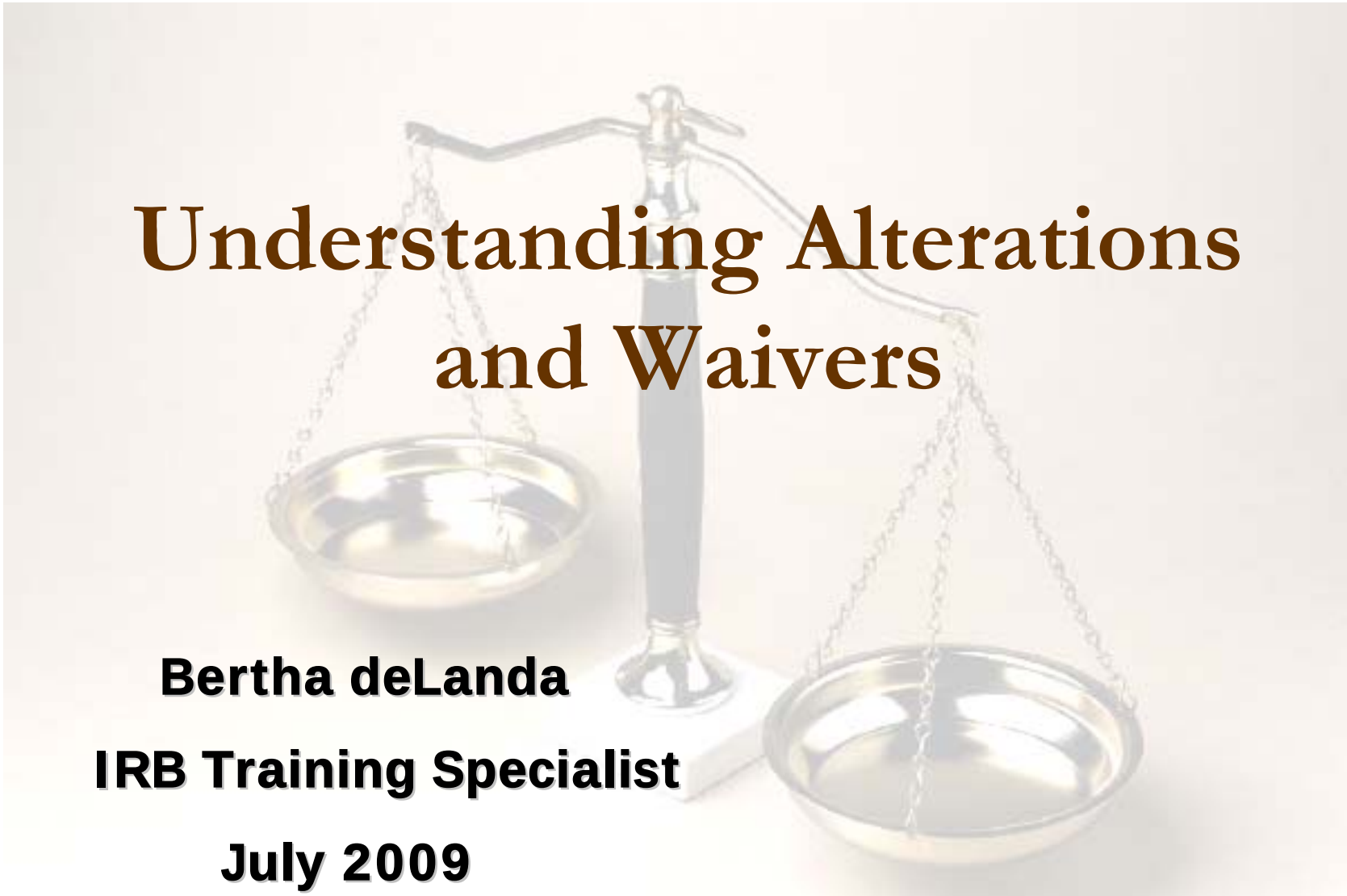

Understanding Alterations and Waivers

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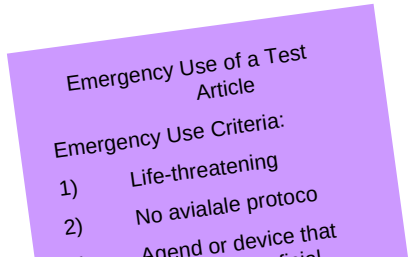
Types of Alterations and Waivers

- Waiver of Informed Consent
- Alteration of Informed Consent
- Waiver of Documentation of Informed Consent (Waiver of Signature)

FDA regulated studies are NOT eligible for a waiver or alteration of consent except for emergency use or planned emergency research



Definition of Alteration or Waiver of Consent

45 CFR 46.116(d)

"A consent procedure which does not include, or which alters, some or all of the elements of informed consent…or waive(s) the requirements to obtain informed consent"

To waive or alter consent, IRB must make findings:

1. no more than minimal risk
2. rights/welfare of subject are not adversely affected
3. research can't be carried out without it
4. pertinent information provided when appropriate

Types of Alterations and Waivers

- **Waiver of Informed Consent**
- Alteration of Informed Consent
- Waiver of Documentation of Informed Consent (Waiver of Signature)

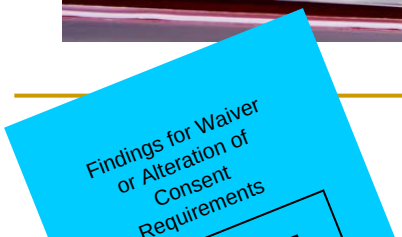
Waiver of Informed Consent Example

IRB finds that it can waive the requirement to obtain informed consent

Retrospective Records Review

IRB findings for consent waiver request:

- ✓ **Researcher de-identifies the information (1,2)**
- ✓ **Consent is not easily obtained (3)**
- ✓ **Not necessary to provide subject with any pertinent information (4)**



Types of Alterations and Waivers

- Waiver of Informed Consent
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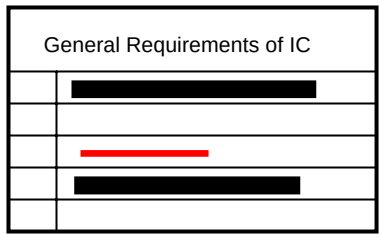
Alteration of Informed Consent

IRB can approve the elimination or alteration of one or more of the 8 required elements of consent



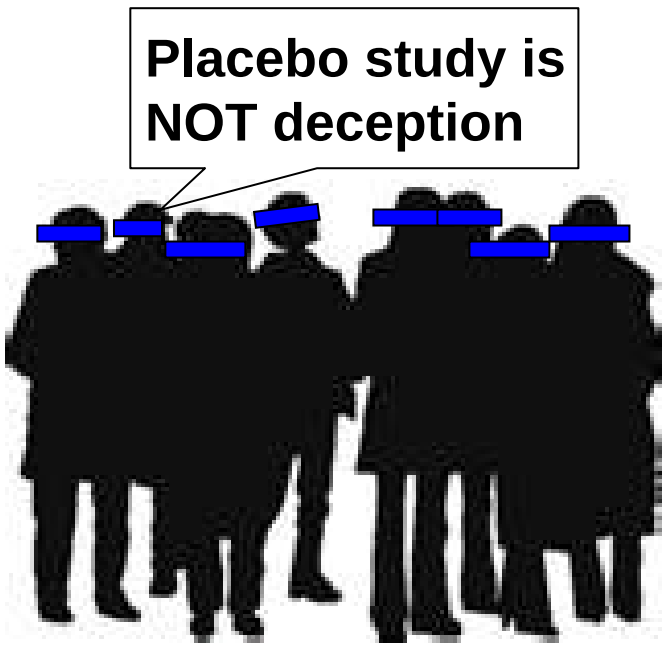
IRB must find **and document** that the 4 criteria are met

Same 4 criteria whether it is a waiver or alteration request

Alteration of Informed Consent: Example

- Requires **protocol-specific** justification

Deception



- **Must document** in the minutes (or in review process) how the research meets the 4 criteria
  - 45 CFR 46.116(d)

- **Mostly occurs** in non-medical studies, but can occur in medical studies

Types of Alterations and Waivers

- Waiver of Informed Consent
- Alteration of Informed Consent
- **Waiver of Documentation of Informed Consent (Waiver of Signature)**

Waiver of Documentation (signature) of Consent

Full consent is given, but there is no signature. Two examples:

- **Phone/internet interview study (oral script) for a minimal risk survey**

45 CFR 46.117(c)(2) and

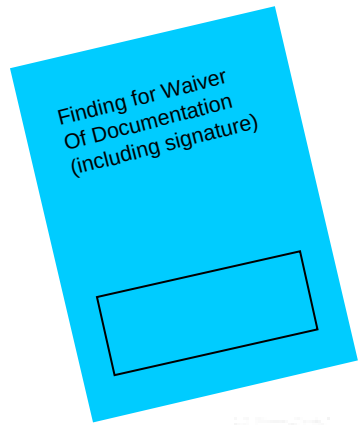
21 CFR 56.109(C)(1)

- research presents no more than minimal risk of harm
- procedure does not normally require consent
- may require investigator to give subjects written statement regarding research

Waiver of Documentation (signature) of Consent

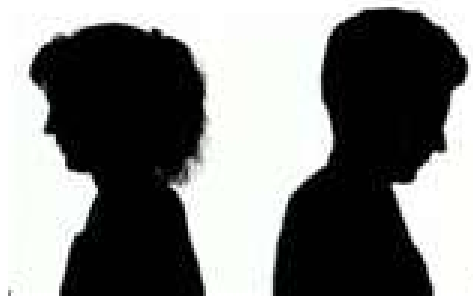
- **A study where the principal risk would be harm from breach of confidentiality**

45 CFR 46 117(C)(1)



- Eg: a study that involved illegal activity, such as gang behavior, substance abuse

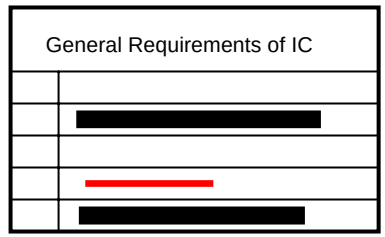
- Only research not subject to FDA regulation may qualify for this waiver



Types of Waivers and Alterations Recap

- **Waiver of Consent**
  - none of the required elements of consent are given

- **Alteration of Consent**
  - one or more of the 8 requirements is eliminated or altered



- **Waiver of Documentation (signature) of Consent**
  - consent is given, but there is no signature