# University Medical Center of Southern Nevada (UMC) CLINICAL TRIALS office

# Research Patient Enrollment Notification, Patient Identification, & Tracking

SOP # CTO - 1003.1

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| **Original Date** | **Review Dates** | **Revision Dates** |
| 3/2015 | 3/2015 | TBD |

**POLICY**

1. Policy Purpose
2. The purpose of this policy is to outline the process by which University Medical Center of Southern Nevada (UMC) Clinical Trials Office (CTO) tracks research participant’s visits. The procedures that follow address research patient enrollment notification, patient identification, and tracking.
3. This process begins after the research participant has signed the Informed Consent Form.
4. This process ends when the participant completes all study related procedures and all charges have been entered into the billing system and adjudicated.
5. Policy Statements
6. Principal Investigator or designee, must notify the CTO that a patient has been consented by submitting the Research Patient Notification Form with 24 hours.
7. Research participants are registered in the Research Participant Log.
8. Research participant will be flagged in the billing system as clinical trial participant, including the associate IRB and NCT number.
9. Principal Investigator or designee, must notify the CTO of each corresponding visit (name and date) by submitting the Research Patient Billing form with 24 hours of the study visit.
10. Research participant study visits are registered in the Research Participant Log.
11. Principal Investigator or designee, must notify the CTO when the research participant is off study by completing and submitting the Research Patient Off-Study form once the participant is no longer receiving study related items or services that require UMCSN resources.
12. Research participant off-study date will be recorded in the Research Participant Log.

**DEFINITIONS**

Research Patient Log

Research Patient Notification Form

Research Patient Billing Form

Research Patient Off-Study Form

**PROCEDURE/GUIDELINE**

**Research Patient Notification, Identification and Tracking**

1. After the research participant signs the informed consent form, the Principal Investigator (PI) or their designee performs the following tasks:
   1. Completes the Research Patient Notification Form (RPNF) with the following information:
      1. Research Information Section
         1. IRB Number
         2. Protocol Number
         3. Principal Investigator
         4. NCT Number
      2. Patient Information Section
         1. Patient Name
         2. Date of Birth
         3. Medical Record Number
         4. Service Location
         5. Enrollment Date
         6. Study Visit Name and Date
      3. Visit Information Section
         1. Item/Service Name
         2. CPT Code
         3. Routine Care, or
         4. Research
   2. Emails the completed Research Patient On-Study Form and a copy of the signed Informed Consent to the CTO within 24 hours of participant’s consent.
2. Upon receipt and review of the RPNF, the CTO
   1. enters the following information from the RPNF into the Research Participant Log:
      1. Study Name/ID
      2. Participant Name
      3. Medical Record Number
      4. Date of Birth
      5. Principal Investigator
      6. NCT Number
      7. IRB Number
      8. Study Start Date
3. For every corresponding research visit the Principal Investigator (PI) or their designee will submit a Research Billing Form (RBF) to the CTO within 24 hours of the research visit.
   * 1. Research Information Section
        1. IRB Number
        2. Protocol Number
        3. Principal Investigator
        4. NCT Number
     2. Patient Information Section
        1. Patient Name
        2. Date of Birth
        3. Medical Record Number
        4. Service Location
        5. Enrollment Date
        6. Study Visit Name and Date
     3. Visit Information Section
        1. Item/Service Name
        2. CPT Code
        3. Routine Care, or
        4. Research
4. Upon receipt and review of the RBF, the CTO enters the following information from the RPNF into the Research Participant Log:
   1. Study Visit Name and Date
   2. Item/Service Name
   3. CPT Code
   4. Routine Care, or
   5. Research
5. After the research participant completes all study related items and services that require UMCSN resources, the CTO considers the participant off study. The PI or their designee performs the following tasks:
6. Completes the RPNF Research Participant Off Study Information
7. Emails or faxes the RPNF to the CTO.
8. Upon receipt and review of the RPNF, the CTO updates the “Study ‘Flag’ Stop Date” and the “Date of Last Service” in the Research Participant Database.

**Visit Tracking**

**ATTACHMENTS**

Research Patient Notification Form

Research Patient Billing Form

Research Patient Off-Study Form

Visit Log

**FOR MORE INFORMATION CONTACT**

Director, Clinical Trials Office

**APPROVAL BODIES**

Clinical Trials Office

# KEYWORDS

Clinical Research

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| **Research Information** | |
| IRB Number |  |
| Protocol Number |  |
| Principal Investigator Name |  |
| National Clinical Trial Number |  |

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| --- | --- |
| **Patient Information** | |
| Patient Name |  |
| Date of Birth |  |
| Patient MRN |  |
| Service Location | UMC Hospital  UMC Facility  Non-Affiliated UMC Facility |
| Enrollment Date (On-Study) |  |
| Study Visit and Date | Visit Name:       Date: |

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| **Visit Information** | | | |
| Item/Service Name | CPT Code | Routine Care Required per Protocol | Research item billed to study |
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This form must be provided electronically to the Clinical Trials Office via [research@umcsn.com](mailto:research@umcsn.com) within 24 hours of patient consent and must include a copy of the signed informed consent. The study team is responsible for notifying the Clinical Trials Office of each corresponding research visit and date utilizing the Research Billing Form.

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| **UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA:** |  |
| Consented by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

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|  | UMC CTO Research Billing Form | |
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| **Research Information** | |
| IRB Number |  |
| Protocol Number |  |
| Principal Investigator Name |  |
| National Clinical Trial Number |  |

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| **Patient Information** | |
| Patient Name |  |
| Date of Birth |  |
| Patient MRN |  |
| Service Location | UMC Hospital  UMC Facility  Non-Affiliated UMC Facility |
| Study Visit and Date | Visit Name:       Date: |

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| **Visit Information** | | | |
| Item/Service Name | CPT Code | Routine Care Required per Protocol | Research item billed to study |
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This form must be provided electronically to the Clinical Trials Office via [research@umcsn.com](mailto:research@umcsn.com) within 24 hours of each patient corresponding study visits. The study team is responsible for notifying the Clinical Trials Office of each corresponding research visit and date.

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| **UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA:** |  |
| Submitted by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

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|  | UMC CTO Patient Off-Study Form | |
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| **Research Information** | |
| IRB Number |  |
| Protocol Number |  |
| Principal Investigator Name |  |
| National Clinical Trial Number |  |

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| **Patient Information** | |
| Patient Name |  |
| Date of Birth |  |
| Patient MRN |  |
| Off-Study/Discharge Date |  |
| Off-Study Reason | Study Completed  Early Term  Death/Drop/Withdrawal **Date:**  Patient Discharged from UMC (*billing for research activities at UMC has ceased*) |

This form must be provided electronically to the Clinical Trials Office via [research@umcsn.com](mailto:research@umcsn.com) within 24 hours of patient off-study and/or discharged from UMC. By submitting the UMC CTO Off-Study Form the Principal Investigator or designee attest that all billable items/services and costs to UMC have concluded for the above referenced research participant for the above referenced clinical trial.

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| **UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA:** |  |
| Submitted by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |