Requirements for waiver and alteration of Consent

45 CFR 46.116(e)(3)

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Requirements for waiver and alteration flow chart

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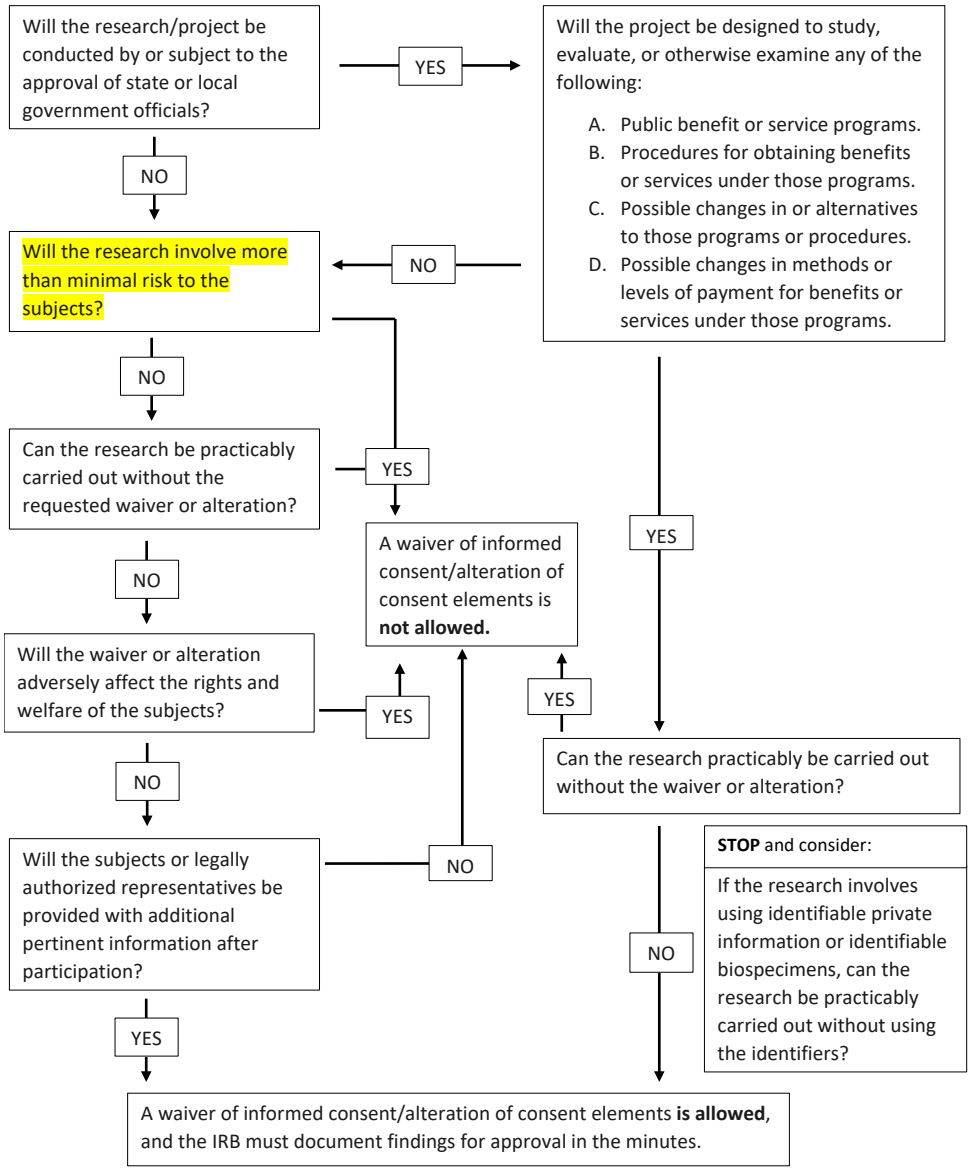

What qualifies a study as minimal risk?

- The research activities must present no more than minimal risk to human subjects.
- The research activities involve only procedures listed in one or more of the Expedited categories.

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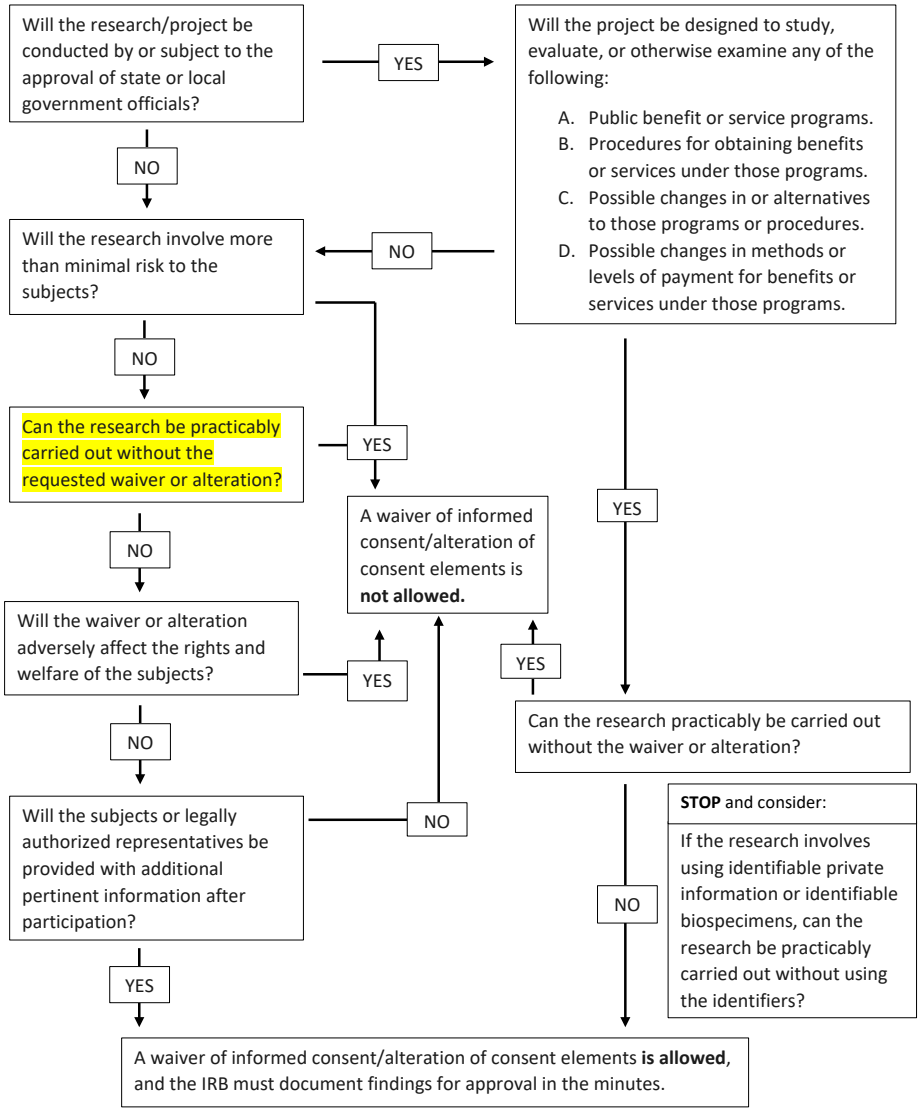

What is practicable?

- Commonly accepted definitions of the term “practicable” are (a) feasible; (b) capable of being affected, done or put into practice; and (c) that may be practiced or performed; capable of being done or accomplished with available means or resources.

Examples of accepted Impracticality:

- Sample size required is so large (epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be draw or bias the sample such that conclusions would be skewed.
- The subjects for whom records would be reviewed are no longer followed or may be lost to follow-up.
- Ethical Concerns would be raised if consent were required. For example:
  - There is a risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek consent.
  - There is a risk of inflicting psychological, social, or other harm by contacting individuals or families.

Practicability should not be determined solely by considerations of convenience, cost, or speed.

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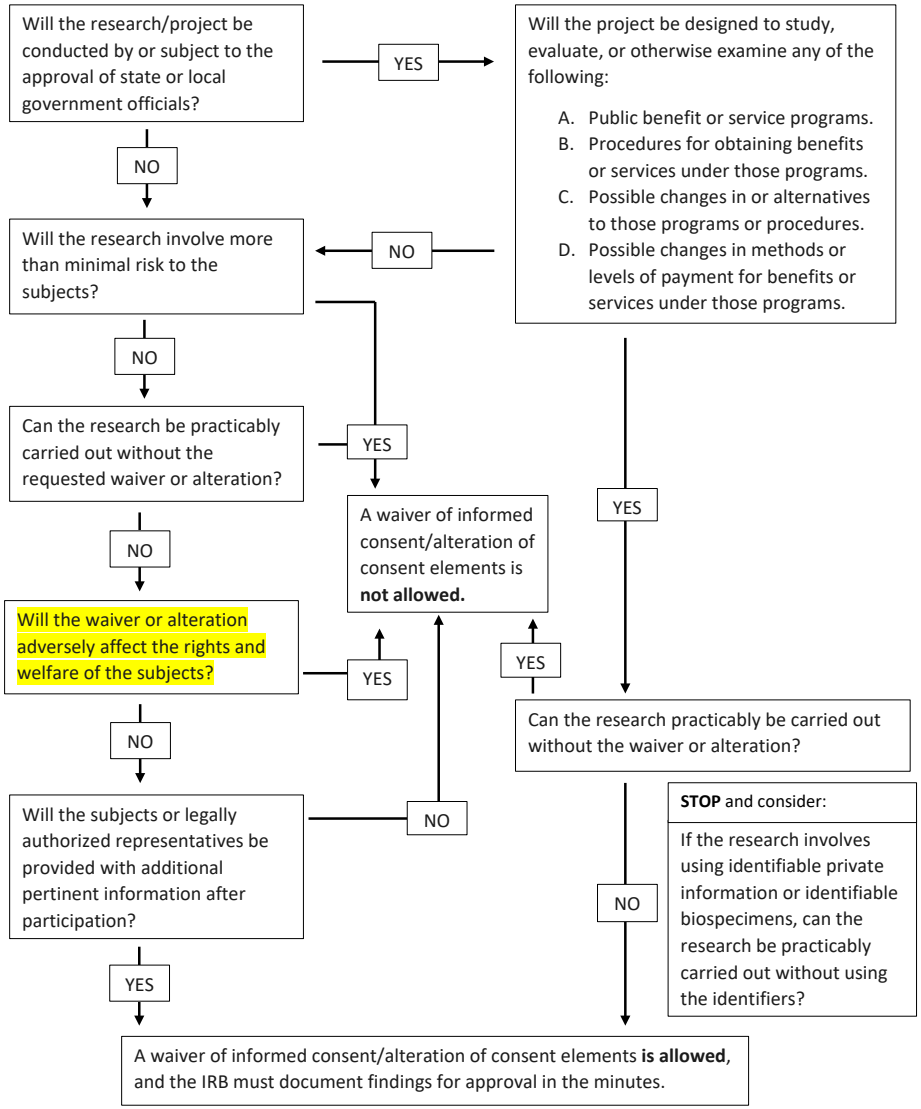

Will the waiver or alteration negatively impact the participant's rights or welfare?

- The following is considered when making this determination:
  - Any federal, state, or local laws that provide rights to potential subjects to require informed consent.
  - Whether the subject population, in general, would object if they knew the waiver and its intent in facilitating research.
  - Whether the subject population, in general, would consider that the waiver has the potential to cause consequences for their welfare or general well-being.

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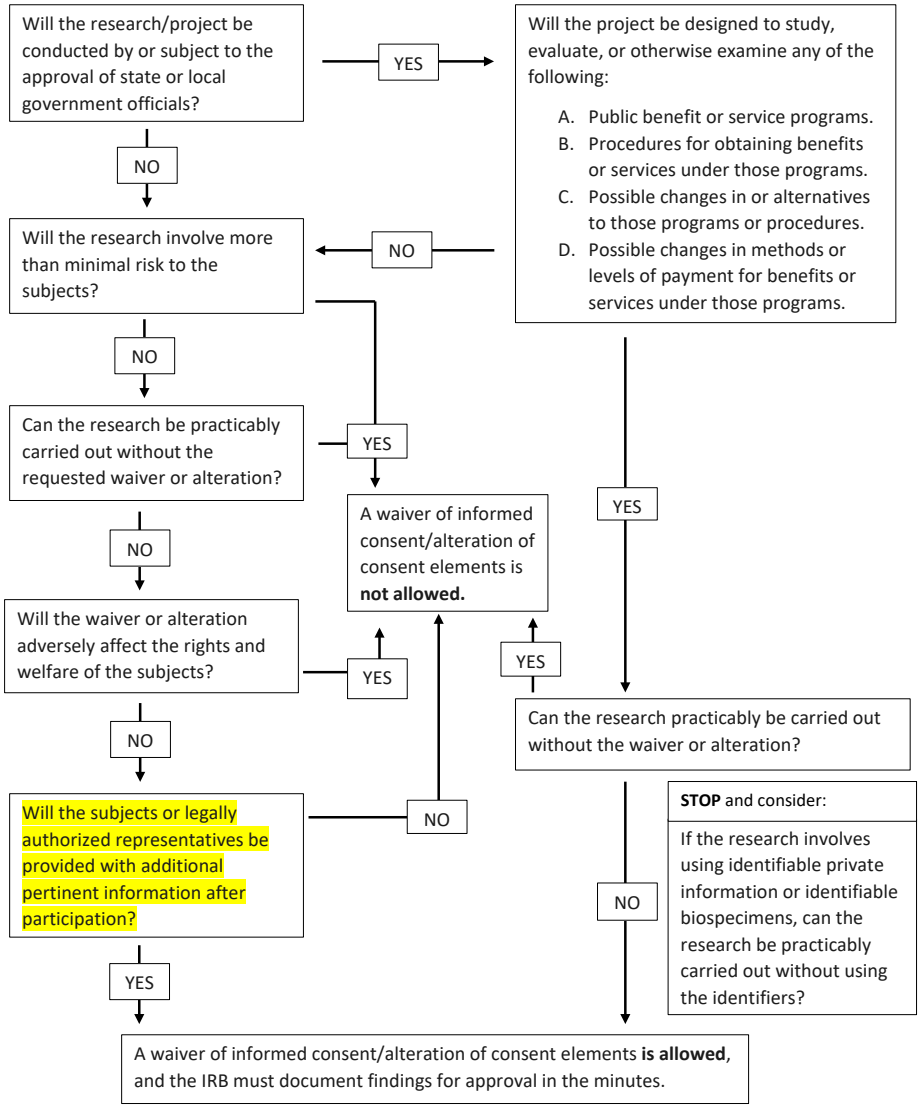

Will pertinent information be provided to subjects later?

- It should be noted that not all protocols which include an informed consent waiver are required to provide additional information to subjects after their participation.
- This criterion is intended to refer to the need to consider debriefing after research is conducted.
- This is typically a concern with studies involving deception.

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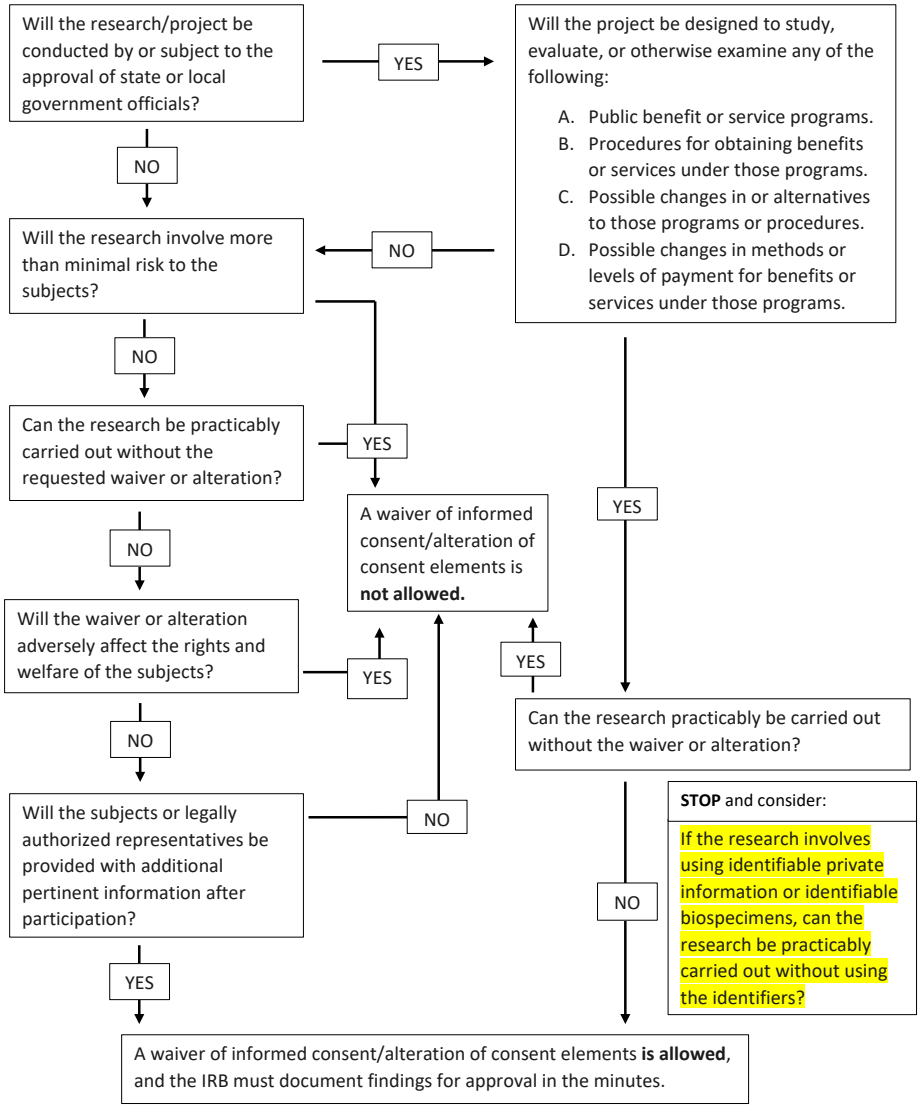

What If the study uses data or specimens that contain identifiable information?

- The IRB should consider if the research could be done without the identifiers in order to decrease the risk of a breach of privacy or confidentiality.
- If it is possible to do the research without using identifiable information, and the study team wishes to use the identifiable information, the study team should consent participants for the use of their identifiable information. If it is not possible to do the research without the use of identifiers, and all other waiver requirements are met, the IRB may waive consent.