Informed Consent: Waivers and Alterations

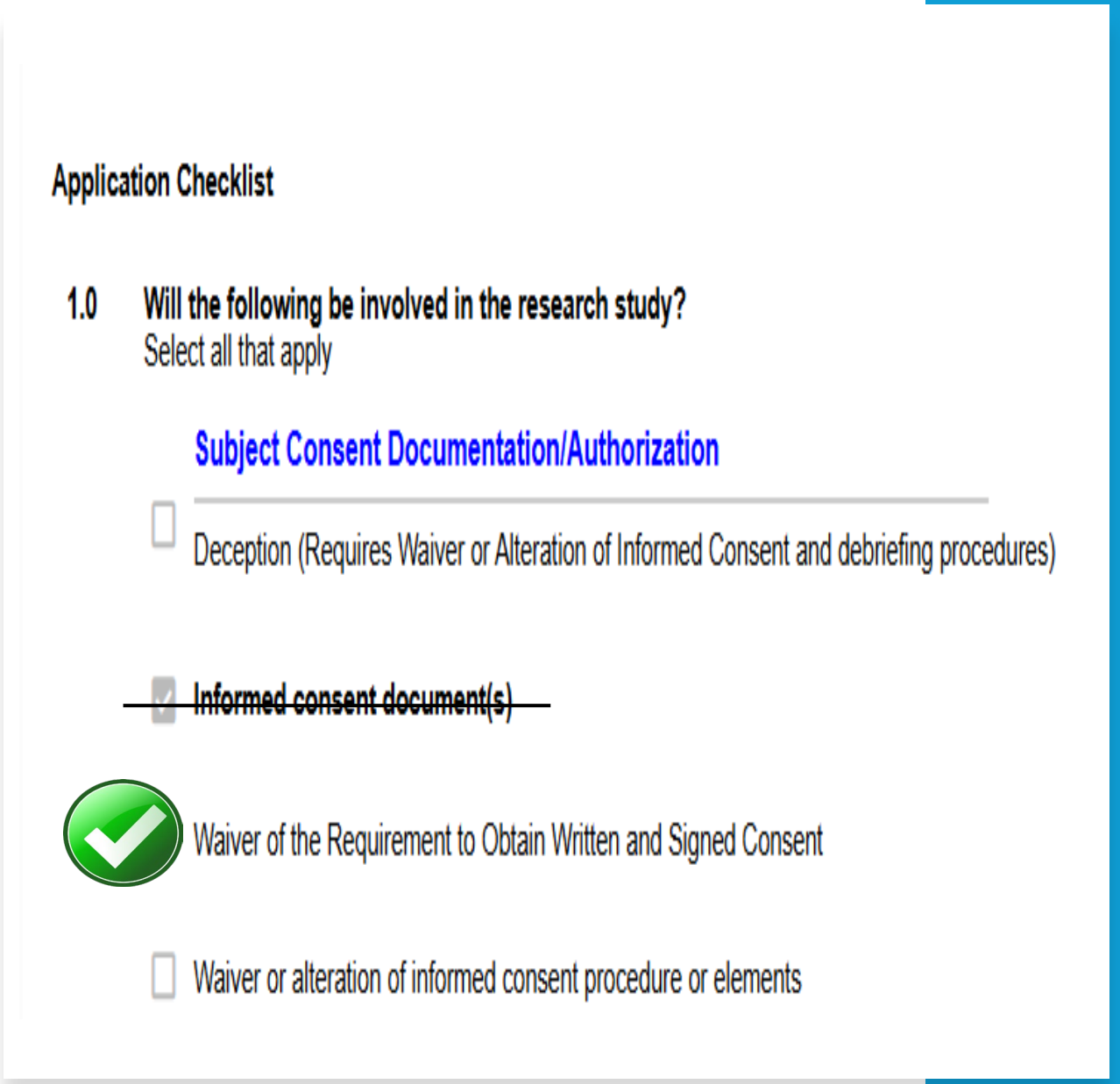
IRB HRPP Policy 6.2

IRB Staff Continuing Education May 2025

Waiver of Written & Signed Informed Consent

Waiver of Written & Signed Consent 45 CFR 46.117

- The IRB may approve a request to **<u>waive the documentation</u>** of informed consent
  - All elements of consent – REQUIRED
  - Subject's signature – NOT REQUIRED
  - "Verbal Consent"
- Subjects should be offered a copy of the consent information for their records
- It is not appropriate to request a waiver of documentation of informed consent for human subject projects that collect biospecimens



Waiver of Written & Signed Consent

45 CFR 46.117(c)(1)

<u>Not FDA Regulated</u> [45 CFR 46.117(c)(1)]

1. Only record linking the subject and the research would be the ICF, and the risk is loss of confidentiality
2. No more than minimal risk and involves no procedures where written consent would be required
3. Subject or subject's LAR is part of a cultural group or community where signing the ICF is out of the norm, no more that minimal risk, and there is an alternative to documenting informed consent

<u>FDA regulated</u> [21 CFR 56.109(c)]

1. No more than minimal risk and involves no procedures for which written consent is normally required

Examples

- Minimal risk study involving phone interviews or data collection via a web-based portal
- A study that collects information about a sensitive topic such as illicit drug use or immigration status where having participant name linked to participation in the study might pose a risk.
- A minimal risk study that involves focus groups in a community where the cultural norm is that individuals affirm agreement via handshake and where requesting a signature would deter participation in research.

Waiver or Alteration of Informed Consent

Waiver or Alteration of Informed Consent

- For research studies in which participants are prospectively enrolled, it is generally assumed that participants are available and prospective consent is feasible.

Waiver of Informed Consent

Informed consent is not obtained from subjects.

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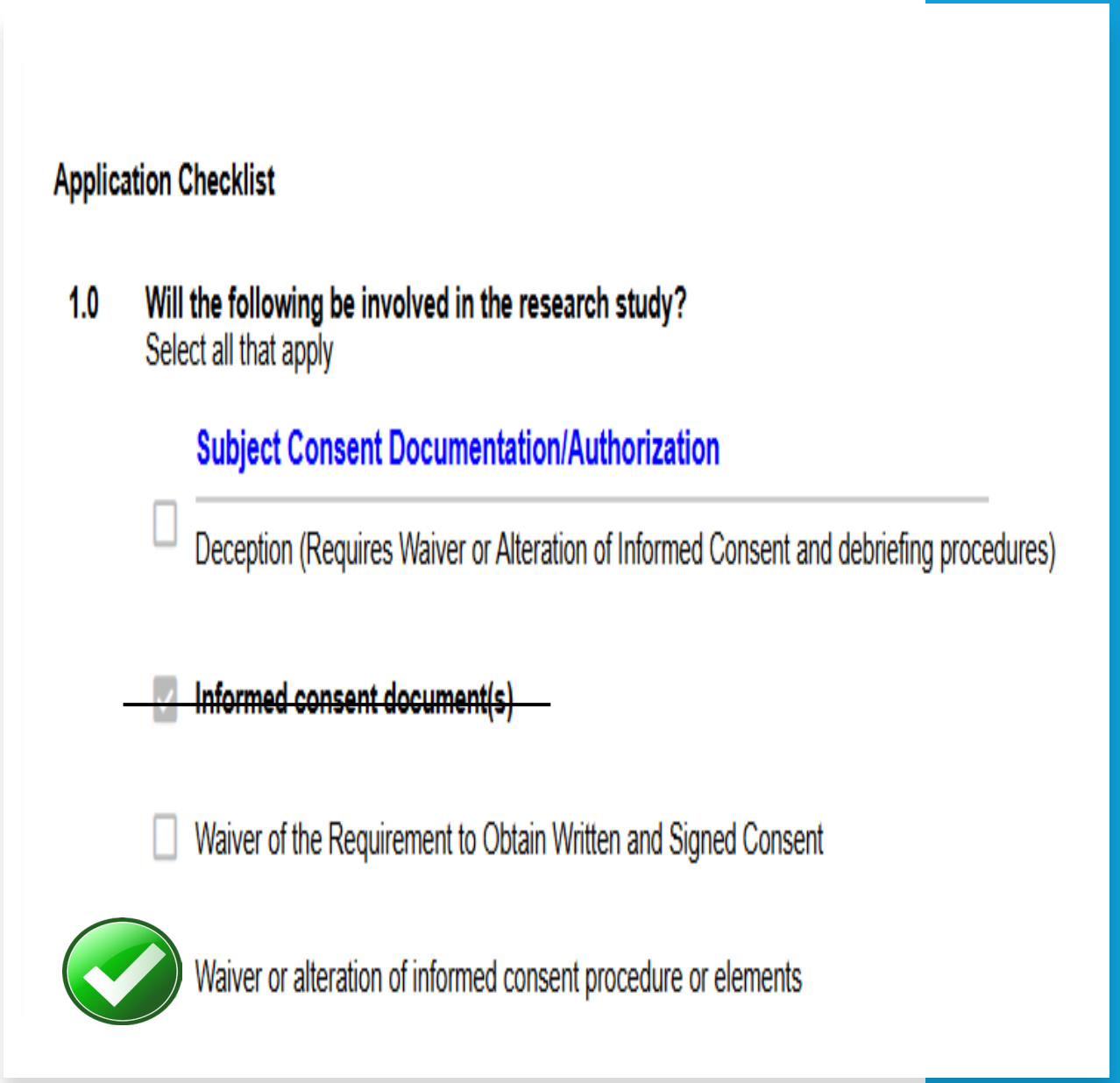
Alteration of Informed Consent

One or more of the elements of consent are altered or eliminated.

Waiver or Alteration of Informed Consent

45 CFR 46.116 & 21 CFR 50.22

1. No more than minimal risk
2. Waiver or alteration will not adversely affect the rights of the participant(s)
3. Research can't be done without the waiver/alteration
4. When appropriate – Subjects or LARs will be provided additional information after participation
5. Research involves using identifiable private information or identifiable biospecimens in an identifiable format AND research can't be done without the waiver/alteration



1. No more than minimal risk

- Researchers must describe how the research poses no more than minimal risk to the subjects.
  - Restating that it involves no more than minimal risk is not sufficient.

Examples:

- Conducting a record review or using data from medical records
  - Is the information sensitive in nature?
  - Is the data being collected derived from clinically indicated procedures?
  - What precautions are being taken to ensure there is no loss of confidentiality?

2. Subjects' rights and welfare will not be adversely affected

- Researchers need to describe why the waiver will not adversely affect subjects.
  - Are test/procedures being done solely for this research or is data being collected on past procedures that are completed?
  - Could the results of the research potentially affect the subject’s regular care?
  - Would use of their information affect subjects’ regular care or deprive them of care?
  - Could participation in the study negatively affect the subjects’ wellbeing?

3. Research can’t be done without the waiver or alteration

- Researchers must describe why it would not be feasible to conduct the study without a waiver or alteration
  - Does the data being reviewed contain out of date contact information for the subjects?
  - Does the number of charts being reviewed make it impractical to contact each subject for consent?
  - Would identifying and contacting each subject to obtain consent be prohibitive?

4. Subjects or LAR will be provided additional pertinent information

- Researchers need to describe whether information resulting from the study will be disclosed to subjects.
  - Will the results from the study have any effect on subjects or their regular care?
  - Are there any anticipated benefits that would change care subjects have already received?

Example

- Study to determine whether some specific blood chemistry values change in people undergoing clinically indicated abdominal surgery, and if there is a correlation of changes with increased complications after surgery.

- Involves review of medical records of all patients who have undergone abdominal surgery in the past 2 years (about 10,000 surgeries), collecting limited data that will be double-coded so link is known only to researchers. Results of the research will not affect clinical care of the individuals, since they will have already left the hospital.

Can Informed Consent be waived or altered?

1. Minimal risk?
2. Are the subjects rights and welfare adversely affected?
3. Can the research be done without the waiver/alteration?
4. Do subjects need to be provided with pertinent information?

Can Informed Consent be waived or altered?

- Questionnaires/surveys that increase the potential risk to subjects (Ex. lengthy questionnaires that make a new, or refute an existing, diagnosis)
- Surveys/questionnaires where subjects' responses may place them at risk of criminal/civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing
- Creation of new data through means other than oral/written communication with the subject or collection of biospecimens solely for research purposes

Informed Consent - Screening

- IRB may approve screening procedures without obtaining prior informed consent only if:

1. the solicited information is limited to the minimum necessary for screening/determining eligibility for the main study AND
2. if these procedures are limited to:
   - obtaining information through oral or written communication with the subject/LAR, or
   - obtaining identifiable private information/biospecimens by accessing records or stored identifiable biospecimens

- Screening procedures must be:
  - brief in duration and
  - limited in nature to focus solely on determining eligibility for the research

- For FDA regulated studies – as long as screening procedures are minimal risk, a waiver of documentation of consent may be granted by the IRB.

Informed Consent - Screening

- HIPAA Authorization is still needed if the information or biospecimens used for the purpose of screening, recruiting, or determining the eligibility of subjects include protected health information (PHI)

- Screening activities to establish eligibility might include:
  - Review of medical records (Ex. admission/clinic logs that contain identifiable private information)
    - consent not required; a waiver of HIPAA Authorization may be requested
  - Asking individuals questions or taking a medical history
    - consent is not required; HIPAA Authorization [when applicable] may be required
  - Performing laboratory tests on stored samples, to see if the results are within the required range
    - consent is not required; HIPAA Authorization may be required
  - Performing laboratory tests on samples obtained solely for the research, to see if the results are within the required range
    - consent and HIPAA Authorization will be required

Informed Consent – Cold Contact

- Informed Consent needs to be considered when cold contact recruitment is used
  - Ensure that individuals are fully informed and voluntarily agree to participate
- IRBs may waive or alter the requirement for informed consent in certain research situations, including cold calling, under specific conditions and when all criteria are met
- IRBs do not have to agree to waive or alter consent when cold contact recruitment is being used.