

City of Brisbane

Planning Commission

TO: Planning Commission

For the Meeting of 04/14/22

SUBJECT: **Removal from the Agenda Concerning Use Permit 2022-UP-2, 1000 Sierra Point Parkway, SP-CRO Sierra Point Commercial District;** Use Permit application to allow the use of minipigs in medical research and development (R&D) by Bristol-Myers Squibb in the existing, approximately 9,000 square foot vivarium; Ricardo Garcia, applicant; HCP LS Brisbane LLC, owner.

As a procedural matter, per Brisbane Municipal Code Section 17.18.035, this use permit is subject to City Council's review and approval authority, not the Planning Commission's. Since the Planning Commission does not have authority over this class of use permits, the item is being removed from tonight's agenda. Given that the item is being removed from the agenda, no oral comments should be heard from the public except under "oral communications" since the item is no longer on the agenda. Any written public comments that have been provided, or will be provided, will be included in City Council's agenda report on the application.

The application will be scheduled for a public hearing with City Council, with a public hearing notice provided at least 10 days prior to the hearing, in accordance with BMC Section 17.54.030. The date of that public hearing is to be determined.

Ken Johnson

Ken Johnson, Senior Planner

John Swiecki

John Swiecki, Community Development Director

City of Brisbane

Planning Commission Agenda Report

TO: Planning Commission

For the Meeting of 04/14/22 **Superseded**

SUBJECT: Use Permit 2022-UP-2, 1000 Sierra Point Parkway, SP-CRO Sierra Point Commercial District; Use Permit application to allow the use of minipigs in medical research and development (R&D) by Bristol-Myers Squibb in the existing, approximately 9,000 square foot vivarium; Ricardo Garcia, applicant; HCP LS Brisbane LLC, owner.

REQUEST: The applicant requests a conditional use permit to utilize the existing approximately 9,000 square foot vivarium on the first floor of 1000 Sierra Point Parkway for conducting cardiovascular R&D using minipigs (*Sus scrofa*).

RECOMMENDATION: Approve Use Permit 2022-UP-2, per the agenda report, via adoption of Resolution 2022-UP-2 with Exhibit A, containing the findings and conditions of approval (Attachment A).

ENVIRONMENTAL DETERMINATION: Use of existing facilities are categorically exempt from the provisions of the California Environmental Quality Act (CEQA) per Section 15301 of the State CEQA Guidelines. The exceptions to the categorical exemptions referenced in Section 15300.2 do not apply.

APPLICABLE CODE SECTIONS: Per Brisbane Municipal Code (BMC) Section 17.18.035.B, a conditional use permit is required for use of live animals for research and development (R&D) that are not otherwise approved or prohibited pursuant to Section 17.18.020.K. The findings required for Use Permit approval are contained in BMC Sections 17.40.060.A & B.

DESCRIPTION OF PROPOSED USE: The applicant proposes to utilize the existing vivarium for cardiovascular medical research using minipigs. The use would be located within the existing 9,000 square foot vivarium on the first floor of this 4-story, approximately 125K square foot R&D building. The applicant has indicated that cardiovascular makeup of minipigs is similar to that of humans and so they serve an important function in this type of research. The BMS project description states that, *“While smaller animals (rats and mice for instance) are valuable contributors at the beginning stages of disease research, many question about how a drug acts in the body need to be studied in an animal that more closely recapitulates the human physiology, metabolism, and disease process.”* The applicant has estimated that approximately 5 to 15 minipigs would be at the facility at any given time. Further details on the use are provided in the applicant’s project description (Attachment B)

The use is under the regulatory authority of the U.S. Department of Agriculture (USDA). Staff contacted the Veterinary Medical Officer with the USDA who oversight responsibility for this

Superseded

facility. He indicated that the use will be subject to unannounced inspections by the USDA to ensure the welfare of the animals and indicated that there were no concerns with the proposed use at this facility.

ANALYSIS AND FINDINGS: Although the use is R&D, which is generally permitted by-right within this zoning district, since the species of animal is not specifically identified in BMC Section 17.18.020.K, a use permit is required. In order to approve the Use Permit, the Planning Commission must make the following findings, per BMC Section 17.40.060:

- A. “In considering an application, the planning commission shall consider and give due regard to the nature and condition of all adjacent uses and structures, and to general and specific plans for the area in question.”
- B. “The planning commission shall determine whether or not the establishment, maintenance or operation of the use applied for will, under the circumstances of the particular case, be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood of such proposed use, or whether it will be injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city.”

The proposal would meet both of the findings, as discussed below.

Adjacent Uses and General Plan Consistency— In regards to the first finding, the property is within Healthpeak’s R&D campus and adjacent to other R&D uses at Sierra Point and the Marina to the west. The use would be conducted indoors within a controlled vivarium environment in an existing R&D building.

The property is designated for a broad range of commercial land uses in the General Plan, including research and development, which is implemented in the SP-SCRO Sierra Point Commercial District zoning (BMC Chapter 17.18). This allows for the use via conditional use permitted.

In reference to the part of the finding related to specific plan consistency, that aspect of the finding is not applicable as there is no adopted specific plan covering this area.

Not Detrimental or Injurious to the Property, Neighborhood or City— The proposal would not be detrimental or injurious to the property, neighborhood or City. As noted above, the use would be conducted indoors within a controlled vivarium environment of an existing R&D building. As such, there would be no detrimental effects on any persons working in the neighborhood and there are no residences in the neighborhood, nor would there be injurious or detrimental effects to property or improvements in the neighborhood or the general welfare of the City. Conversely, the use would provide opportunity to advance research and knowledge into treatment of human heart disease and associated conditions, providing potential broad health benefits beyond the Brisbane community.

This application has been reviewed by the Public Works Department, Police Department and North County Fire Authority, Building Department and the USDA. None of the departments nor the

Superseded

USDA had objections to the proposed application. As noted above, the USDA noted that they have ongoing oversight and perform unannounced inspections of the facility.

ATTACHMENTS:

- A. Draft Resolution 2022-UP-2 with Findings and Conditions of Approval
- B. Aerial photo of site location & vicinity
- C. Applicant's Project Description

Ken Johnson

Ken Johnson, Senior Planner

John Swiecki

John Swiecki, Community Development Director

Superseded

Draft - RESOLUTION 2022-UP-2

ATTACHMENT A

**A RESOLUTION OF THE PLANNING COMMISSION OF BRISBANE
CONDITIONALLY APPROVING USE PERMIT 2022-UP-2
TO ALLOW FOR USE OF MINIPIGS FOR R&D
AT 1000 SIERRA POINT PARKWAY**

WHEREAS, Ricardo Garcia, the applicant, on behalf of the tenant Bristol-Myers Squibb (BMS), applied to the City of Brisbane for a Use Permit to allow for R&D use of minipigs within the existing BMS vivarium at 1000 Sierra Point Parkway, such application being identified as Use Permit 2022-UP-2; and

WHEREAS, on April 14, 2022, the Planning Commission conducted a hearing of the application, at which time any person interested in the matter was given an opportunity to be heard; and

WHEREAS, the Planning Commission reviewed and considered the agenda report relating to said application, the plans and photographs, the written and oral evidence presented to the Planning Commission in support of and in opposition to the application; and

WHEREAS, the Planning Commission finds that the proposed project is categorically exempt from the provisions of the California Environmental Quality Act; and

WHEREAS, the Planning Commission of the City of Brisbane hereby makes the findings attached herein as Exhibit A in connection with the Use Permit.

NOW THEREFORE, based upon the findings set forth hereinabove, the Planning Commission of the City of Brisbane, at its meeting of April 14 2022, did resolve as follows:

Use Permit 2022-UP-2 is approved per the conditions of approval attached herein as Exhibit A.

ADOPTED this 14th day of April, 2022, by the following vote:

AYES:
NOES:
ABSENT:

Chairperson

ATTEST:

JOHN A. SWIECKI, Community Development Director

EXHIBIT A

Superseded

Action Taken: Conditionally approve Use Permit 2022-UP-2 per the staff memorandum with attachments, via adoption of Resolution 2022-UP-2.

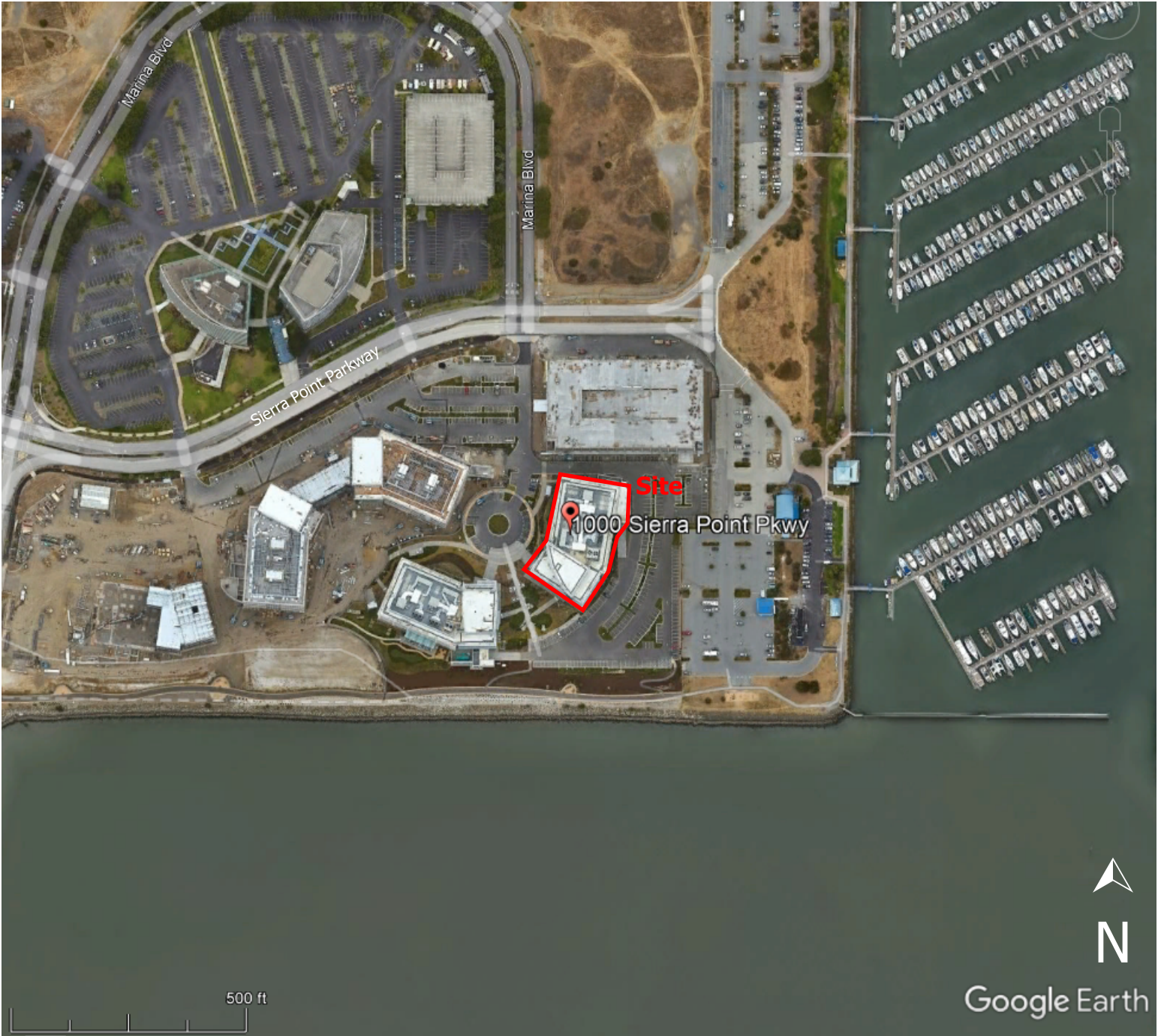
Findings:

1. The Planning Commission has considered and given due regard to the nature and condition of adjacent uses and structures and the use permit is consistent with the general plan and there is no specific plan adopted by the city council for the area in question.
2. The establishment, maintenance and operation of the use applied for will not, under the circumstances of the particular case, be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood of such proposed use, nor will it be injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city.

Conditions of Approval:

- A. The operator shall maintain its Business License with the City of Brisbane.
- B. The operator shall comply with the performance standards provided in BMC Section 17.18.045 regarding R&D uses.
- C. Operator shall comply with the requirements of the USDA, to ensure the welfare of the animals complies with USDA standards.
- D. Minor modifications to the use permit may be approved by the Community Development Director in conformance will all applicable requirements of the Municipal Code.

1000 Sierra Point Parkway Site Vicinity Map



Introduction

This application describes a request for a use permit for the use of minipigs (*Sus scrofa*) in research in the existing Bristol-Myers Squibb (BMS) vivarium at 1000 Sierra Point Parkway, per Sections 17.18.020(K), 17.18.035(B) of the City of Brisbane Municipal Code. The BMS vivarium at Sierra Point is already constructed and staffed with suitability for indoor pig housing. The permit for the existing structure was granted by the City in 2008 as Building D of the Shore at Sierra Point project, an approximately 23-acre research and development campus in the current SP-CRO Sierra Point Commercial District. Occupancy began in 2020; the site is currently fully operational with approximately 150 full-time employees.

No modifications to the building are proposed in this application or associated with this proposed use. No changes in hazardous chemical storage or noise/odor generation are associated with this proposed use. The facility itself will be used to house swine that will be the subject of ongoing scientific investigation to advance scientific knowledge and treatment of human heart disease and associated conditions. Typical laboratory equipment, office space and other furnishings typical of a science lab are housed within the building on the property in question.

Background and Objective

While smaller animals (mice and rats, for instance) are valuable contributors at the beginning stages of disease research, many questions about how a drug acts in the body need to be studied in an animal that more closely recapitulates the human physiology, metabolism, and disease process. Pigs are a particularly valuable species and are especially notable for their similarities to the human cardiovascular system. BMS employs sound, scientifically advanced methods to develop swine populations that mirror heart disease found in humans.

Project Conduct

BMS has substantial experience and expertise in conducting a wide range of scientific research which often necessarily involves the use of animals. It is for this reason that BMS has established strict internal policies and practices that are designed to meet our own standards and those of all applicable governmental agencies. BMS proudly promotes a culture of excellence in animal welfare, with an active oversight committee, 24/7 availability of laboratory animal veterinarians and veterinary staff, regular internal welfare assessments, and third-party accreditation in AAALAC International, the leading, internationally-recognized organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. All animal activities will comply with federal and local regulations, and the site has obtained and maintains a research registration with the United States Department of Agriculture. Additionally, the animal program will adhere to or exceed the standards described in the Guide for the Care and Use of Laboratory Animals (Institute for Laboratory Animal Research, National Research Council).

BMS is committed to the humane and scientifically appropriate use of animals in research, in unison with our dedication to innovative clinical advancements. Through sophisticated study methods and rigorous scientific principles, our investigators drive the development of high-quality medicines that address the unmet medical needs of patients with serious diseases. Establishing this research at the Sierra Point site will connect our existing cardiovascular team with the resources needed to rapidly develop and progress novel therapies to waiting patients. Beyond satisfying the City's permit requirements, BMS views its commitment to its planned operation at this location as vital to the continued scientific advances critical to our public health mission.

With approval, we look forward to initiating this much-needed work. We have carefully reviewed the permit submission requirements and guidance and believe we have furnished all information necessary to support issuance of the requested use permit. We appreciate the City Council's thoughtful review of this permit application for the use of minipigs in research at the BMS Sierra Point site. We are available for any questions, clarifications, or additional information the Council would find helpful during the review process.

Selected Scientific Publications:

Olivotto, I., Oreziak, A., Barriales-Villa, R., Abraham, T. P., Masri, A., Garcia-Pavia, P., Saberi, S., Lakdawala, N. K., Wheeler, M. T., Owens, A., Kubanek, M., Wojakowski, W., Jensen, M. K., Gimeno-Blanes, J., Afshar, K., Myers, J., Hegde, S. M., Solomon, S. D., Sehnert, A. J., ... Yamani, M. (2020). Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial. *The Lancet*, 396(10253), 759-769. [https://doi.org/10.1016/s0140-6736\(20\)31792-x](https://doi.org/10.1016/s0140-6736(20)31792-x)

Ho, C. Y., Mealiffe, M. E., Bach, R. G., Bhattacharya, M., Choudhury, L., Edelberg, J. M., Hegde, S. M., Jacoby, D., Lakdawala, N. K., Lester, S. J., Ma, Y., Marian, A. J., Nagueh, S. F., Owens, A., Rader, F., Saberi, S., Sehnert, A. J., Sherrid, M. V., Solomon, S. D., Wang, A., ... Heitner, S. B. (2020). Evaluation of Mavacamten in Symptomatic Patients With Nonobstructive Hypertrophic Cardiomyopathy. *Journal of the American College of Cardiology*, 75(21), 2649-2660. <https://doi.org/10.1016/j.jacc.2020.03.064>

Silva, K., & Emter, C. A. (2020). Large Animal Models of Heart Failure: A Translational Bridge to Clinical Success. *JACC. Basic to translational science*, 5(8), 840-856. <https://doi.org/10.1016/j.jacbts.2020.04.011>

Stricker-Krongrad, A., Shoemake, C., Brocksmith, D., Liu, J., Hamlin, R., & Bouchard, G.. (2017). Comparative cardiovascular physiology and pathology in selected lineages of minipigs. *Toxicology Research and Application*, 1, 239784731769636. <https://doi.org/10.1177/2397847317696367>

Gutierrez, K., Dicks, N., Glanzner, W. G., Agellon, L. B., & Bordignon, V. (2015). Efficacy of the porcine species in biomedical research. *Frontiers in genetics*, 6, 293. <https://doi.org/10.3389/fgene.2015.00293>

Animal Welfare Resources:

Animal Welfare Act and Regulations (USDA): <https://www.nal.usda.gov/legacy/awic/animal-welfare-act>

Guide for the Care and Use of Laboratory Animals, 8th Ed. ("The Guide"):
<https://www.ncbi.nlm.nih.gov/books/NBK54050/>

AAALAC International: <https://www.aaalac.org/>

The "3Rs": <https://nc3rs.org.uk/the-3rs>

Attachment A

How has the project been designed and operated in order to be compatible with the nature and condition of all adjacent uses and structures, and with general and specific plans for the area in question?

This proposal incorporates no alterations to the existing area at or around 1000 Sierra Point Parkway. All work will be conducted entirely inside the facility.

How will the proposed use be designed and operated in order to not be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood?

The proposed use would have no detrimental effect on the safety, comfort, or general welfare of the persons residing in the Brisbane community. All elements of this work will be contained within the facility. All scientific work within BMS is designed and conducted in compliance with local, federal, and company safety requirements under the direction of the BMS biosafety officer.

How will the proposed use be designed and operated in order to not be injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city?

The proposed use will be conducted entirely within the BMS facility, therefore, there is no risk of detrimental impact on the property or improvements in the neighborhood. The objective of all scientific work at BMS is for the ultimate improvement of human health, and seeks to improve the welfare of patients at a city level and global scale.