NEW MEDICAL TECHNOLOGY & DEVICE REQUEST FORM





A medical device is defined by the FDA as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or is intended to affect the structure or any function of the body; and does not achieve its primary intended purposes through chemical action within or on the body; and is not dependent upon being metabolized for the achievement of this primary intended propose(s).

Note: Computer software may fall under this definition of device.

Please Check the Technology/Equipment/Device Request Type

| Evaluation: | Start Date: | Technology/Equipn | nent/Device For Patient Research | |
|--|-------------|---|--|--|
| Intended purchase/Loan of new technology/ equipment/device | | Intended to reprocess a supply labeled for single use | | |
| Complete the applicable sections of the form, obtain approval (electronic or hardcopy) and route with accompanying literature to: Health Plan of San Joaquin UM Department Your request will be routed for internal processing. You will be notified by e-mail, fax or letter once the request has been registered. | | | | |
| Section A: Request Information | | | | |
| Date of Request: | | equestor Name: | | |
| Department: | | Date use of technology/equipment/device to begin: | | |
| | | Estimated End Date: | | |
| Box #: | Phone #: | Fax #: | Email: | |
| Section B: Technology/Equipment/Device Information | | | | |
| Proposed use of the technology/equipment/device (choose one): Clinical Research | | | | |
| Product Name: | | | Model/Catalog #: Not Applicable, Investigational Device | |
| Manufacturer: | | | | |
| Vendor/Sponsor: | | Vendor/Sponsor Pho | Vendor/Sponsor Phone #: | |

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| Section B: Technology/Equipment/Device Information | (Cont.) | | | |
|--|---|--|--|--|
| Packaging Unit (e.g., box, case, pack) Not Applicable, Investigational Device | | | | |
| Briefly describe the intended clinical/research use of the tech | nology/equipment/device: | | | |
| Describe other required components/accessories as applicab | le: | | | |
| Section C: FDA and Other Regulatory Information | | | | |
| Is this technology/equipment/device FDA approved for the intended use? Yes No | | | | |
| If no, is a letter on file from the manufacturer/sponsor stating | FDA status? Yes <i>(send copy with request)</i> No Not Applicable, Investigational Device | | | |
| Is this an FDA trackable device (e.g., implant, tissue, etc.)? | Yes No | | | |
| Is this technology/equipment/device wireless? Yes (Freque | ency:) No | | | |
| Section D: Impact to Patient Care And Operations | | | | |
| Will the requested technology/equipment/device supplemen performing the same function? Yes No If yes, please list product(s): | t current in-house products/devices now | | | |
| Where will technology/equipment/device be primarily used? Hospital, Specify: | | | | |
| Clinic, Specify: Other, Sp | ecify: | | | |
| What other departments/services will use and/or be affected its accessories? | by the technology/equipment/device or | | | |
| What procedures will be performed with this technology/equ | ipment/device? (Be as specific as possible) | | | |
| What is the anticipated reimbursement for this technology/eddollar amounts. Not Applicable, Investigational Device | quipment/device? Provide codes and | | | |
| What effect will this technology/equipment/device have to in (e.g., costs reductions)? Not Applicable, Investigational Device | nprove patient care, patient safety, and/or other | | | |
| Section E: Please Send Supporting Documentation or L | iterature Review References | | | |
| Requestor Name: | Title: | | | |
| Signature: | Date: | | | |