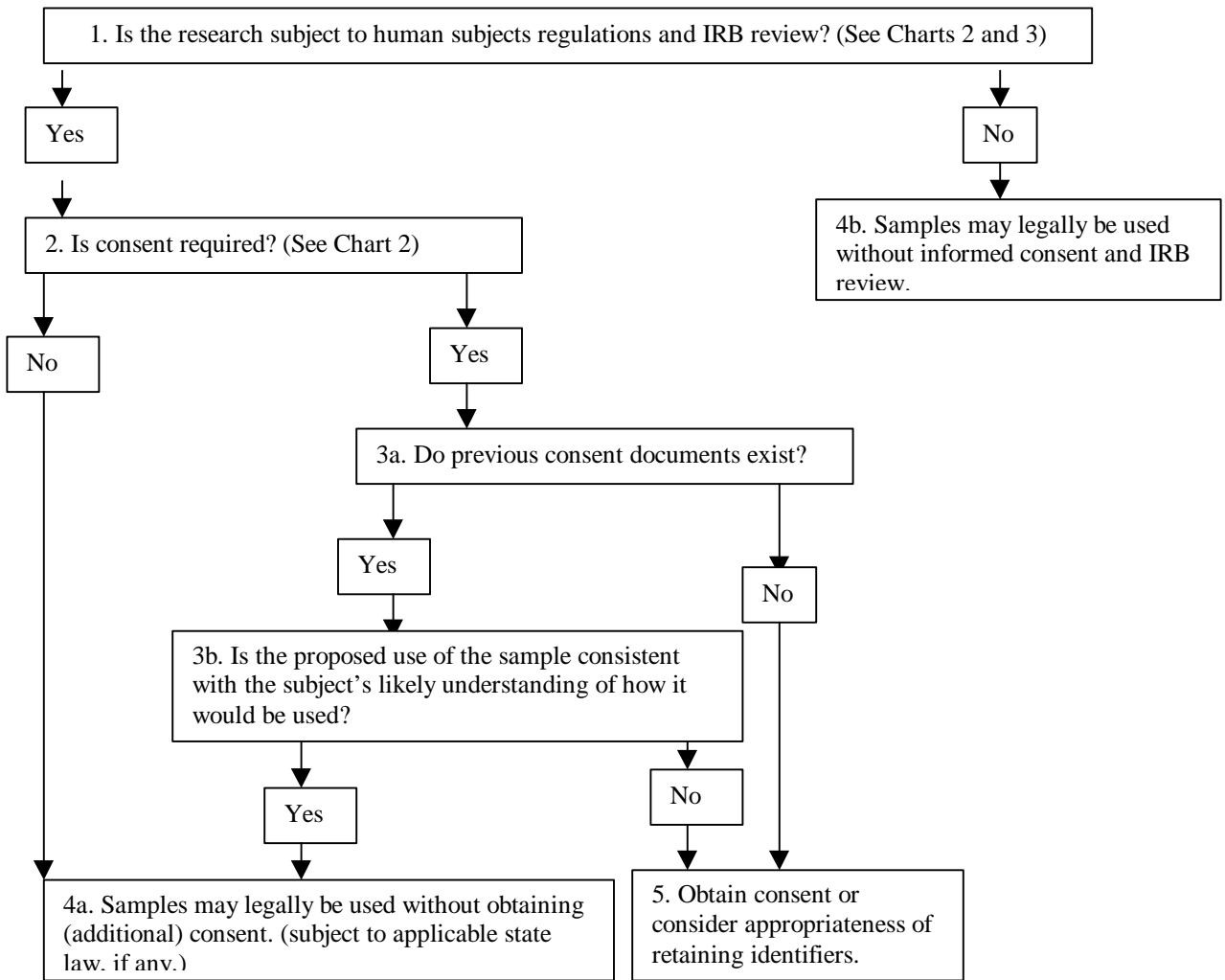


Chart 1: Proposed Process for Research Using Human Biological Materials



**Key to Guidance in the Report**

- 1) Activities that are subject to IRB review
  - “Activities that Constitute Research” (p. 173)
  - “Current Criteria for Exemption from the Federal Policy for Protection of Human Subjects” (p. 174)
  - “Identifiability of Samples” (p. 179)
- 2) Requirements for informed consent
  - “Issues Regarding Minimal Risk and Rights and Welfare” (p. 186)
  - “Consent Requirements” (p. 192) (Note recommended use of opt out)
  - Note recommended changes in requirements
- 3) How to consider existing consent documents
  - “Consent Requirements – Informed Consent Requirements for the Use of Existing Samples” (p. 198)
- 4) a) and b) Use of existing samples where consent is not legally required
  - “Consideration of Potential Harms to Others” (p. 210)
- 5) Obtaining Consent