OFFICE USE ONLY CRC Project#_ Date Rec'd _

CRC REQUEST FOR SERVICES FORM (BUDGET/COS)

| Protocol Title: | |
|--------------------|--|
| Funding Source(| s): |
| ClinicalTrials.gov | NCT: |
| IRB Number: | IRB Expiration date: |
| Project PI: | eRA Commons ID: |
| PI Department: | PI Phone Number: |
| PI Email Address | : |
| Co-Investigators | : |
| Project MD: | |
| Study Coordinat | or: |
| Coordinator Pho | ne: Coordinator Email: |
| | ceeived a scientific review? (check all that apply) ages Adults ages Elderly ages |
| Inpatien | : (If protocol specifies hospitalization, admission at UF Health Shands). |
| | Please contact Theresa O'Connell at oconta@shands.ufl.edu to request COS |
| Outpatie | nt—CRC (CTRB) visits, contact April Braxton at abraxton@ufl.edu to request COS and Budget |
| FOR INPA | ATIENT STUDIES: |
| Subjects | are hospitalized on: _ different occasions for: _ day(s) per admission (Cost of service includes 24 hour stay with nursing services and meals) |
| CRC will | provide research nursing coverage (scatter-bed) between 7AM-5PM to perform: |
| | or: hours per day |
| FOR OUT | PATIENT STUDIES: |
| Subjects | are seen every for hours per visit for visits. |
| Subject v | isit(s): Regular CRC Hours (0700-1700) Extended hours (1700-2400) Overnight (1700-0700) |
| Choose r | ursing services for extended and overnight stays: |

| 3. | The length of the study | for each participa | ant is _ months | | | |
|----|---|---------------------|-----------------------|-------------------------|-----------------------|----------------|
| 4. | The anticipated duration | n of study from th | ne first consented p | participant to the fina | al participant's last | visit is: |
| | _ months | | | | | |
| 5. | Participant accrual start | date: | | | | |
| 6. | Participant accrual end | date: | | | | |
| 7. | The anticipated start da | te: | | | | |
| 8. | This study is a: single | e site study | multi center s | tudy with _ site | S | |
| | | the coordinating | | | | |
| | Total | number of subje | ects to be enrolled a | at UF: _ | | |
| | | | CTSI PROJECTE | D UTILIZATION | | |
| | Study Type: | | | Category: | | |
| | Year | 2020 | 2021 | 2022 | 2023 | 2024 |
| | Target subject enrollment # | | | | | |
| | # Outpatient days per year | | | | | |
| | # Inpatient days per year | | | | | |
| 7. | NURSING SERVICES - se | rvices that nursir | ng staff should per | form (check all that | apply): | |
| | | (single blood dra | - | ` | ,, | |
| | Insertion of he | eparin lock (multi | ple blood draws w | ithin a visit) | | |
| | Monitoring of | vital signs | | | | |
| | Administratio | n of research dru | g: oral | IV infus | sion | other: _ |
| | Administratio | n of IV fluids: | as flu | ush post drug infusio | on in addition | on to infusion |
| | Timed blood o | lraws /PK sampliı | ng/blood draws mo | ore than once within | a visit | |
| | Urine Collection | on | once | serial | 24 hour | |
| | Saliva Collecti | on | once | serial | 24 hour | |
| | ECG | | once | serial | 24 hour | |
| | BMR | | 0.100 | 55.14. | | |
| | BodPod | | | | | |
| | Conscious sed | ation for (proced | lure) _ | | | |
| | Assistance wit | :h procedure(s) sp | pecify | | | |
| | Glucose moni | toring once | e seria | I | | |
| | Other (specify |): <u>-</u> | | | | |
| 8. | INVESTIGATIONAL DRU (Please contact IDS@shands | • | | • | | |
| | Research Prot | ocol involves Inv | estigational Drug | | | |
| | Emergency m | eds anticipated | | | | |
| | Routine meds | required (include | es premeds, meds | to treat anticipated i | reactions) | |
| | Spec | ify | | | | |
| | Performing Co | onscious Sedation | ı | | | |
| | Need local and | esthetics for a pro | ocedure | | _ | |

STUDY MEDICATION

9.

List all drugs in named in protocol and source (e.g. supplied by sponsor, NIH, cooperative group, purchase from pharmacy by investigator or departmental funds, billed to third party payer or subject's insurance)

| | Drug | Source |
|-----|--|--|
| | | |
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| | | |
| | | |
| 9. | NUTRITIONAL SERVICES: (check all that | apply) |
| | Controlled meal (foods weighe | d) |
| | Modified meal (foods not weig | hed) |
| | Regular meal (Frozen Entrée, S | nack and Drink) |
| | Regular CRC snacks (crackers & | juices) |
| | Daily nutrient intake calculation | าร |
| | Food record analyses | |
| | 24-hr food recalls | |
| | Nutrition assessment | |
| | Nutrition education/ Diet teach | ning Nutrition |
| | Data Management | |
| | Other (specify) | |
| 10. | UF CRC CORE LAB SERVICES (check all th | at apply) |
| | Lab manual for this study is ava | ailable and will be provided |
| | Simple specimen Processing La | boratory (Spin, separate & transfer to aliquot) |
| | Use of additives, incubation or | any other complex sample processing |
| | Urine HCG/pregnancy testing | |
| | Other test(s) with study supplie | ed testing equipment (specify) |
| | Send specimen for Shands Lab | analysis (Set-up R99 @ <u>LabCustomerService@shands.ufl.edu</u>) |
| | Shipping from CRC to | |
| | | FedEx picks up daily between 1530 – 1630). Dry ice can be of use. Please indicate amount in lbs. and date needed and |

| | Lab Tests | Kits Provided? | Analysis done at | Same day shipping? |
|---------|----------------------------------|--|------------------------------|------------------------------|
| Example | СВС | No | Shands | N/A |
| Example | Drug Level | Yes | Central Lab | Yes |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| RESEARO | CH COORDINATOR SE | RVICES: | | |
| | Research Coordinat | | k for weeks | months |
| | | | Entire study durati | ion |
| EQUIPM | Use CRC equipment Specify equ | only (no nursing assistance in a specific control of the control o | · | tood plaase contact Nurse M |
| | for approval) | it to CKC (Storage or equipm | ent within CKC is not guaran | teed, please contact Nurse M |
| | Specify eq | uipment and size _ | | |
| | | | | |
| ADDITIO | NAL REQUIRED DOC | UMENTS: Please click the lin | ks below to attach required | document files: |
| Add | attachments | Please add the most c | urrent protocol for this s | study. |
| Add | Attachments | Please add the most c | urrent Draft ICF for this | sstudy. |
| | Attachments | | urrent PI CV for the stu | 1 77 |