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Pearls of Wisdom: IRB Review

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IRB REVIEW

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CTMB Guideline 4.4

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

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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.

IRB REVIEW



Alliance Policy 2.8.7.1

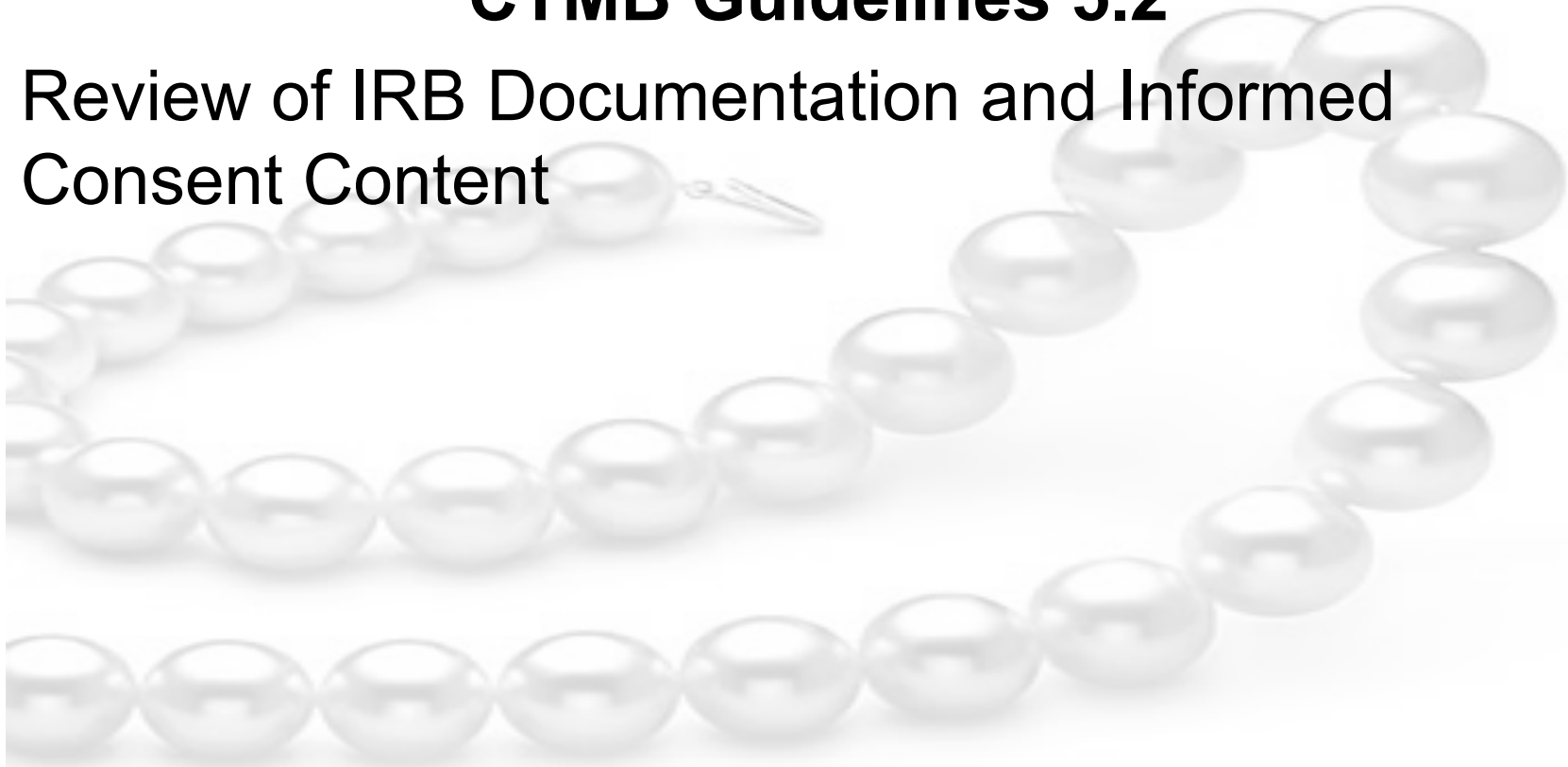
Assessing Audit Findings

An audit consists of reviewing and evaluating:
Conformance to IRB and informed consent
content requirements

IRB REVIEW

CTMB Guidelines 5.2

Review of IRB Documentation and Informed Consent Content



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:

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

IRB REVIEW PROBLEM # 1

IRB REGULATORY RECORDS



IRB REVIEW PROBLEM # 1

IRB REGULATORY RECORDS

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



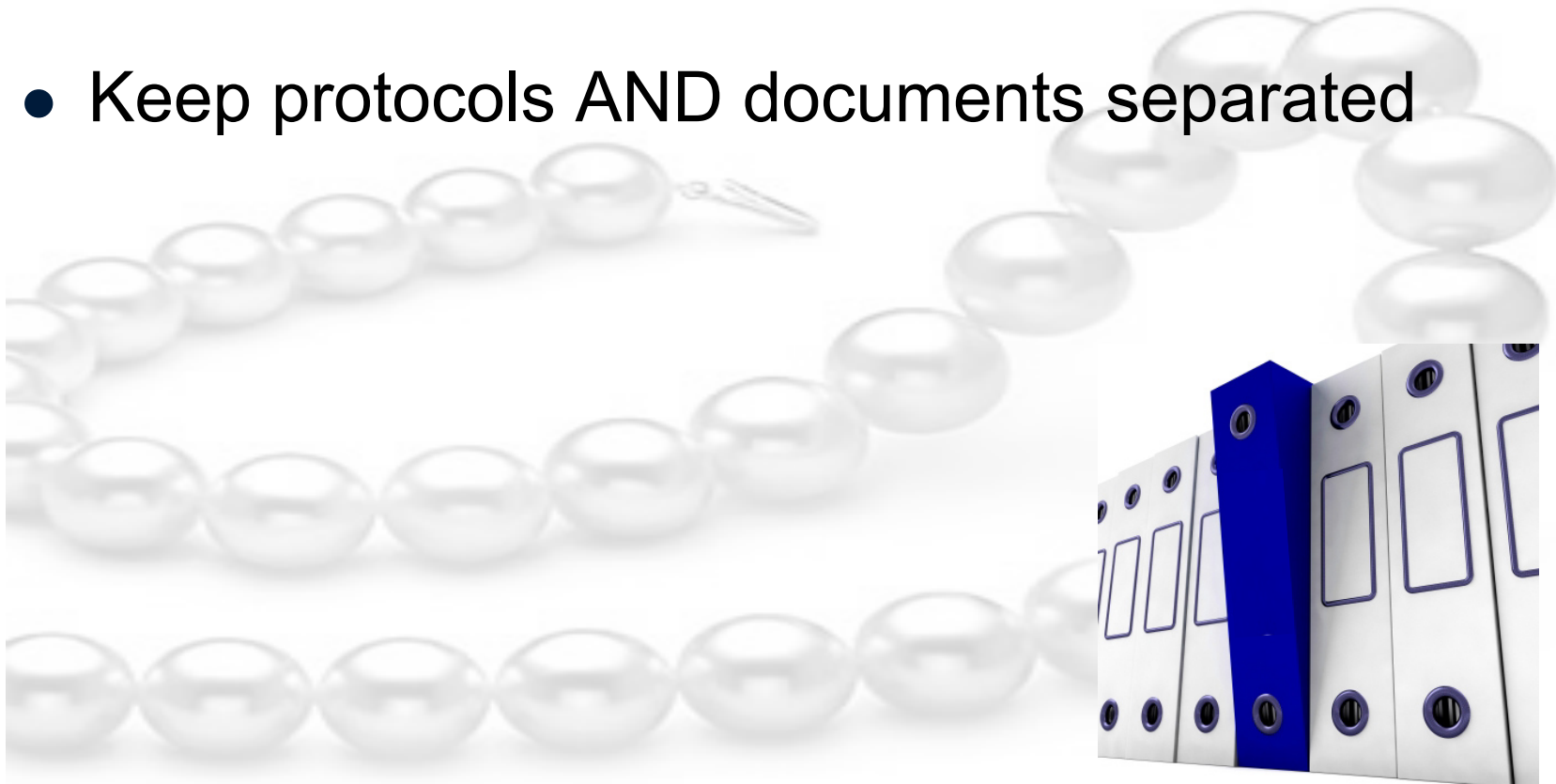
PEARL

A necklace of pearls is shown against a white background. The necklace is composed of many small, round, white pearls. In the center of the necklace, the word "ORGANIZE!" is written in a large, bold, dark blue font. The necklace is arranged in a loose, circular shape, with the word "ORGANIZE!" positioned in the middle of the loop. The pearls are highly reflective, showing bright highlights and soft shadows.

ORGANIZE!

PEARL: ORGANIZE!

- Keep protocols AND documents separated



PEARL: ORGANIZE!

- Keep protocols AND documents separated
- Create a separate folder / dividers



PEARL: ORGANIZE!

- Keep protocols AND documents separated

- Create a separate folder / dividers

Initial Approval

Continuing Reviews

Amendment Approvals



PEARL: ORGANIZE

TIP!



FLAG AND FILE As You Go!

DON'T WAIT for a notice of an audit.

PEARL: ORGANIZE

TIP!



FLAG AND FILE As You Go!

FLAG and FILE each approval when it is received!

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!

PEARL: ORGANIZE

TIP!

On each FLAG write the following information

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

PEARL: ORGANIZE

TIP!

ALTERNATIVELY

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

PEARL: ORGANIZE

REMEMBER!

CIRB: IRB of Record

Per CTMB Guidelines 5.2

The following will need to be on file for review

PEARL: ORGANIZE

REMEMBER!

CIRB: IRB of Record

Per CTMB Guidelines 5.2

The following will need to be on file for review

- _____
- _____
- _____

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

A pearl necklace is shown against a white background. The necklace consists of several white pearls and one brown pearl. The text "CRP PEARL" is overlaid in the center of the necklace.

CRP PEARL

IRB REVIEW PROBLEM # 2

LATE SUBMISSIONS TO IRB



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



PEARL

DOCUMENT TRACKING



PEARL: DOCUMENT TRACKING

Conduct An Internal Audit of Protocol Document Submissions Monthly / Quarterly

Keep a Running List of Required Approvals / Deadlines



PEARL: DOCUMENT TRACKING

For automated systems / databases

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



PEARL: DOCUMENT TRACKING

TIP!

Highlight pertinent information
for easy review/tracking

Approval types

Approval deadlines

Review type

A pearl necklace is shown against a white background. The necklace consists of several white pearls and one prominent brown pearl. The text "CRP PEARL" is overlaid in large, bold, black capital letters across the center of the necklace.

CRP PEARL

IRB REVIEW

INFORMED CONSENT CONTENT



INFORMED CONSENT

Reason for the procedure:
Cataract (cloudy lens) in the eye

The procedure:
Lens - Cataract Extracapsular Extraction with insertion of intraocular lens.
This procedure involves removing the cloudy lens from the eye and putting in a new artificial lens. The artificial lens is called an intraocular lens (IOL).

Procedure anatomical location:
Right eye

Benefits:
The procedure may allow you to experience better vision.

Risks:
Bleeding, changes in vision, droopy eye, etc.

PATIENT'S ACCEPTANCE OF RISKS
I have read the above information (or it was read to me) and have discussed it with my physician. I understand that it is impossible for the physician to inform me of every possible complication that may occur. My physician told me that results cannot be guaranteed and that more treatment or surgery may be necessary. By signing below, I agree that my physician has answered all of my questions and that I understand and accept the risks, benefits and alternatives of _____ surgery. I have been offered a copy of this document.

Patient (or person authorized to sign for patient) (signature) Date _____

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.

INFORMED CONSENT CONTENT

Required Elements

- _____
- _____
- _____

INFORMED CONSENT CONTENT

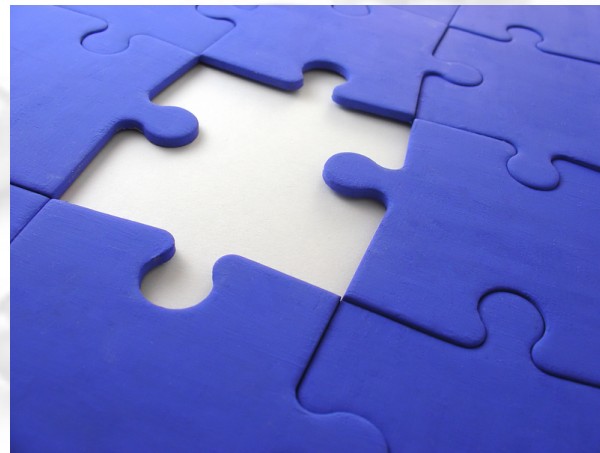
Informed Consent Content (ICC) Review
(Table B)

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

INFORMED CONSENT CONTENT PROBLEM

LOCAL CONSENT MISSING REQUIRED ELEMENTS



INFORMED CONSENT CONTENT PROBLEM

Local Consent Missing Required Elements

Common Missing Elements

- _____
- _____
- _____

INFORMED CONSENT CONTENT PROBLEM

Local Consent Missing Required Elements

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



PEARL



Duplicate Model Consent!

PEARL: Duplicate Model Consent!

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

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

PEARL: Duplicate Model Consent!

If CIRB is the IRB of Record

The Local Consent should match the
Model word for word

PEARL: Duplicate Model Consent!

TIP!

Cut and Paste from the Model

**Double check that adding.....
does not omit**

PEARL: Duplicate Model Consent!

REMEMBER!

If local IRB requires changes obtain
Lead Center / Sponsor Approval

FIRST

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

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



CRP PEARL

Pearls of Wisdom: IRB Review

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