F

Application for Certificate of Need

Barnes-Jewish West County Hospital Acquire Neurosurgery Robot System

Project #6089 HS

Submitted To
Missouri Health Facilities Review Committee

February 2024



NEW OR ADDITIONAL EQUIPMENT APPLICATION

Applicant's Completeness Checklist and Table of Contents

Project Name:	Project No:
Project Description:	

Done Page N/A

Description

Divider I. Application Summary:

- 1. Applicant Identification and Certification (Form MO 580-1861)
- 2. Representative Registration (From MO 580-1869)
- 3. Proposed Project Budget (Form MO 580-1863) and detail sheet with documentation of costs.

Divider II. Proposal Description:

- 1. Provide a complete detailed project description and include equipment bid quotes.
- 2. Provide a timeline of events for the project, from CON issuance through project competition.
- 3. Provide a legible city or county map showing the exact location of the project.
- 4. Define the community to be served and provide the geographic service area for the equipment.
- 5. Provide other statistics to document the size and validity of any user-defined geographic service area.
- 6. Identify specific community problems or unmet needs the proposal would address.
- 7. Provide the historical utilization for each of the past three years and utilization projections through the first three (3) **FULL** years of operation of the new equipment.
- 8. Provide the methods and assumptions used to project utilization.
- 9. Document that consumer needs and preferences have been included in planning this project and describe how consumers had an opportunity to provide input.
- 10. Provide copies of any petitions, letters of support or opposition received.
- 11. Document that providers of similar health services in the proposed service area have been notified of the application by a public notice in the local newspaper.
- 12. Document that providers of all affected facilities in the proposed service area were addressed letters regarding the application.

Divider III. Service Specific Criteria and Standards:

- 1. For new units, address the minimum annual utilization standard for the proposed geographic service area.
- 2. For any new unit where specific utilization standards are not listed, provide documentation to justify the new unit.
- 3. For additional units, document compliance with the optimal utilization standard, and if not achieved, provide documentation to justify the additional unit.
- 4. For evolving technology address the following:
 - Medical effects as described and documented in published scientific literature;
 - The degree to which the objectives of the technology have been met in practice;
 - Any side effects, contraindications or environmental exposures;
 - The relationships, if any, to existing preventive, diagnostic, therapeutic or management technologies and the effects on the existing technologies;
 - Food and Drug Administration approval;
 - The need methodology used by this proposal in order to assess efficacy and cost impact of the proposal;
 - The degree of partnership, if any, with other institutions for joint use and financing.

Divider IV. Financial Feasibility Review Criteria and Standards:

- 1. Document that sufficient financing is available by providing a letter from a financial institution or an auditor's statement indicating that sufficient funds are available.
- Provide Service-Specific Revenues and Expenses (Form MO 580-1865) projected through three (3) FULL
 years beyond project completion.
- 3. Document how patient charges are derived.
- 4. Document responsiveness to the needs of the medically indigent.

Divider I. Application Summary:

- 1. Applicant Identification and Certification (Form MO 580-1861). See attached.
- ${\it 2. Representative Registration (Form \, MO \, 580\text{-}1869)}.$

See attached.

3. Proposed Project Budget (Form MO 580-1863) and detail sheet. See attached.



APPLICANT IDENTIFICATION AND CERTIFICATION

The information provided must match the Letter of Intent for this project, without exception.				
1. Project Location (Attach additional pages as necessary to identify multiple project sites.)				
Title of Proposed Project Barnes-Jewish West County Hospadd Globus	robot s	ystem	Project Number 6089HS	
Project Address (Street/City/State/Zip Code) 12634 Olive Blvd, St. Louis, MO 63141			St. Louis	
2. Applicant Identification (Information n	must agre	e with previously submitted Letter o	of Intent.)	
List All Owner(s): (List corporate entity.)		Address (Street/City/State/Zip	c Code) T	elephone Number
Barnes-Jewish West County Hosp.	1	12634 Olive Blvd, St. Louis, MO 63	3141	314-323-1231
(List entity to be List All Operator(s): licensed or certified.)	Addres	ss (Street/City/State/Zip Code	Telepho	ne Number
Barnes-Jewish West County Hosp.		12634 Olive Blvd, St. Louis, MO 63		314-323-1231
3. Ownership (Check applicable category.)				
✓ Nonprofit Corporation ☐ Indiv	vidual	☐ City	☐ District	
☐ Partnership ☐ Corp	poratio	n 🗆 County	Other_	
4. Certification				
In submitting this project application, the ap	pplican	nt understands that:		
 (A) The review will be made as to the community need for the proposed beds or equipment in this application; (B) In determining community need, the Missouri Health Facilities Review Committee (Committee) will consider all similar beds or equipment within the service area; (C) The issuance of a Certificate of Need (CON) by the Committee depends on conformance with its Rules and CON statute; (D) A CON shall be subject to forfeiture for failure to incur an expenditure on any approved project six (6) months after the date of issuance, unless obligated or extended by the Committee for an additional six (6) months: (E) Notification will be provided to the CON Program staff if and when the project is abandoned; and (F) A CON, if issued, may not be transferred, relocated, or modified except with the consent of the Committee. 				
We certify the information and date in this a representative's signature below:	applicat	tion as accurate to the be	st of our knowledge and	d belief by our
5. Authorized Contact Person (Attach a	a Contact			
Name of Contact Person		Title		
Greg Bratcher Fax Numb Telephone Number Fax Numb	oer		, Government Relations	
314-323-1231 314-747			atcher@bjc.org	
Signature of Contact Person		Dat	e of Signature 2/22/2023	

MO 580-1861 (03/13)



REPRESENTATIVE REGISTRATION

(A registration form must be completed for each pro	ject prese	ented.)
Project Name Barnes-Jewish West County Hospadd Globus robot system	Number 6089H \$	3
(Please type or print legibly.)		
Name of Representative	Title	
Greg Bratcher	Dir., Go	ov. Relations
Firm/Corporation/Association of Representative (may be different from below, e.g., law firm, consultant, other)		Telephone Number
BJC HealthCare		314-323-1231
Address (Street/City/State/Zip Code)		
4901 Forest Park Ave, Suite 1220, MS 90-75-574, St. Louis, MO 63108		
Who's interests are being represented? (If more than one, submit a separate Representative Registration Form for e	ach.)	
Name of Individual/Agency/Corporation/Organization being Represented		Telephone Number
BJC HealthCare		314-323-1231
Address (Street/City/State/Zip Code)		
4901 Forest Park Ave, Suite 1220, MS 90-75-574, St. Louis, MO 63108		
Check one. Do you: Relati	onship t	o Project:
✓ Support	None	
	🗹 Emp	loyee
\square Neutral	Lega	l Counsel
	Cons	sultant
	Lobb	pyist
Other Information:	Othe	er (explain):
I attest that to the best of my belief and knowledge the testimony me is truthful, represents factual information, and is in compliant which says: Any person who is paid either as part of his normal esupport or oppose any project before the health facilities review concluding to chapter 105 RSMo, and shall also register with facilities review committee for every project in which such person hundred whether such person supports or opposes the named project. The the names and addresses of any person, firm, corporation or associated registering represents in relation to the named project. Any person subsection shall be subject to the penalties specified in § 105.478,	ce with { mployme nmittee s h the sta as an in registrat viation th violatin	§197.326.1 RSMo ent or as a lobbyist to shall register as a iff of the health terest and indicate ion shall also include tat the person

MO 580-1869 (11/01)



PROPOSED PROJECT BUDGET

<u>Descrip</u>	<u>otion</u>	<u>Dollars</u>
COSTS	:*	Fill in every line, even if the amount is "\$0".)
1.	New Construction Costs ***	
2.	Renovation Costs ***	
3.	Subtotal Construction Costs (#1 plus #2)	<u>\$0</u>
4.	Architectural/Engineering Fees	
5.	Other Equipment (not in construction contract)	
6.	Major Medical Equipment	\$2,400,000
7.	Land Acquisition Costs ***	
8.	Consultants' Fees/Legal Fees ***	
9.	Interest During Construction (net of interest earned	d) ***
10.	Other Costs ***	
11.	Subtotal Non-Construction Costs (sum of #4 thro	ough #10 \$2,400,000
12.	Total Project Development Costs (#3 plus #11)	\$2,400,000 **
FINAN	CING:	
13.	Unrestricted Funds	\$2,400,000
14.	Bonds	
15.	Loans	
16.	Other Methods (specify)	
17.	Total Project Financing (sum of #13 through #16)	\$2,400,000 **
18.	New Construction Total Square Footage	
19.	New Construction Costs Per Square Foot *****	
20.	Renovated Space Total Square Footage	
21.	Renovated Space Costs Per Square Foot ******	

^{*} Attach additional page(s) detailing how each line item was determined, including all methods and assumptions used. Provide documentation of all major costs.

^{**} These amounts should be the same.

^{***} Capitalizable items to be recognized as capital expenditures after project completion.

^{****} Include as Other Costs the following: other costs of financing; the value of existing lands, buildings and equipment not previously used for health care services, such as a renovated house converted to residential care, determined by original cost, fair market value, or appraised value; or the fair market value of any leased equipment or building, or the cost of beds to be purchased.

^{*****} Divide new construction costs by total new construction square footage.

^{*****} Divide renovation costs by total renovation square footage.

Divider II. Proposal Description:

1. Provide a complete detailed project description.

Barnes-Jewish West County Hospital seeks to acquire a specialized robotic system to be used in neurosurgery. That system is the Globus surgical system.



The Globus system is used to more precisely place medical devices that stabilize the spine, e.g., medical screws and rods. The system is comprised of an innovative intraoperative imaging device that can perform the functions of fluoroscopy and CT scanning, along with a robotic arm that is guided by the imaging system.

Medical images from diagnostic visits are imported into the Globus system and are used to generate a surgical plan. In the operating room, the two components of the Globus system work together to direct the robotic arm to a specific region of the spine. The surgeon uses a pathway plotted by the system to place screws or rods with a refined degree of accuracy, using instruments guided by the surgeon and aided by the system's imaging system.

Throughout the procedure, the surgical instruments and implants are continuously displayed on the screen for the surgeon to monitor. This gives live feedback during a procedure.

In traditional spine surgery, there is a possibility for screw placement to be suboptimal. In a clinical study, the Globus system resulted in optimal placement of

the surgical screws 99% of the time, and as importantly, did not require any patients be returned to surgery to modify a screw placement. ¹

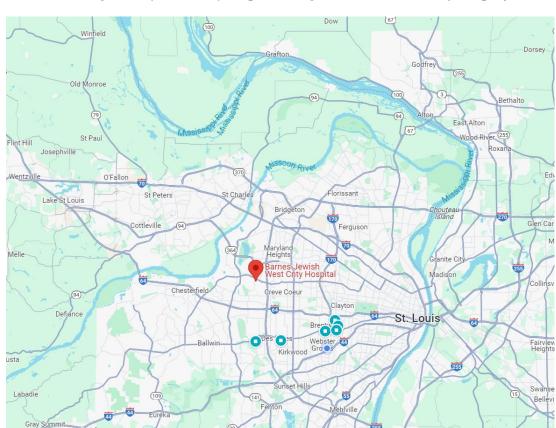
The estimated total cost of the replacement project is \$2,400,000. It is expected to be operational by early October.

2. Provide a timeline of events for the project, from CON issuance through project competition.

Provided a CON is issued, this estimated timeline should follow:

Order system	If approved, later in May
Machine arrival and testing	Late May
First patient	Late May

¹ Huntsman, K.T., Ahrendtsen, L.A., Riggleman, J.R. et al. Robotic-assisted navigated minimally invasive pedicle screw placement in the first 100 cases at a single institution. J Robotic Surg 14, 199–203 (2020). https://doi.org/10.1007/s11701-019-00959-6



3. Provide a legible city or county map showing the exact location of the project.

4. Define the community to be serve and provide the geographic service area.

High Ridge

Barnes-Jewish West County Hospital offers a full continuum of medical and surgical services, including heart, cancer, gastrointestinal, orthopedic, advanced therapies, and wound and pain management services. As a sister site to Barnes-Jewish Hospital, it offers care provided by the world-recognized physicians at the Washington University School of Medicine.

Barnes-Jewish West County Hospital considers metropolitan St. Louis to be its primary service area for its general acute-care services. The following table reflects an estimate of the metro service area population from the State of Missouri, as required by CON rules:

County	2025 Total Co. Pop.	2025 65+ Co. Pop
Crawford	22,797	5,154
Franklin	106,645	21,530
Jefferson	228,389	40,939
St. Charles	432,828	78,620
St. Louis	990,180	202,698
St. Louis City	277,256	45,114
Total	2,058,095	394,055

5. Provide other statistics to document the size and validity of any user-defined geographic service area.

Barnes-Jewish West County Hospital is uniquely situated in the center of St. Louis County. The service area provided is the same as that used in previous CON applications submitted by the hospital for its general acute-care services.

6. Identify specific community problems or unmet needs the proposal would address.

Providing advanced care beyond the confines of Barnes-Jewish Hospital is one of the overarching goals of this project. Implementing this program will offer advanced minimally invasive spine surgery in a community setting. Offering this service will increase access to the St. Louis metropolitan region and its community members.

7. Provide historical utilization for each of the past three years and utilization projections through the first three years of operation of the new equipment.

The system will be a new technology at Barnes-Jewish West County Hospital. The following is the projected utilization after the system is operational:

	2025	2026	2027	2028
# of UNITS	1	1	1	1
AMT OF UTILIZATION*	96	99	102	105

8. Provide the methods and assumptions used to project utilization.

Combining the expertise from Barnes-Jewish Hospital and Barnes-Jewish West County Hospital, Washington University School of Medicine, and the Globus company, estimates were made using the hospital's neurology cases as a base.

9. Document that consumer needs and preferences have been included in planning this project and describe how consumers had an opportunity to provide input.

Barnes-Jewish West County Hospital has a board comprised of community and business leaders. This group's counsel has been solicited and many of their ideas have been incorporated into components of the project. Furthermore, as is a standard process throughout BJC, departmental planning teams incorporate feedback from doctors and patient-care staff, who are on the frontlines and aggregate the needs and preferences of patients.

10. Provide copies of any petitions, letters of support or opposition received.

Letters will be provided as they become available.

11. Document that providers have been notified of the application by a public notice in the local newspaper.

A public notice seeking comment has been published in the *St. Louis Post-Dispatch* and was also posted to the paper's website.

12. Document that providers of all affected facilities were addressed letters regarding the application.

Sent via separate email is a folder with an Excel file showing the list of recipients of this notice and a copy of the "sent" receipt for each recipient. The text of the notice is included in the receipts.

Divider III. Community Need Criteria and Standards:

1. For new units address the need formula for the proposed geographic service area.

NA

2. For new units, address the minimum annual utilization standard for the proposed geographic service area.

NA

3. For any new unit where specific need and utilization standards are not listed provide the methodology for determining need.

NA

4. For additional units, document compliance with the optimal utilization standard, and if not achieved, provide documentation to justify the additional unit.

NA

- 5. For evolving technology address the following:
- Medical effects as described and documented in published scientific literature

As mentioned in the project description, this hyperspecialized system combining advanced imaging and robotic technology increases precision in the placement of surgical screws and stabilizing rods in spinal surgery. The project description summarized one study showing that the Globus system resulted in optimal placement of surgical screws 99% of the time and did not require any patients be returned to surgery to modify a screw placement.

- The degree to which the objectives of the technology have been met in practice

The company has over 230 product launches to date. The technology has proven to be effective.

- Any side effects, contraindications, or environmental exposures

On the contrary, the Globus system reduces the side effects seen in traditional spinal surgeries.

- The relationships, if any, to existing preventive, diagnostic, therapeutic or management technologies and the effects on the existing technologies

This is a specialized system used for spinal surgery. Other than using the word "robotic," it is really unrelated to systems like the DaVinci robot.

- Food and Drug Administration approval

The Globus Excelsius3D system was FDA approved in 2021.

- The need methodology used by this proposal in order to assess the efficacy and cost impact of the proposal; and

Clinicians extensively reviewed the technology with the company and reviewed studies and other data.

- The degree of partnership, if any, with other institutions for joint use and financing.

Washington University School of Medicine physicians have helped evaluate the technology and will often use the technology at its sister facility, Barnes-Jewish West County Hospital.

Divider IV. Financial Feasibility Review Criteria & Standards:

1. Document that sufficient financing is available by providing a letter from a financial institution or an auditor's statement indicating that sufficient funds are available.

Audited statements were recently submitted.

2. Provide Service-Specific Revenues and Expenses (Form MO 580-1865) projected through three (3) years beyond project completion.

See attached financial forms.

3. Document how patient charges were derived.

Charges, in general, are arrived at by determining the reasonable and customary unit charge for delivering a given procedure through routine market checks of pricing at other facilities and comparing the expected unit cost using a cost accounting package tailored specifically for hospitals. Finally, annual inflation adjustments are made, usually averaging 2% to 3%.

4. Document responsiveness to the needs of the medically indigent.

BJC is one of the largest providers of charity care, unreimbursed care, and community benefits in the state of Missouri, offering the community over \$900 million in care and services. BJC hospitals have a long-standing policy of providing charity care and reduced-fee care to those in need. This policy will continue.

The hospital offers financial counseling for all patients to ensure adequate coverage is obtained. For patients who are indigent, our financial counselors assist these families in obtaining Medicaid assistance. If financial assistance is not attainable, charity care may be extended as appropriate. The hospital financial assistance guidelines are based on family size and income relative to the US poverty level guidelines. Each case is reviewed on an individual basis.

Although community benefit is often measured by the value of current programs, BJC's contributions also sustain the future of health care by investing in the education of health professionals. BJC invested more than \$220 million in educating nurses, doctors, therapists, pharmacists, and medical technologists in 2021.

BJC and its hospitals and health service organizations impact countless lives daily with programs that bring health and wellness resources into schools, neighborhoods, workplaces, houses of worship, and wherever neighbors gather. During 2021, BJC organizations contributed \$19 million to community health and wellness programs throughout metropolitan St. Louis and southern Illinois. These programs provided almost half a million individual services to children, adults, and seniors.

SERVICE-SPECIFIC REVENUES AND EXPENSES

Project Title: BJWC Globus Project #: 6089

Historical Financial Data for Latest Three Full Years plus Projections Through Three Full Years Beyond Project Completion

Use an individual form for each affected service with a		Year	
sufficient number of copies of this form to cover entire period, and fill in the years in the appropriate blanks.	2024	2025	2026
Amount of Utilization:*	92	96	99
Revenue:			
Average Charge**	\$62,789	\$65,928	\$69,224
Gross Revenue	\$5,776,588	\$6,329,088	\$6,853,176
Revenue Deductions	3,621,006	4,012,348	4,392,403
Operating Revenue	2,155,582	2,316,740	2,460,773
Other Revenue	0	0	0
TOTAL REVENUE	\$2,155,582	\$2,316,740	\$2,460,773
Expenses:			
Direct Expenses			
Salaries	970,455	1,043,028	1,107,892
Fees	0	0	0
Supplies	0	0	0
Other	0	175,000	175,000
TOTAL DIRECT	\$970,455	\$1,218,028	\$1,282,892
Indirect Expenses			
Depreciation	371,429	371,429	371,429
Interest***	0	0_	0
Rent/Lease	0	0	0
Overhead****	0	0	0
TOTAL INDIRECT	\$371,429	\$371,429	\$371,429
TOTAL EXPENSES	\$1,341,884	\$1,589,457	\$1,654,321
NET INCOME (LOSS):	\$813,698	\$727,283	\$806,452

^{*}Utilization will be measured in "patient days" for licensed beds, "procedures" for equipment, or other appropriate units of measure specific to the service affected.

^{**}Indicate how the average charge/procedure was calculated.

^{***}Only on long term debt, not construction.

^{****}Indicate how overhead was calculated.

SERVICE-SPECIFIC REVENUES AND EXPENSES

Project Title: BJWC Globus Project #: 6089

Historical Financial Data for Latest Three Full Years plus Projections Through Three Full Years Beyond Project Completion

Use an individual form for each affected service with a		Year	
sufficient number of copies of this form to cover entire period, and fill in the years in the appropriate blanks.	2027	20??	20??
Amount of Utilization:*	102	0	0
Revenue:			
Average Charge**	\$72,686	\$0	\$0
Gross Revenue	\$7,413,972	\$0	\$0
Revenue Deductions	4,802,489		0
Operating Revenue	2,611,483	0	0
Other Revenue	0	0	0
TOTAL REVENUE	\$2,611,483	<u>\$0</u>	<u>\$0</u>
Expenses:			
Direct Expenses			
Salaries	1,175,708	0	0
Fees	0	0	0
Supplies	0	0	0
Other	175,000		
TOTAL DIRECT	\$1,350,708	\$0	\$0
Indirect Expenses			
Depreciation	371,429		
Interest***	0	0	0
Rent/Lease	0	0	0
Overhead****	0		0
TOTAL INDIRECT	\$371,429	\$0	\$0
TOTAL EXPENSES	\$1,722,137	<u>\$0</u>	<u>\$0</u>
NET INCOME (LOSS):	\$889,346	<u>\$0</u>	<u>\$0</u>

^{*}Utilization will be measured in "patient days" for licensed beds, "procedures" for equipment, or other appropriate units of measure specific to the service affected.

^{**}Indicate how the average charge/procedure was calculated.

^{***}Only on long term debt, not construction.

^{****}Indicate how overhead was calculated.



(610) 930-1800 QUOTE

Quote Information

Quote ID	GMQT-072423-1	
Quote Date	07/24/2023	
Expiration Date	12/31/2023	
Regional Sales Manager	Britteni Rice	
Phone Number	720-485-1190	
Email	brice@globusmedical.com	

Customer Information

Customer Name	BJC West
Customer ID	
City	St Louis
State	MO
Contact Name	
Telephone	

Items

Capital		
Set/Part Number	Description	Qty
6143.2103	Fixture, Fluoro Navigation, 12 in	1
9143.9001	End Effector, GPS	4
6143.1001	System, EXCELSIUS GPS, 120V	1
9143.9016	Articulating Arm I, GPS	2
999.905	ExcelsiusGPS - Interbody Solutions Software Module	1
999.893	ExcelsiusGPS - Spine Software Module	1
999.894	ExcelsiusGPS - Fluoroscopy Software Module	1
Capital E3D		
Set/Part Number	Description	Qty
6161.1000	Excelsius3D	1
Navigation Instruments		
Set/Part Number	Description	Qty
6143.2546	Intra-Op CT Registration Fixture Pivoting Arm	1
9143.9017	Navigation II, GPS	2
9143.9002	Navigation, GPS	4
6143.2545	Intra-Op CT Registration Fixture	1
nstrument Sets		
Set Number	Description	Qty
9143.9020	RISE-L & ELSA, GPS	2
9143.9679	CREO Optimized Set, GPS	4
9143.9018	Lateral Disc Prep, GPS	2
9143.9008	SI-LOK, GPS	2
9143.9019	Posterior Disc Prep, GPS	2
9143.9009	Ellipse & Quartex, GPS	2
Power Items		
Set Number	Description	Qty
9143.9013	Power System, GPS Instrument Set	4
9205.9002	Power System Charger & Batteries Set	4
Freight		
Part Number	Description	Qty
999.892	ExcelsiusGPS - US Shipping	1
Service		
Part Number	Description	Qty

Service				CON #6089 page 16
Part Number	Description			Qty
999.870	Excelsius3D - 1 Year Warranty			1
999.890	ExcelsiusGPS - 1 Year Warranty			1
Quote Summary				
			Total List Price	\$ 2,928,268.00
			Total Discounted Value	\$ (439,650.60)
			Discounted Subtotal	\$ 2,488,617.40
			Additional Discount	\$ (88,617.40)
			Total Package Price	\$ 2,400,000.00
Extended Service				
Set/Part Number	Description	Qty	Unit Price	Total Price
999.048	Excelsius3D – 1 Year Service Contract	5	\$ 80,000.00	\$ 400,000.00
999.891	ExcelsiusGPS - 1 Year Service Contract	5	\$ 95,000.00	\$ 475,000.00

Terms and Conditions

Pricing valid through the Expiration Date stated above. This quotation sets forth the pricing offered by Globus but does not constitute a contract for sale. Final purchase and terms of sale shall be exclusively governed by Globus' Sales License and Service Agreement. Prices quoted are exclusive of all sales, use, excise, gross receipts, or other federal, state, or local taxes or other assessments as well as any export and import duties and associated fees, if applicable.