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| CTN-POL-019 | AUTHORIZATION FOR PROTOCOL INITIATION | Date Approved: April 2001 |
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A. Introduction

There are a series of requirements that a CTP needs to meet before starting the study plan or protocol. These requirements are indicated in the particular protocol or study plan and by the Node Principal Investigator (PI).

B. Purpose

This policy indicates the procedure for authorizing protocol or study plan initiation at a CTP.

C. Policy

1. The Node PI (or designee) will confirm that the CTP is prepared and will approve to start the protocol or study plan.
2. The protocol Lead Investigator (LI) will approve the CTP to start the protocol or study plan.
3. NIDA will approve the CTP to start the protocol or study plan.
4. All three: Node PI, LI and NIDA will have to concur that a CTP is ready to start and will sign the endorsement form (Appendix A).
5. If there is disagreement between the three, then the Operations Committee will make recommendations to the Steering Committee, who in turn will make a decision.

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Protocol Initiation Endorsement

Protocol #/Name: NIDA-CTN _____/_____

CTP Code/Name: _____/_____

Node Code/Name: _____/_____

Node Principal Investigator

As the Node Principal Investigator (or designee), I confirm that the CTP named above has completed all the required elements for this protocol/study plan and authorize to start the study at this site.

Signature of Principal Investigator or Designee Date
Name _____

Lead Investigator

As the Lead Investigator (or designee) for the protocol/study plan named above, I authorize study initiation at this CTP.

Signature of LI or designee Date
Name _____

NIDA

As NIDA representative, I authorize study initiation at this CTP

Signature Date
Name _____

Once a CTP is authorized by the PI, LI and NIDA to start a protocol; this document is to be returned to the Lead Investigator.