HAWAI'I STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

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STANDARD APPLICATION - CERTIFICATE OF NEED PROGRAM

Application Number: #23-08 (To be assigned by Agency)

Date of Receipt:

APPLICANT PROFILE

Project Title: Establishment of Positron Emission Tomography/Computer Tomography (PET-CT) Scanner Services

Project Address: 677 Ala Moana Boulevard, Suites 108 & 120, Honolulu, HI 96813

Applicant Facility/Organization: Worldwide Molecular Solutions, LLC

Name of CEO or equivalent: Ron Sancho

Title: President of Worldwide Molecular Solutions

Address: 19006 S Augusta Dr., Baton Rouge, LA 70810

Phone Number: (504)453-2464 Fax Number: _____

Contact Person for this Application: Bruce Guier

Title: Director of Worldwide Molecular Solutions

Address: 1600 Ala Moana Boulevard, Suite 2302, Honolulu, HI 96815

Phone Number: (816)210-4172 Fax Number: _____

CERTIFICATION BY APPLICANT

I hereby attest that I reviewed the application and have knowledge of the content and the information contained herein. I declare that the project described and each statement amount and supporting documentation included is true and correct to the best of my knowledge and belief.

Signature

11/22/2023
Date

Bruce Guier
Name (please type or print)

Director of WMS
Title (please type or print)

1. **TYPE OR ORGANIZATION:** (Please check all applicable)

Public	____
Private	X
Non-profit	____
For-profit	X
Individual	____
Corporation	____
Partnership	____
Limited Liability Corporation (LLC)	X
Limited Liability Partnership (LLP)	____
Other: _____	____

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2. **PROJECT LOCATION INFORMATION:**

A. Primary Service Area(s) of Project: (Please check all applicable)

Statewide:	____
O`ahu-wide:	X
Honolulu:	____
Windward O`ahu:	____
West O`ahu:	____
Maui County:	____
Kaua`i County:	____
Hawai`i County:	____

3. **DOCUMENTATION** (Please attach the following to your application form):

A. Site Control documentation (e.g., lease/purchase agreement, DROA agreement, letter of intent)
Lease agreement is contingent upon the approved CON. Final signatures will be obtained upon approval of this CON. See Attachment A-1, Letter of Intent dated 14 March 2023.

B. A listing of all other permits or approvals from other government bodies (federal, state, county) that will be required before this proposal can be implemented (such as building permit, land use permit, etc.)
Building Permits - City & County of Honolulu
Certificate of Occupancy - City & County of Honolulu
Fire Marshal's Approval - City & County of Honolulu, Fire Prevention Bureau
Department of Health Licensure as a Radiation Facility providing Radiation Services - Indoor and Radiological Health Branch Radiation Section
Nuclear Regulatory Commission Licensure

C. Your governing body: list by names, titles, and address/phone numbers
See Attachment A-2, Worldwide Molecular Solutions Governing Body.

D. If you have filed a Certification of Need Application this current calendar year, you may skip the four items listed below. All others, please provide the following:
Articles of Incorporation
- By-Laws – N/A
- Partnership Agreements – See Articles of Organization in Attachment A-3 (Articles of Incorporation).
- Tax Key Number (project's location) – 3057297 (677 Ala Moana Blvd., Honolulu, Hawaii, 96813)

4. **TYPE OF PROJECT.** This section helps our reviewers understand what type of project you are proposing. Please place an "x" in the appropriate box.

	Used Medical Equipment (over $400,000)	New/Upgraded Medical Equip. (over $1 million)	Other Capital Project (over $2 million)	Change in ownership	Change in service/ establish new service/facility	Change in Beds
Inpatient Facility						
Outpatient Facility		X	X		X	
Private Practice						

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5. **TOTAL CAPITAL COST:** $5,350,000

6. **BED CHANGES.** Please complete this chart only if your project deals with a change in your bed count and/or licensed types. Again, this chart is intended to help our reviewers understand at a glance what your project would like to accomplish. Under the heading "Type of Bed," please use only the categories listed in the certificate of need rules. **N/A**

Type of Bed	Current Bed Total	Proposed Beds for your Project	Total Combined Beds if your Project is Approved
TOTAL			

7. **CHANGE IN SERVICE.** If you are proposing a change in service, then please briefly list what services will be added/modified. Be sure to include the establishment of a new service or the addition of a new location of an existing service. Please consult Certificate of Need Rules Section 11-186-5 for the categories of services. If you are unable to determine which category best describes your project, please consult with agency staff.

New provider of PET-CT scanning services. Categories of services per Section 11-186-5, Non-Bed Services: Diagnostic Radiology, Computed Tomography Stationary and Nuclear Medicine.

8. PROJECT COSTS AND SOURCES OF FUNDS (For Capital Items Only)

A. **List All Project Costs:** **AMOUNT:**

1.	Land Acquisition	Lease
2.	Construction Contract	$2,000,000
3.	Fixed Equipment-General Electric (medical equipment supplier) (2 PET-CTs ($1,990,000), 2 Medrad injectors ($60,000))	$2,050,000
4.	Movable Equipment	None
5.	Financing Costs	$0
6.	Fair Market Value of assets acquired by lease, rent, donation, etc.	$1,300,000
7.	Other: _____	_____
	TOTAL PROJECT COST:	$5,350,000

B. **Source and Method of Estimation**

Describe how the cost estimates in Item "A" were made, including information and methods used:

Construction contract based on architectural and construction estimated by architectural firm.
Cost estimates for PET-CTs and injectors are per GE quotes.
FMV-includes PET-CT area, wait room & control room.
$650 / sqft x 2,000 sqft = $1,300,000

C. **Source of Funds** **AMOUNT:**

1.	Cash	_____
2.	State Appropriations	_____
3.	Other Grants	_____
4.	Fund Drive	_____
5.	Debt (See Attachment A-4 for Letter of Credit)	$4,050,000
6.	Other: FMV of leased space to be paid by monthly rent	$1,300,000
	TOTAL SOURCE OF FUNDS:	**$5,350,000**

9. **IMPLEMENTATION SCHEDULE:** Please present a projected time schedule for the completion of this project from start to finish. Include all of the following items that are applicable to your project:

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a) Date of site control for the proposed project – Lease agreement is contingent upon approved CON. Final signatures will be obtained upon approval of this CON. See Attachment A-1, Letter of Intent dated 14 March 2023.
b) Dates by which other government approvals/permits will be applied for and received – Upon approval of this CON, WMS will apply for other government approvals/permits, as required.
c) Dates by which financing is assured for the project – Financing is assured and immediately available.
d) Date construction will commence – 3 months after CON approval
e) Length of construction period – 15 months
f) Date of completion of the project - 18 months after CON approval
g) Date of commencement of operation – 2 years after CON approval

Please remember that the Agency does monitor the implementation of Certificates approved. Non-implementation of a project as described in your application may result in a fine and/or withdrawal of the Certificate of Need.

10. **EXECUTIVE SUMMARY:** Please present a brief summary of your project. In addition, provide a description of how your project meets each of the Certificate of Need criteria listed below. If a new location is proposed, please attach an easy to read map that shows your project site. See Attachment 5, project site map. Location of project site is the bolded outlined area.

Worldwide Molecular Solutions (herein referred to as "WMS"), seeks to provide Positron Emission Tomography/Computer Tomography (PET-CT) scanner services at 677 Ala Moana Boulevard, Suites 108 & 120, Honolulu, Hawaii 96813. WMS requests approval from the State Health Planning and Development Agency (SHPDA) to install 2 PET-CT scanners (cutting-edge 3-D imaging equipment) and associated clinical spaces. Increasing the accessibility and availability of this state-of-the-art imaging service will support bringing forward the most innovative oncology, neurology, cardiology, urology and theranostic patient services that are not available in the State of Hawai'i. It will also help supplement PET-CT scanning services for cancer treatment and diagnosis, which is currently underserved and insufficient. In addition to the improved services, state-of-the-art medical technology will bring experts and experienced medical professionals to our community. The ultimate vision of WMS is to provide patients in the State of Hawai'i the best quality of service and care available anywhere in the world.

a) Relationship to the State of Hawai'i Health Services and Facilities Plan
WMS is an organization looking to develop a Medical Center and Ancillary Services to bring state-of-the-art research, diagnosis, treatment and follow up care for oncology, cardiology, urology and neurology patients in the State of Hawai'i. Examples of how WMS meets the State of Hawai'i Health Services and Facilities Plan (HSFP) CON standards / goals as follows:

- Per 2017 Department of Energy data, there were approximately 2,500 PET-CT scanners in the USA, which equates to 133,693 persons per 1 PET-CT for a population of approximately 334 million. There are only 4 PET-CTs in the State of Hawai'i. To adequately support the diagnostic imaging needs similar to the capacity on the mainland, the State of Hawai'i would need more than ten (10) PET-CT scanners.
- The new Medical Center's two (2) cyclotrons will produce the entire gamut of diagnostic medical radioisotopes (Rp's) (there are 6 major Rp's currently available), of which only one (FDG) Rp is produced in the State of Hawai'i by a 25 year old cyclotron. When the Medical Center is in full operation, it will support the most innovative and diverse oncology, cardiology, urology, and neurology diagnostic / treatment / research medical services. In addition, theranostic trials will flourish and typically require 3 to 4 PET-CT scans. When these clinical trials commence, the need for PET-CT scans will escalate.
- The cornerstone of this project relies on producing medical isotopes that are not available in Hawai'i and then making them available to local healthcare facilities so that their patients don't have to travel to the mainland for their care. WMS intends to introduce new, unavailable medical technology and enable/enhance current systems in place. The goal is to provide the best quality care available and improve the life expectancy of patients.
- WMS expects the need for PET-CT scans to rise significantly due to generation of Rp's for neurology (e.g., Alzheimer's), urology (e.g., prostate cancer), cardiology (e.g., cardiac PET) and theranostics (clinical research trials). These services are not available today in the State of Hawai'i and are new and only possible by the new Medical Center's ability to produce the entire spectrum of Rp's (not just FDG). As subsequently explained, it is not the intent of the new Medical Center to take away the cancer diagnostic / treatment services currently provided by the healthcare facilities in the State of Hawai'i. Our intent is to enhance the quality of healthcare in Hawai'i by providing all available Rp's to healthcare facilities.
- The proposed service will greatly improve the State's diagnostic imaging capability including early detection, increase accuracy of therapy planning/decision using state-of-the-art scanning equipment, support the latest healthcare treatment options (including treatment monitoring and research related studies on cancer and other diseases) not currently available in the State of Hawai'i. Increasing the availability of this state-of-the-art imaging equipment will provide services to a greater population and support the continually growing medical advances in determining cancer care plans and coordination, reducing the wait time for establishing the effectiveness of treatments and determining subsequent treatment plans. Research findings have shown the earlier cancer is diagnosed and treated, quality of life and survival rates are significantly improved.
- WMS plans to collaborate with all hospitals in the State of Hawai'i (including the neighbor islands) by providing the option to own a part of the Medical Center. WMS' business plan is predicated upon not competing with hospitals, but rather partnering with and providing hospitals with the best technology available so they can offer the finest-quality care and treatments for all patients. By building this coalition, our center's goal is to be able to provide a full line of products at a much lower cost, making healthcare more affordable for our residents.
- Installation of 2 PET-CTs supports the State-wide Health Coordination Council's priorities by increasing and retaining the healthcare workforce to enable access to the appropriate level of care in a timely manner by improving the number of radiology professionals and support staff, and other resources. The state-of-the-art medical

technology WMS is bringing to the State of Hawai'i will lure experts and experienced medical professionals to our community. Hawai'i struggles with having too few doctors and nurses, and we are losing more each year. Bringing medical advancement and limitless research options to our islands will spark the interest of medical professionals who otherwise might find Hawai'i lacking in availability of medical equipment and care when compared to the rest of the U.S. This has become enough of a concern that Governor Josh Green is in the process of implementing new incentives and programs to attract and retain medical professionals. Bringing state-of-the-art medical technology to Hawai'i will help to attract and keep medical professionals here in our state.

- The mission of WMS is to provide a comprehensive enterprise solution for molecular imaging and theranostics for Hawai'i's clinicians and their patients. WMS intends to produce and supply the full range of Rp's to support oncology, neurology, urology and cardiology where needed across the State of Hawai'i. Our plan is unique as we seek to stabilize the Rp's supply chain while implementing state-of-the-art molecular imaging and theranostics for clinicians and their patients in Hawai'i.

b) Need and Accessibility

- WMS' service area is Oahu wide. This service will be available to any person requiring these services including low-income persons, racial and ethnic minorities, women, people with disabilities, other underserved groups, and the elderly.
- The target population includes any person who requires the highest technology for cardiology (e.g., cardiac SPECT), neurology (e.g., Amyvid for Alzheimer's) and urology (e.g., prostate cancer) medical services. These are new medical services that are not available today in the State of Hawai'i, they are only possible through the new Medical Center's ability to generate the entire spectrum of Rp's (not just FDG). The target population also includes patients who are seeking an accurate diagnosis when conventional diagnosis options prescribed in the State of Hawai'i are not definitive (i.e., does not provide conclusive evidence that a biopsy and/or surgery is required). In the near future, cancer patients will also have access to clinical trials (theranostic services) which may help improve their quality of life. When the Medical Center is in full operation, there will be other services (that are not currently available today) to improve the quality of care for neurology, urology and cardiology related patient care.
- Based on national benchmarks, the State of Hawai'i is currently underserved by PET- CT scans with rates per 1,000, approximately half (1/2) of the United States as a whole. WMS will increase the capacity of this service for the State of Hawai'i benefiting all residents, at the very minimum. Given that Hawai'i PET-CT procedures per 1,000 is significantly less than the national average is an indication that there is additional room for PET-CT unit growth with more providers needing to furnish this service in the State of Hawai'i.
- There are significant delays in receiving a PET-CT scan for patients who are newly diagnosed with cancer in the State of Hawai'i. Only 17% of Kaiser Permanente (one of the largest health plan providers in the State of Hawai'i with members totaling 266,000) received a routine PET-CT scan within the target wait time of 14 days and only 26% of members received an urgent PET-CT scan within the target wait time of 7 days.

c) Quality Criteria

- The need for PET-CT scanners is expected to grow due to technological advancements in PET imaging for oncology, advancement in diagnostic applications, and a higher demand for precision diagnostics. Per the American Cancer Society 2022 update, the estimated number

of new cancer cases in the United States is anticipated to be 1,918,030 with 290,560 new cases of breast cancer, 268,490 new prostate cancer cases and151,030 new cases of colorectum cancer cases in 2022. It is prudent to use PET-CT scanners since this imaging technology enables early detection of some cancers giving patients the best odds to beat cancer. The earlier cancer is detected, the higher the odds are of curing it before it becomes severe.

- The utilization of PET-CT scanners is becoming more common in several oncologic procedures, such as tumor staging and restaging, treatment efficacy assessment during or after treatment ends, and radiotherapy planning. This is because PET-CT scanners help patients be evaluated more accurately and effectively during the staging process and before surgery, if appropriate.

d) Cost and Finances (include revenue/cost projections for the first and third year of operation)

- WMS' plan to collaborate with all hospitals in the State of Hawai'i (including the neighbor islands) by providing the option to own a part of the Medical Center. WMS hopes to partner with other hospitals and plans to provide hospitals with the best technology available (PET-CT units are state-of-the-art) so they can offer the finest-quality care and treatments for all patients at lower costs, making healthcare more affordable for our residents.
- The benefits of PET-CT scanning are to confirm cancer cases early (PET-CT can detect potential cancer sooner than other tests provided in Hawai'i), to determine exact and accurate details on the location of the cancer and how far the cancer has spread, determine how well it's responding to treatment and improve staging of tumors. These state-of-the-art PET-CT scans will provide a better opportunity to treat cancer, particularly in the early stages, and therefore improve the quality of life for cancer patients. The overall costs would be lowered due to diagnosis / treatment being accurate, eliminating unnecessary surgeries, misdiagnosis, etc. This service will be available/accessible to all cancer patients including, but not limited to, low-income persons, racial and ethnic minorities, women, persons with disabilities, elderly, and other underserved groups.
- WMS projects that the net savings/excess funds from operations for Year 1 of the proposed project will be $1,171,643 above annual operating/internal costs of $2,668,357 and net savings/excess funds from operations for Year 3 of the proposed project will be $2,382,591 above annual operating/internal costs of $3,377,409.

e) Relationship to the Existing Health Care System

- Based on national benchmarks, the State of Hawai'i is currently underserved by PET-CT scans with rates per 1,000 approximately half (1/2) of the United States. This results in significant delays and furthermore, medical professionals and/or patients may choose less than optimal diagnostic and treatment plans. WMS will increase the capacity for this service for the State of Hawai'i to provide the best treatment care/outcomes possible and provide a full line of Rp's at a much lower cost, making healthcare more affordable for our residents.
- The predominant patient population served by the medical community in the State of Hawai'i is the elderly population (persons 65 and older). This population is the most rapidly growing segment of our population that has an increasing incidence of cancer. The proposed new PET-CT scanners will fill a gap in services and expand the accessibility to quality images, treatment, and care to these patient populations.

- The PET-CT scanner service will strengthen the research capabilities of the State. Hawai'i is a melting pot of ethnicities, which makes Hawai'i an ideal location for research trials. This will bring the newest medical Rp's to the State of Hawai'i allowing patients another option to potentially improve their treatment outcomes.
- Building critical partnerships is a key aspect to the vision of the new Medical Center and involves having all hospitals in the State of Hawai'i (including the neighbor islands) own a part of our center. Our business plan is predicated upon not competing with hospitals, but rather partnering with and providing hospitals with the best technology available so they can offer the finest-quality care and treatments for their patients. By building this coalition, our center's goal is to be able to provide a full line of products at a much lower cost, making healthcare more affordable for our Hawai'i residents.

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f) Availability of Resources

- WMS has obtained the financial resources to secure all equipment and staffing resources required for the proposed project.
- Our opportunity for recruiting is strong as this project is addressing a known gap in Hawai'i's healthcare, in addition to securing the Rp's clinical supply across Hawai'i.