# Waiving Informed Consent

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# Outline

- Considerations for All Consent Waivers
- General Waivers of Informed Consent
- Waivers of Informed Consent for Public Benefit and Service Program Research
- When a Waiver of Consent is Not Required
- References

| | Waiver of Consent | Alteration of Consent | Waiver of Documented Consent | Exception from Informed Consent (EFIC) |
|---|---|---|---|---|
| Consent Process? | No | Yes | Yes | Eventually[v] |
| Consent Document/ Information Sheet? | No | Yes | Yes | Yes |
| Elements of Consent Changed or Missing? | No | Yes | Maybe* | Maybe* |
| Consent Signed by Subject/LAR? | No | Maybe* | No | Eventually[v] |

*The alteration of consent may be combined with the waiver of documented consent or EFIC when all criteria are met.

[v]EFIC requires that there be a consent process and signed consent when practicable. For subjects enrolled without consent, researchers must continue to attempt to obtain consent after enrollment.

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# Considerations for All Consent Waivers

- The research is no greater than minimal risk
- The research could not be practicably done without the waiver
- The research is not a medical experiment under California law
- The research does not involve non-viable neonates
- No individuals were asked to provide broad consent and declined

# General Waivers of Informed Consent

**In addition to considerations for all waivers:**

- The waiver won't adversely affect the rights and welfare of subjects
- If identifiable private information or identifiable biospecimens are needed, must have justification why identifiers are needed
- When appropriate, the subject or LAR will be provided with additional pertinent information after participation

# Waivers of Informed Consent for Public Benefit and Service Program Research

**In addition to considerations for all waivers:**

- The research is not FDA regulated
- The research is to be conducted by or subject to the approval of state or local government officials
- The research is designed to study, evaluate, or examine:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services under those programs
  - Possible changes in or alternatives to those programs or procedures
  - Possible changes in methods or levels of payment for benefits or services under those programs

# When a Waiver of Consent is Not Required

- Common Rule (45 CFR 46.116(g)):
  - An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
    - (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
    - (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
- Examples of #1: screening scripts, written screening surveys, etc.
- Examples of #2: medical record chart review, archived tumor blocks, etc.

# When a Waiver of Consent is Not Required

- FDA Guidance:
  - Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility without first obtaining consent.
    - E.g. medical record review, H&E stain and read of tumor specimen, etc.
  - On the other hand, informed consent must be obtained prior to initiation of any clinical screening procedures that is performed solely for the purpose of determining eligibility for research.
    - E.g. wash-out, tests for non-standard of care biomarkers, etc.

# References

- 21 CFR 50.22
- 45 CFR 46.116(e), (f), & (g)
- California Health and Safety Code Section 24174
  - Definition of a "medical experiment"
- FDA Guidance "Screening Tests Prior to Study Enrollment"
- OIA-410