



Regulatory Considerations for the CALGB Principal Investigator

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Overview

- General responsibilities of the PI
 - Adverse event reporting
 - Study drugs
 - Regulatory requirements
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General Responsibilities of the PI

- The PI is responsible for the conduct of CALGB activities, including the integrity of all data submitted by the main member and affiliates.
 - Since the “unit of membership” in CALGB is the institution, the PI is responsible to ensure that the institution meets its obligations.
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Responsibilities of the PI

- Adherence to the protocol
 - Assure that other investigators, sub-investigators also adhere to the protocol
 - Oversee preparation and submission of protocols for IRB approval
 - Oversee informed consent process
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Responsibilities of the PI

- Oversee preparation and submission of adverse event reports
 - In trials involving industry collaboration, refer any requests for information to the Central Office. Communication with industry is generally only needed for issues related to drug shipment.
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Adverse Event Reporting

- Routine reporting: AE forms are part of every treatment study. They should be completed with every cycle of treatment. More frequent submission of AE forms may be required if toxicity monitoring is specified in the protocol.
 - Expedited reporting: Serious and unexpected events are reported in an expedited manner via AdEERS (Adverse Event Expedited Reporting System).
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Considerations for the Submission of an Adverse Event Report

- The CRA can prepare the report for submission and submit electronic reports.
 - The treating physician is responsible for the content and must review the report
 - Assure that the correct (accurate) term for the event has been selected
 - Assess the severity of the event and its attribution to study drugs, disease, other meds, co-existing conditions
 - Compliance with timelines for submission
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Study Drugs

- For drugs from NCI, the ordering physician (not necessarily the PI) must have a current 1572, NCI registration, and Financial Disclosure Form on file with NCI/RSS.
 - The person completing the order must be the ordering physician or the physician's (pre-specified) ordering designee.
 - The shipping address should be at the site where the patient is to be treated.
 - Affiliates should do their own ordering.
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Study Drugs

- Satellites are “branches” of the primary site, not affiliates.
 - If satellites are far away, drug should be shipped to them directly. Investigators can only receive drug at one address, so if all of the investigators are registered at the primary site, drug can't be shipped to the satellite.
 - Shipment requirements for drugs coming from pharma are qualitatively similar - they may be less restrictive.
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Study Drugs

- Never use a study drug outside the protocol.
 - Never charge for a study drug that is provided free from NCI or pharmaceutical company.
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Regulatory Requirements

- Regulatory requirements (documents that must be submitted before patients can be enrolled) are specified in most protocols.
 - Specific requirements (e.g. certifications) vary according to the IND holder and the manufacturer.
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Regulatory Requirements

- For any study, IRB approval must be documented before a patient can be enrolled in a study.
 - If an affiliate has their own IRB, that approval must be documented before the affiliate can enroll patients.
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