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

# Research Approval Policy

SOP # CTO - 1001.1

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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 research studies at University Medical Center of Southern Nevada (UMCSN) are approved via the Clinical Trials Office (CTO) and IRB. The procedures that follow address this dual approval process.
3. This process begins when a new clinical trial opportunity becomes available to a PI.
4. This process ends when the CTO and IRB have sent a letter of approved or not approved to the PI.
5. Policy Statements
6. Investigator must submit approval forms to the CTO and the IRB.
7. The investigator should also include a copy of the protocol, informed consent, Clinical Trial Agreement and budget with the approval form. *(See CTO Approval Form)*

**PROCEDURE/GUIDELINE**

**Research Approval – Clinical Trials Office**

1. After receiving a new clinical trial opportunity, the PI/study team reviews the trial to determine their level of interest in participating.
2. If interested, the PI/study team completes the CTO approval form.
3. Submit CTO approval form.
4. Submit additional information as required, including the protocol, informed consent, Clinical Trial Agreement and study budget.
5. The CTO reviews the application materials received from the PI. The CTO will either
6. Approve the trial (CTO will send an approval notification to the PI);.
7. The CTO may request additional information from the PI; or
8. The CTO may not approve the trial (CTO will notify the PI the study is not approved).

**Research Approval – IRB**

A. After receiving a new clinical trial opportunity, the PI/study team reviews the trial to determine their level of interest in participating.

B. If interested, the PI/study team completes the IRB approval form.

1. Submit IRB approval form.
2. Submit additional information as required.
3. The IRB reviews the application materials received from the PI. The IRB meets monthly. The IRB will either
4. Approve the trial (IRB will send an approval notification to the PI);
5. The IRB may request additional information from the PI; or
6. The IRB may not approve the trial (IRB will notify the PI the study is not approved).

**ATTACHMENTS**

Research Approval Form

**FOR MORE INFORMATION CONTACT**

Director, Clinical Trials Office

**APPROVAL BODIES**

Office of Research

# KEYWORDS

Clinical Research