| **HealthONE Research Study Build Submission Form**  **PLEASE NOTE: To initiate a new study build, please first call x4400 and have the Call Center enter a ticket for your new study. Enter the ticket number in the appropriate place on the form below. Next, complete this form (with your ticket number included) and email it to** [HealthOneResearch@uchc.edu](mailto:HealthOneResearch@uchc.edu)  **All fields marked with \*\* are REQUIRED before form will be processed** | |
| --- | --- |
| ***Question*** | ***Response*** |
| HealthONE Call Center (HCC) Ticket #**\*\*** |  |
| Study Name (or short title)\*\* |  |
| Short Title/Acronym (Health**ONE** Display)\*\* |  |
| IRB number\*\* [Must be provided as soon as available] |  |
| Principal Investigator\*\* |  |
| Primary research coordinator\*\* |  |
| Backup research coordinator(s) |  |
| PI Department/Specialty\*\* |  |
| NCT# (National Clinicaltrials.gov number  For pharmaceutical trials, please contact your sponsor or CRO. You can also reference [www.clinicaltrials.gov](http://www.clinicaltrials.gov) |  |
| IND?\*\* | Yes (IND# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) No |
| IDE?\*\* | Yes (IDE# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) No |
| Study design (if appropriate) |  |
| Funding Source and Sponsor\*\* [Pharmaceutical, NIH, etc.] |  |
| **Space Requirements** | |
| Outpatient/Inpatient? (please check) | Outpatient [ ]  Inpatient [ ]  Both [ ] |
| If **outpatient**, please indicate whether or not the study has procured approved, dedicated research space to conduct their research visits | Yes (indicate physical location/dept here):  No (may require operational discussions): |
| If **outpatient**, please indicate how many total outpatient research visits will occur |  |
| If **inpatient**, please indicate whether or not the study has procured approved, dedicated hospital space to conduct their overnight research visits | Yes (indicate physical location/dept/unit here):  No (may require operational discussions): |
| If **inpatient**, please indicate the length of the patient’s hospital stay | \_\_\_\_\_\_\_\_\_\_ Nights  \_\_\_\_\_\_\_\_\_\_\_ Days |
| Will the study require the use of the CT Clinical Research Center (CRC) (Space needs only) | Yes No |
| **Laboratory Requirements** | |
| Will all labs be processed and run through JDH? | Yes No |
| If **NO**, please include central (alternative) lab details here: | Central (alternative) lab requirements: |
| Do lab results require anonymization (cannot be identified in medical record) (***REQUIRES OVPR REVIEW AND SIGNATURE***)?\*\* | Yes No  Please provide justification for leaving lab results out of Health**ONE**: |
| If anonymized, should laboratory results be faxed? | Faxed |
| Please provide ATTN TO: and FAX NUMBER. | ATTN TO: Fax #: |
| **Pharmacy Requirements** | |
| Requires investigational drug/agent?\*\* | Yes No |
| Drug Supplier (if applicable) | Investigational Commercial |
| Drug NDC (if applicable) |  |
| Requested research drug display name(s) in *HealthONE\*\**  If blinded, consider adding “placebo” to drug name. Ex: Etanercept/Placebo |  |
| Active research drug name(s) if appropriate |  |
| Drug strength(s)\*\* |  |
| Drug dose(s)\*\* |  |
| Drug route(s)\*\* |  |
| Drug frequency(ies)\*\* |  |
| Administration instructions (high level)\*\*  OR ATTACH IRB PHARMACY REVIEW WITH THIS APPLICATION |  |
| Drug infusion duration/rate if appropriate |  |
| J Code  J codes are a subset of the HCPCS Level II code set used to primarily identify injectable drugs. A J code may cover the supply, injection or infusion of a drug or biological.  HCPCS J codes typically includes drugs that cannot self-administered, are reasonable and necessary for the treatment of the injury or illness and considered effective by the FDA, among other requirements. Drugs dispensed to a patient and immunizations are likely not covered by a J code.. <http://hcpcscodes.org/jcodes> |  |
| **Imaging Requirements** | |
| Requires research-related imaging procedures?\*\* | Yes No |
| IF ***YES***, PLEASE COMPLETE QUESTIONS 16a – 16d AS APPROPRIATE (\*\* REQUIRED) | |
| Are the procedures funded by the sponsor or considered part of conventional care (SOC)? | Sponsor Conventional Care |
| Are results allowed to be in the legal medical record? | Yes No |
| Are images going to be read at UConn or by a central agency? \*If NO, please complete question below – 16d) | Yes, UConn No, Central agency |
| Are results required to be de-identified prior to being sent to central agency for interpretation? | Yes No |
| **Cancer Center Involvement** | |
| Is this study cancer-related or being conducted in the Cancer Center? | Yes No  WILL REQUIRE ***PRE-BUILD*** MEETING WITH STUDY STAFF IF YES |
| **END OF FORM** | |

Submitted By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Submission: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Anticipated Patient Recruitment Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**HEALTHONE STAFF ONLY (BELOW):**

|  |  |  |
| --- | --- | --- |
| HealthONE Research Analyst: | HealthONE Beaker Analyst: | HealthONE Willow Analyst: |
| Health**ONE** Radiant Analyst: | Health**ONE** Orders Analyst: | Health**ONE** HB/HIM Analyst: |
| Health**ONE** Cadence Analyst: | Dr. Wesley Byerly (OVPR) (if required): | |
| FootPrints and CM Ticket Numbers: |  | |