

REGULATORY SUPPORT SYSTEM FLOWSHEET

WHO

All sites participating in NCI-supported clinical trials

The Cancer Trials Support Unit (CTSU) Regulatory Office is the central document intake and storage facility for all regulatory documents that are required for the participation in NCI-sponsored clinical trials.



WHY

The Regulatory Support System (RSS) database at the CTSU Regulatory Office has been designed to track regulatory compliance in an effort to reduce the administrative and regulatory burden on the Lead Protocol Organizations, permitting them to focus on the science of conducting clinical trials.



WHAT

- RSS contains required regulatory documents for **ALL** NCI-supported clinical trials.
- Documents to be submitted for **ALL** trials collected in RSS include:
 - **Initial IRB approvals**
 - **IRB-approved consent forms (*when mandated*)**
 - **Continuing review approvals**
 - **Amendment / Revision approvals (*when mandated*)**
 - **Protocol-specific regulatory requirements**



WHEN

It is encouraged that all regulatory documents be submitted to the CTSU Regulatory Office as soon as possible.



WHERE

CTSU Regulatory Office
 1818 Market Street, Suite 1100
 Philadelphia, PA 19103
 Fax: 215-569-0206
 Email: CTSURegulatory@ctsu.cocccg.org



REQUIRED DOCUMENTS

It is recommended that the following be included in each regulatory documentation submission to the CTSU:

1. CTSU IRB Transmittal Sheet
2. CTSU IRB Certification Form
 - **Protocol Number and Version Date (*when mandated*)**
 - **Protocol Title (*partial or short version acceptable*)**
 - **Institution Name and NCI Institution Code**
 - **Name of Principal Investigator and NCI Investigator Number**
 - **Required by the IRB: Review Type, Approval Type, Date of Approval, IRB Number, Expiration Date and Signature of IRB Official**



Helpful Tools can be found on the Regulatory Tab of the CTSU website (www.ctsu.org)

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| <ul style="list-style-type: none"> • Frequently Asked Questions • Optional Form 1: Withdrawal for Protocol Participation • CTSU Site Addition Form | <ul style="list-style-type: none"> • CTSU IRB Certification Form • CTSU IRB Transmittal Sheet • Guidance Document for Regulatory Forms |
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For more information, call the CTSU Help Desk at 888-823-5923 or the Regulatory Help Desk at 866-651-CTSU