

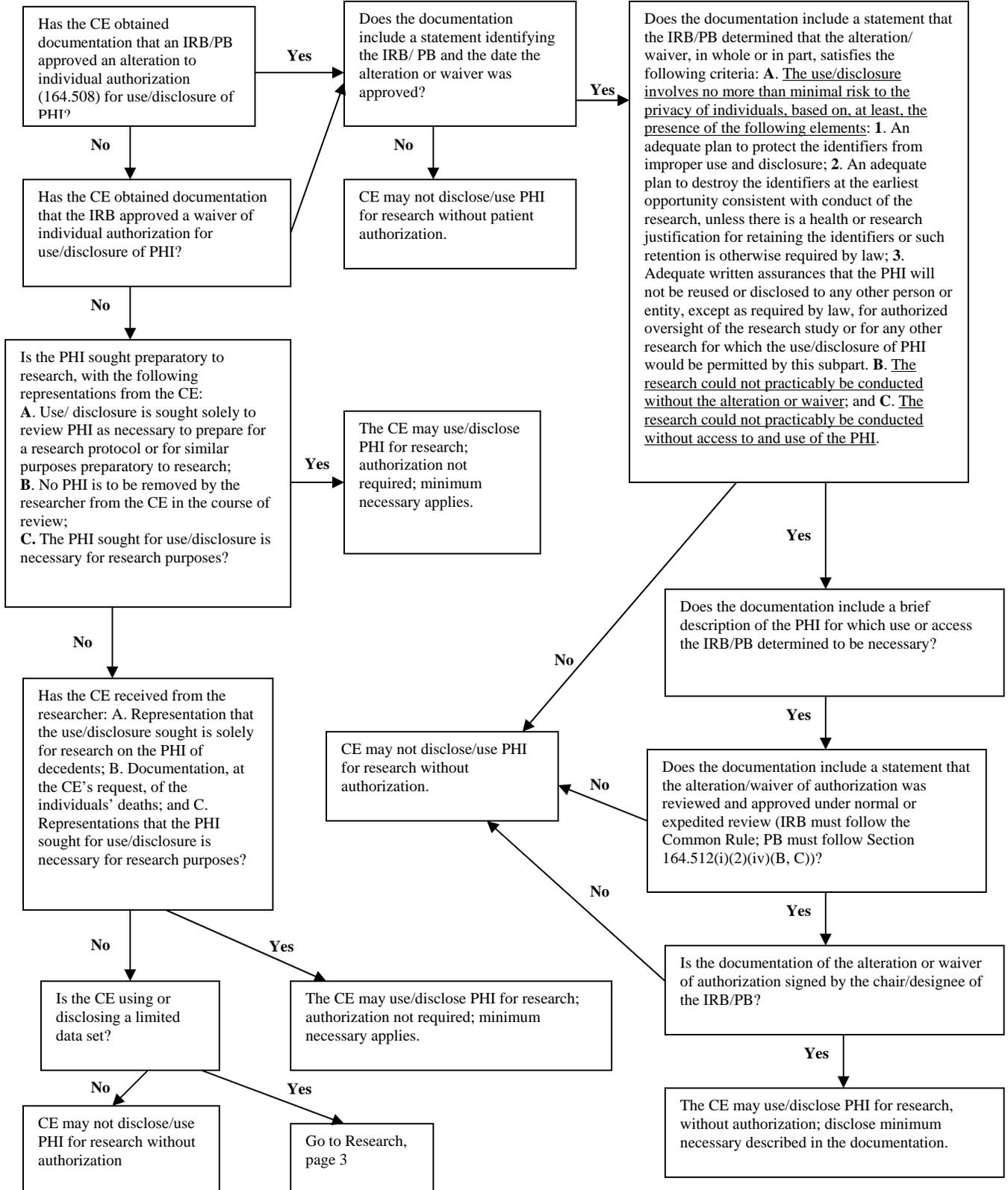
## Human Research

### Obtaining PHI for Research without an Authorization

Q: Can researcher use PHI without authorization? (Funding source irrelevant).

Code: IRB = internal review board; PB = privacy board

Citation: 45 CFR 164.512(i).

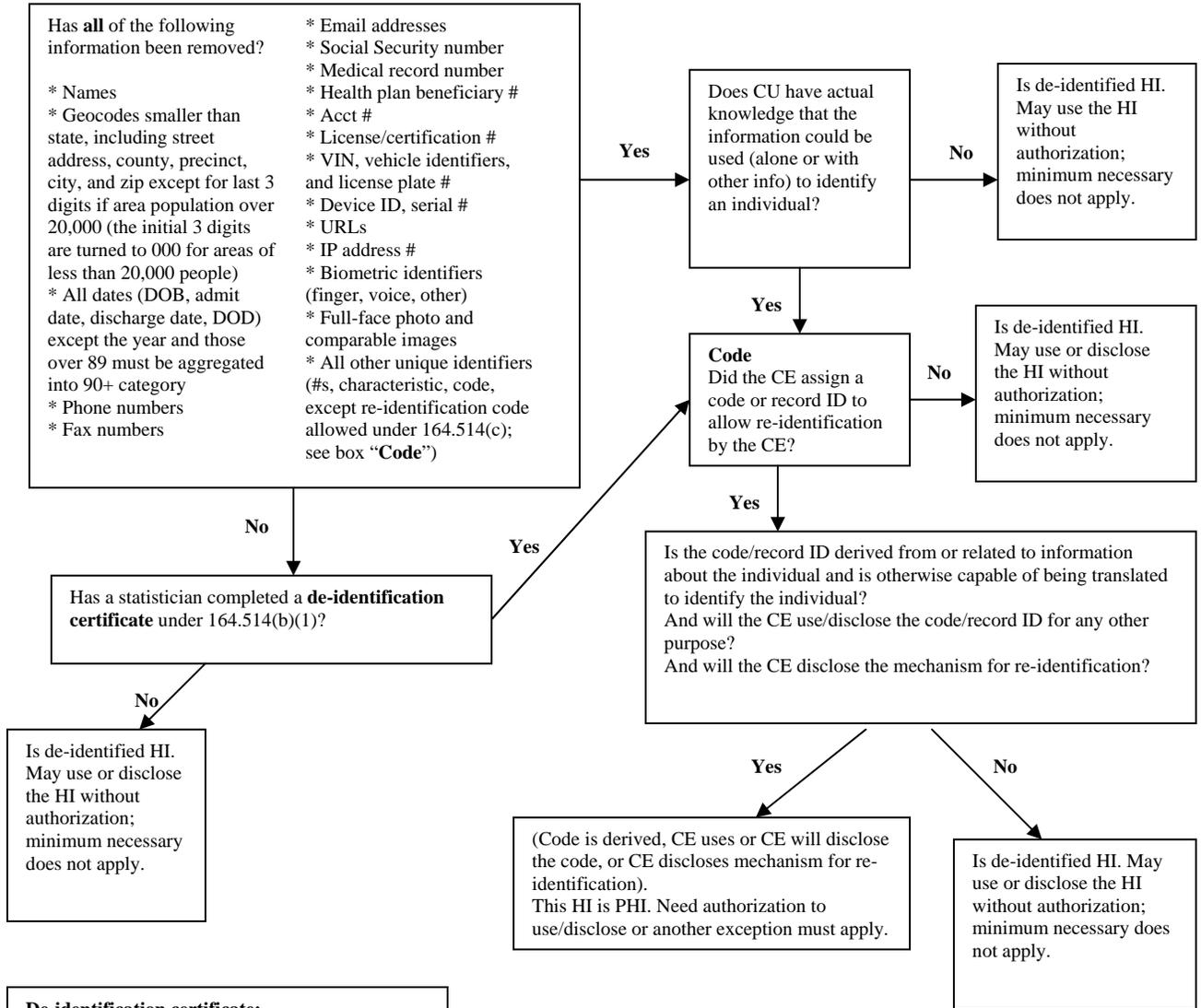


# Human Research

## Use/Disclosure of De-Identified PHI

Q: Health information (“HI”) that is de-identified and with respect to which there is no reasonable basis to believe it can be used to identify an individual is not individually identifiable HI and may be used or disclosed by a CE. At what point is PHI de-identified?

Cite: 45 CFR 164.514(a), (b), (c).



**De-identification certificate:**

1. Created by person with appropriate knowledge and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable;
2. Person applies such principles and methods, determines risk that the information could be used, alone or in combination with other reasonably available information by an anticipated recipient to identify an individual who is a subject of the information is very small; and
3. Person documents the methods and results of the analysis that justify such determination.

# Human Research

## Use/Disclosure of Limited Data Sets

Q: A limited data set may be used or disclosed by a CE. What is a limited data set and when can the CE use/disclose it?

Cite: 45 CFR 164.514(e).

LDS = Limited Data Set

