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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **INSTRUCTIONS** | | | | | | | | | | |
| For all new research studies that require CTO review and approval, please complete and submit this form with copies of the study protocol, informed consent form, clinical trial agreement and budget to the Clinical Trials Office (CTO) at UMCSN. Please note that this form is required in addition to the existing UMCSN IRB requirements. The CTO, separate from the IRB, uses the information you report herein to evaluate the following:   * Whether the study is a Qualifying Clinical Trial based on billing compliance regulations? * Whether or not procedures, items, or services will be conducted at a UMCSN facility (regardless of whether they are considered “routine care” or “research” related)?   + For procedures conducted at UMCSN, the CTO will document a coverage analysis and logistics review to ensure the research can be properly supported. * What impact those services may have on UMCSN from a billing compliance, regulatory, and financial perspective? | | | | | | | | | | |
| Principal Investigator Information | | | | | | | | | | | |
| Name: | | | | Office Number: | | | | | Cell Number: | | |
| Address:       City:       State: NV Zip: | | | | | | | | | | | |
| Primary email: | | | | | | Secondary email: | | | | | |
| UMC Employee:  Y  N | | UMC Contract Employee:  Y  N | | | | | UMC Privileged only:  Y  N | | | | |
| If not a UMC employee, provide the name of employer: | | | | | | | | | | | |
| Clinical Research Coordinator Information | | | | | | | | | | | |
| Name: | | | | Office Number: | | | | | Cell Number: | | |
| Primary email: | | | | | | | | | | | |
| Study Team Information | | | | | | | | | | | |
| Study Personnel Name | | | | | Role in Research | | | | | UMCSN Employee | |
|  | | | | |  | | | | | Y  N | |
|  | | | | |  | | | | | Y  N | |
|  | | | | |  | | | | | Y  N | |
|  | | | | |  | | | | | Y  N | |
|  | | | | |  | | | | | Y  N | |
|  | | | | |  | | | | | Y  N | |
|  | | | | |  | | | | | Y  N | |
| Study Location(s)  Check all that apply | | | | | | | | | | | |
| University Medical Center of Southern Nevada  University Medical Center of Southern Nevada affiliated site, please name location:  Other location, please name location: | | | | | | | | | | | |
| Study Information | Length of Study:       Months or       Years | | | | | | | | | | |
| Study Sponsor: | | | | | | | | | | | |
| Protocol Title: | | | | | | | | | | | |
| Short Title/ Acronym: | | | | Protocol Version and Date: | | | | | | | |
| IRB#: | | | | ClinicalTrials.gov (NCT)#: | | | | | | | |
| PI Initiated:  Y  N:  Y  N | | | | Inpatient  Outpatient  Combination | | | | | | | |
| Drug or Device Information (check all that apply) | | | | | | | | | | | |
| Drug Study:  Y  N  N/A IND#: | | | IND Exempt?:  Y  N  N/A | | | | | IND Holder: | | | |
| Device Study:  Y  N  N/A IDE#: | | |  | | | | | | | | |

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| Check whether the research involves any of the following: | |
|  | Use of a UMCSN facility to perform procedures/services on subject *If so, complete and submit* ***Appendix A****: Procedures Performed at UMCSN Facility* |
|  | Humanitarian Use Device (HUD), Please refer to SOP #CTO HUD/HED 1005.1 |

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| Appendix A:  Procedures Performed at UMCSN Facility | | | |
| List all:  Procedures/Services/Tests to be performed at a UMCSN Facility | | | |
| Service/Test Name: | Routine Care (RC) or Research (R) | UMCSN Site: | CPT Code (if known) |
|  | RC  R |  |  |
|  | RC  R |  |  |
|  | RC  R |  |  |
|  | RC  R |  |  |
|  | RC  R |  |  |
|  | RC  R |  |  |
|  | RC  R |  |  |
|  | RC  R |  |  |
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