Australian Lab reported that sera from the mice challenged with the \( B. vietnamiensis \) and \( B. thailandensis \) strains yielded titers of 1:8 and were labeled as “positive” for exposure to \( Bp \). Sera from the uninfected, control mice yielded titers of 1:4 and were labeled as “suspect” for exposure to \( Bp \). Their tests and positive criteria are different than those used by the CDC but based upon their validation data they wrongly identified these as positive for exposure to \( Bp \). These results demonstrate clearly that the Australian Lab testing procedures are yielding false positive results and, thus, are not adequate for detecting the exposure of wildlife species to \( Bp \).

**Recommendations:** To date there is no clear and specific scientific hypothesis being tested through wildlife sampling, no evidence of environmental contamination with \( Bp \), no wildlife that have been cultured as positive, and no reason to believe that wildlife testing will act as a sensitive sentinel of any present or continuing problem as it is not used as a surveillance tool in \( Bp \)-endemic regions. Thus, on balance, we believe that the benefits of continued wildlife testing are weak at best and outweighed by the costs imposed in terms of testing resources and the ethical considerations of unnecessary wildlife mortality. TNPRC should discuss with regulators the uncertain meaning of the results of the Australian Lab’s testing. Until and unless the accuracy of this testing is resolved, present results must be interpreted with caution, and the limited testing resources available would be devoted more appropriately to testing of animal species maintained at TNPRC. Nonetheless, if testing continues, then TNPRC should test some wildlife from control sites.

**D. Scope of Future Environmental Testing Should be Considered Carefully**

At the time of this report, two environmental sampling studies have been completed. The first study by the EPA and CDC, with samples collected in February 2015, employed a sampling regime of soil, water and air. The second study by Dr. Wagner’s team, with samples collected in April 2015, was larger, more systematic and involved soil in the area of the field cages associated with Case 1 and Case 2. Both sampling studies failed to detect \( Bp \) in the environment, although other species of \( Burkholderia \) (“near neighbors”) were observed as anticipated. While there is no evidence of \( Bp \) in the environment, this does not lead to the conclusion that \( Bp \) is not and has never been present in the TNPRC environment, as an absence of evidence is not conclusive evidence of absence. Given the difficulties with detecting \( Bp \) in environmental
samples, a comprehensive, structured program of environmental testing would be labor intensive and, even then, negative results could never give total reassurance. We acknowledge the concerns of both the community and local regulatory and administrative agencies that the environment surrounding TNPRC could be capable of sustaining Bp. Such concerns should be allayed at least somewhat by a recent publication in the journal *Nature Microbiology* that considered the suitability of the environment surrounding TNPRC for *Bp* and concluded that “[t]he *B. pseudomallei* suitability level is very low [in the geographic area] at the Center (suitability level 0.02) and is moderately high in New Orleans, 35 miles south of the Center (suitability level 0.55).”

**Recommendations:** Without the discovery of new evidence supporting a different approach to environmental testing (*e.g.*, laboratory or epidemiologic evidence of an environmental source of infection), further environmental testing appears to be of limited value and should not be continued. Any future environmental testing should be hypothesis-driven and designed to investigate possible links between animals that are identified as having been exposed.

**E. Environmental Remediation is Not Indicated and, Depending upon the Agent Used, Could be Dangerous**

TNPRC has had conversations with state government officials regarding potential remediation of the two field cages in which Case 1 and Case 2 were housed prior to hospital admission. Recent comprehensive soil testing within and around those two cages, however, has failed to indicate any presence of *Bp*. Environmental remediation should be used only under extreme circumstances, to be defined by data suggesting a genuine hazard. There is no scientific evidence regarding the optimal remediation methods and their likely efficacy.

**Recommendations:** Considering that soil testing has not identified positive *Bp* sites on the TNPRC campus, we recommend against environmental remediation unless *Bp* is detected in the environment. Without detection, it also would be impossible to know whether remediation has had any effect. In the event remediation is required by regulatory authorities, careful consideration must be given to the methods employed so as to avoid an inadvertent negative impact on the environment, including surrounding communities and their residents.

**F. Infection Control Practices Should Be Re-Examined and Compared with Best Practices at Other Primate Centers, So That They Can Assuredly Be “Best in Class”**

Dr. Michael Tapper, a Committee member and an infection control expert, toured the animal care and veterinary care areas of TNPRC on April 6, 2015, almost two months before the Committee’s May 2015 Site Visit, to observe infection control practices. The Committee also inspected these areas and facilities during its Site Visit. On these visits, staff demonstrated awareness of infection control practices and precautions. Nevertheless, several breaks in infection control techniques and practices were identified.

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4 See Direk Limmmathurotsakul et al., *Predicted Global Distribution of Burkholderia pseudomallei and Burden of Melioidosis*, 1 *Nature Microbiology* 1 (2016). Dr. Dance, a member of the Committee, is a co-author of this paper.
**Recommendations:** Given that multiple experimental infectious agents (not limited to Select Agents) are in use at TNPRC, and there are natural disease events in the colony, it would be appropriate for TNPRC to undertake a thorough comparison of its infection control practices, and related SOPs and training materials, with those of the other national primate centers to assure that TNPRC’s practices are “best in class.” In undertaking this exercise, TNPRC should also strive to improve on the standards for infection control practices and set higher standards for those practices, especially given the research use at TNPRC of Select Agents, with the special risks that they present. Specifically, the Committee recommends that:

- Signage and illustrations be up at all entrances and exits from the veterinary hospital to guide staff and visitors in the proper method of donning and doffing PPE;
- TNPRC consider whether the use of multi-dose vials could be reduced or eliminated;
- Storage of oral medications outside of closed-labeled containers be eliminated, and sealed sterile items, such as syringes and gauze bandages, only be opened at the time of use;
- TNPRC consider tracking drug vials used in the veterinary hospital via an electronic system that would enable Vet Med staff to scan a vial’s bar code before, during and/or after use on a particular animal, or that would allow similar tracking of the use of multi-use vials;
- Cleaning protocols for hospital procedure rooms be incorporated in SOPs, and compliance be documented and periodically monitored, including via annual training;
- Invasive and other procedures carried out in the field cages that have a risk of cross-infection among NHPs should be reviewed and revised, as appropriate, to reduce or eliminate infection risks; and
- To meet the critical need for infection control expertise, training and monitoring of staff and equipment at TNPRC, TNPRC seek out such expertise and assure that it is used to support biosafety and occupational health functions, as well as to inform research and veterinary practices and procedures.

**G. Additional Resources and Infrastructure are Required to Support Long-Term Monitoring and Testing Efforts**

The clinical microbiology laboratory facility at TNPRC is limited in space and capacity. Although the lab is staffed by dedicated and experienced individuals whose suspicions and interest were roused immediately by the recognition of two unusual isolates over a short period of time, the *Bp* Incident revealed that the laboratory facility was unable to identify specifically (or to send to another lab for rapid confirmation) a pathogen currently under study at TNPRC.

**Recommendations:** The clinical microbiology and diagnostics units at TNPRC require additional resources and infrastructure to accommodate routine microbiology, long-term monitoring of NHP serology and basic molecular diagnostics such as PCR. Such resources and infrastructure will ensure that TNPRC may work independently through its long-term monitoring and testing protocols without being forced to rely on external laboratories and agencies (e.g., CDC) for support in these areas. Resource improvements should include upgrades in technology for culture, serologic and DNA-based methods, as well as methods for rapid identification of *Bp* and of other Select Agents used at TNPRC.
H. A Comprehensive Quality Assurance ("QA") Program Could Strengthen TNPRC

One management strategy that we have recommended be implemented at TNPRC is a QA program for the reporting and analysis of sentinel events. Such a program should be made up of TNPRC staff members from different organization levels and from different disciplines and roles within TNPRC. Instituting a program along these lines would represent appropriate professional management of a complex entity like TNPRC. In such a program, adverse incidents and deviations from professional and regulatory standards (including those related to infection control) must be reported and their causation analyzed through a “root cause” process. Indeed, as part of the QA program, root cause analyses should be conducted for all significant incidents, and resolutions should be shared with affected staff in an effort to “close the loop” and build confidence in TNPRC leadership and functioning. The results and remediations from root cause analyses should be compiled into a database for future reference and used as a mechanism for ongoing quality review and systems improvements.

IV. CONCLUSION

The Committee commends Tulane for its commitment to this process and to the improvement of biosafety functions at Tulane and TNPRC. At the same time, there remains much work to be done to identify and resolve problems in biosafety and in related management functions at TNPRC, at least some of which have been identified because of the Bp Incident and the scrutiny that ensued. In this report, the Committee has described its various findings and has recommended a number of steps and initiatives that should, in the Committee’s view, be undertaken to address problems related to the Select Agents research program and related Tulane and TNPRC functions. The improvement of the functioning and safety of TNPRC (including its Select Agents research program and internal communications practices) should remain a priority of the first order for Tulane.