
POLICIES & PROCEDURES

Category: Policy

Title: **Policy for Oncology Clinical Trials**

Department(s):SKCC

1 Definitions

CRO	Clinical Research Organization
PSU	Protocol Support Unit
SKCC	Sidney Kimmel Cancer Center
SOP	Standardized Operating Procedures
TJU	Thomas Jefferson University

2 Introduction

The purpose of this policy is to ensure that all oncology clinical research trials at Thomas Jefferson University are executed using the SKCC Clinical Research Organization's SOPs.

3 Responsible Personnel

All Jefferson Faculty and Staff

4 Procedures

- I. All oncology clinical research studies will be conducted following the SKCC policies and CRO SOPs in addition to all FDA regulations, ICH-GCP guidelines, State laws and Institutional policy.
 - a. This includes all oncology trials whose objective, aim, eligibility or outcome is pre-cancer or cancer-related.
 - b. SKCC CRO PSU will manage all oncology IND/IDE s held by Thomas Jefferson Investigators.

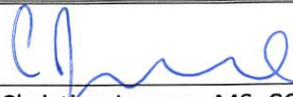
5 References

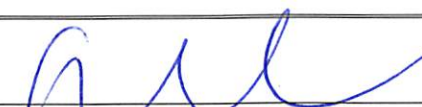
- I. SKCC CRO Document Library
- II. SKCC Study Determination

6 Document History

Version	Effective Date	Description of Change
1.1	11-8-17	Minor administrative
2.0	09-30-2019	IND/IDE addition


7 Approval

Author's Signature  Date of Signature 10/07/19
Christine Jerome, MS ,CCRP
Director of QIU

CRO Executive Director Approval  Date of Signature 10/7/19
Sylvia O'Neill, MD

Does this document require review and approval from the SKCC Associate Director of Clinical Research?

Yes No Initials SO

SKCC Associate Director of Clinical Research Approval  Date of Signature 10/7/19
W. Kevin Kelly, DO

Does this document require review and approval from the SKCC Director or Deputy Director?

Yes No Initials 

SKCC Director/Deputy Director Approval  Date of Signature 10/10/19
Karen Knudsen, PhD/Neal Flomenberg, MD