**University Medical Center of Southern Nevada Clinical Trials Office Required Review Worksheet**

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| WORKSHEET: UMCSN Clinical Trials Office Required Review Questionnaire |
| Full Protocol Title: |       |
| Protocol Number: |       |
| UMC IRB #: |       |
| Principle Investigator Name: |       |

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| The purpose of this worksheet is to provide support for Principal Investigators in making determinations when there is uncertainty regarding a research opportunity that may requires UMC Clinical Trials Office Review and Approval. A copy of this worksheet must be retained by the principal investigator and submitted to the UMC CTO. |
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| **The attached Decision Tree should be utilized as an aid in making a determination** |
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| Yes | No | Questions |
| [ ]  | [ ]  | 1) Is the research being conducted at University Medical Center of Southern Nevada or any University Medical Center of Southern Nevada Facility or Affiliate? |
| [ ]  | [ ]  | 2) Does the study involve human subjects? If yes, what is the UMC IRB#?       |
| [ ]  | [ ]  | 3) Does the study consist ONLY of survey activities, chart review or creation of a Limited Data Set? |
| [ ]  | [ ]  | 4) Are there any costs to UMCSN in the conduct of the study (e.g., lab, pathology, medical records, UMCSN staff effort)? |
| [ ]  | [ ]  | 5) Does the study involve any technical fees for any interventions, drug, device, items, services or procedures that generate a CPT or CDM code where services are rendered at a UMC facility? |
| [ ]  | [ ]  | 6) Does the study involve any professional fees or activities *associated* with any interventions, drug, device, items, services or procedures that generate a CPT code on a UMC bill? |

* UMC Clinical Trial Office review and approval is required if the responses are "Yes" to any one or all of Questions #4, #5, and/or #6.
* UMC Clinical Trials Office review and approval is NOT required if responses are "No" to ALL of Questions #4, #5, and #6.

I attest that the responses regarding the above reference protocol are true and UMC CTO review and approval are not required. Should the conduct of the protocol change to include costs to UMC and/or generate technical or professional fees associated to research I will submit the required CTO submission form and associated documents.

Principal Investigator Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Does your study require CTO review?**

