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FOR CLINICAL TRIALS IN ONCOLOGY

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Pearls of Wisdom: IRB Review

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IRB REVIEW

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IRB REVIEW

CTMB Guideline 4.4

The institution is responsible for ensuring that all relevant materials are available for review at the time of the audit.

IRB documents, copies of the locally utilized informed consent forms, other regulatory documentation, if applicable.

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IRB REVIEW

Alliance Policy 2.8.7.1

Assessing Audit Findings

An audit consists of reviewing and evaluating:

Conformance to IRB and informed consent content requirements

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IRB REVIEW

CTMB Guidelines 5.2

Review of IRB Documentation and Informed Consent Content

5.2.1 IRB For each protocol selected for an audit, the following documents should be the minimum items to be reviewed:

Full Initial IRB approval **AND** Annual re-approval

Approval (or disapproval) of protocol amendments that affects more than minimal risk

Documentation of IRB approval or re-approval prior to patient registration

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IRB REVIEW PROBLEM # 1

IRB REGULATORY RECORDS

- Incomplete
- Difficult to track
- CIRB regulatory records not available

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ORGANIZE!

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PEARL: ORGANIZE!

- Keep protocols AND documents separated

- Create a separate folder / dividers

Initial Approval

Continuing Reviews

Amendment Approvals

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PEARL: ORGANIZE

TIP!

FLAG AND FILE As You Go!

<u>DON'T WAIT</u> for a notice of an audit.

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PEARL: ORGANIZE

TIP!

FLAG AND FILE As You Go!

FLAG and FILE each approval when it is received!

For automated systems (Local and CIRB): **PRINT, FLAG and FILE** immediately!

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PEARL: ORGANIZE

TIP!

On each FLAG write the following information

- Initial Approval/ Amendment/ Continuing Review
- IRB Approval/Acknowledgement Date
- Protocol Version Date (if applicable)

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PEARL: ORGANIZE

TIP!

ALTERNATIVELY

Use the flagging system **WITH** a legend/log accessible in the front of the binder to identify IRB Correspondence

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PEARL: ORGANIZE

REMEMBER!

CIRB: IRB of Record

Per CTMB Guidelines 5.2

The following will need to be on file for review

- Approval letter from the CIRB noting the local IRB accepts CIRB as the IRB of record
- All CIRB approval documents
- The study specific worksheet with local context

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IRB REVIEW PROBLEM # 2

LATE SUBMISSIONS TO IRB

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IRB REVIEW PROBLEM # 2

LATE SUBMISSIONS TO IRB

CTMB Guideline 5.2.1

Amendments (addendums or updates) must be approved by the IRB of record within 90 days of the Group's notification

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DOCUMENT TRACKING

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PEARL: DOCUMENT TRACKING

Conduct An Internal Audit of Protocol Document Submissions Monthly / Quarterly

Keep a Running List of Required Approvals / Deadlines

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PEARL: DOCUMENT TRACKING

For automated systems / databases

Create a report in your local database that can run tracking reports

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PEARL: DOCUMENT TRACKING

TIP!

Highlight pertinent information for easy review/tracking

- Approval types
- Approval deadlines
- Review type

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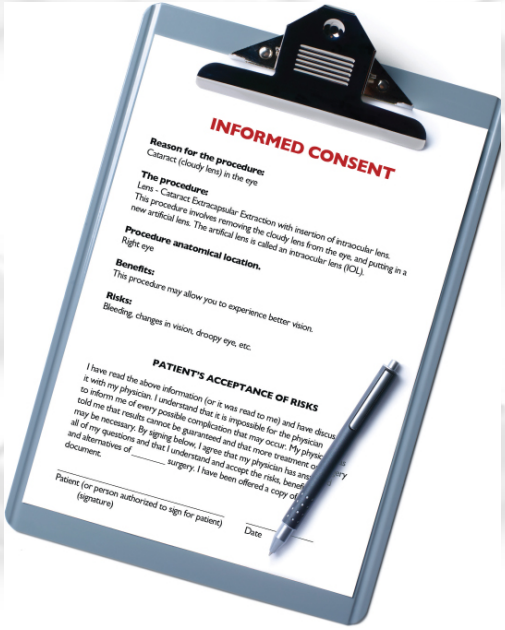
IRB REVIEW

INFORMED CONSENT CONTENT



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INFORMED CONSENT CONTENT

CTMB Guidelines 5.2.2

Each of the informed consent documents selected for audit must be reviewed to ensure they contain the risks and alternatives listed in the model informed consent document approved by the NCI.

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INFORMED CONSENT CONTENT

Informed Consent Content (ICC) Review
(Table B)

	ICC Deficiency Descriptions
Required Elements per the Federal Regulations	Involves research: purposes; duration of participation; description of procedures; identification of experimental procedures
	Description of risks or discomforts
	Description of any benefits to subject or others
	Disclosure of alternative procedures or treatments
	Description of the extent of confidentiality of records
	Explanation regarding compensation and/or whether treatments are available if injury occurs
	Was there an explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject?
	Participation is voluntary; refusal to participate involves no penalty; subject may discontinue participation at any time
	Unforeseeable risks to subject, embryo or fetus
	Circumstances in which subject's participation may be terminated by investigator without subject's consent
	Additional costs to subject which may result from participation in research
	Consequences of subject withdrawal and procedures for orderly termination of participation by subject
	Statement that new findings which may relate to subject's willingness to continue participation will be provided to subject
	Disclosure of approximate number of participants
	Statement stating: "A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."
	Statement that a copy of the consent will be given to study participant

http://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Appendix_2.pdf

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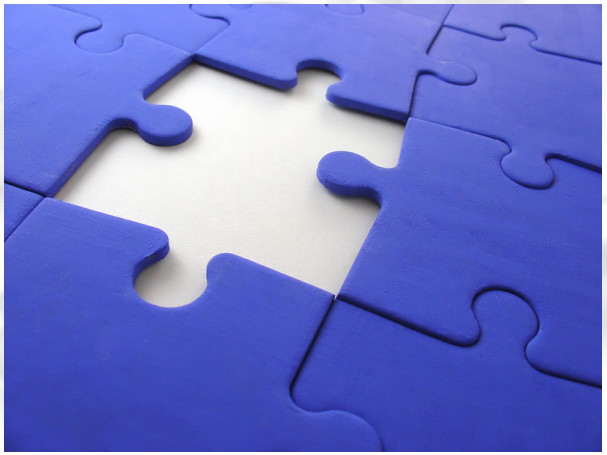
INFORMED CONSENT CONTENT PROBLEM

LOCAL CONSENT MISSING REQUIRED ELEMENTS



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INFORMED CONSENT CONTENT PROBLEM

Local Consent Missing Required Elements

- Omitted Risks or Discomforts
- Missing Statement of Unforeseeable Risks
- Omitted / Changed Alterative Treatments
- Missing Statement that new findings will be discussed
- Omitted study correlative / study companion questions

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Duplicate Model Consent!

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PEARL: Duplicate Model Consent!

- Maintain the order and format of the Model Consent
- Add specific institution information **<u>After</u>** ensuring Model Consent format is in tact

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PEARL: Duplicate Model Consent!

- **Do NOT Omit** Risks
- **Do Not Change** Alternatives to Participation
- **Discourage** your IRB from rearranging the order of the study specific sample questions

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PEARL: Duplicate Model Consent!

If CIRB is the IRB of Record

The Local Consent should match the Model **word for word**

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PEARL: Duplicate Model Consent!

TIP!

Cut and Paste from the Model

Double check that adding……
does not omit

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PEARL: Duplicate Model Consent!

REMEMBER!

If local IRB requires changes obtain Lead Center / Sponsor Approval

FIRST

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PEARL: Duplicate Model Consent!

Alliance Policy 2.8.7.2.2

Any substantive changes of information concerning risks or alternative procedures and/or translational research contained in the model informed consent document must be justified in writing by the Investigator. Investigators must forward copies of such changes, with their justifications, to the Alliance regulatory staff for review

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PEARL: Duplicate Model Consent!

REMEMBER!

- Maintain a copy of Sponsor approved changes in the IRB binder
- If CIRB is the IRB of record the study specific
- worksheet with local context will need to be on file for review

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Pearls of Wisdom: IRB Review

Please save questions for the panel at the end of the presentations.

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