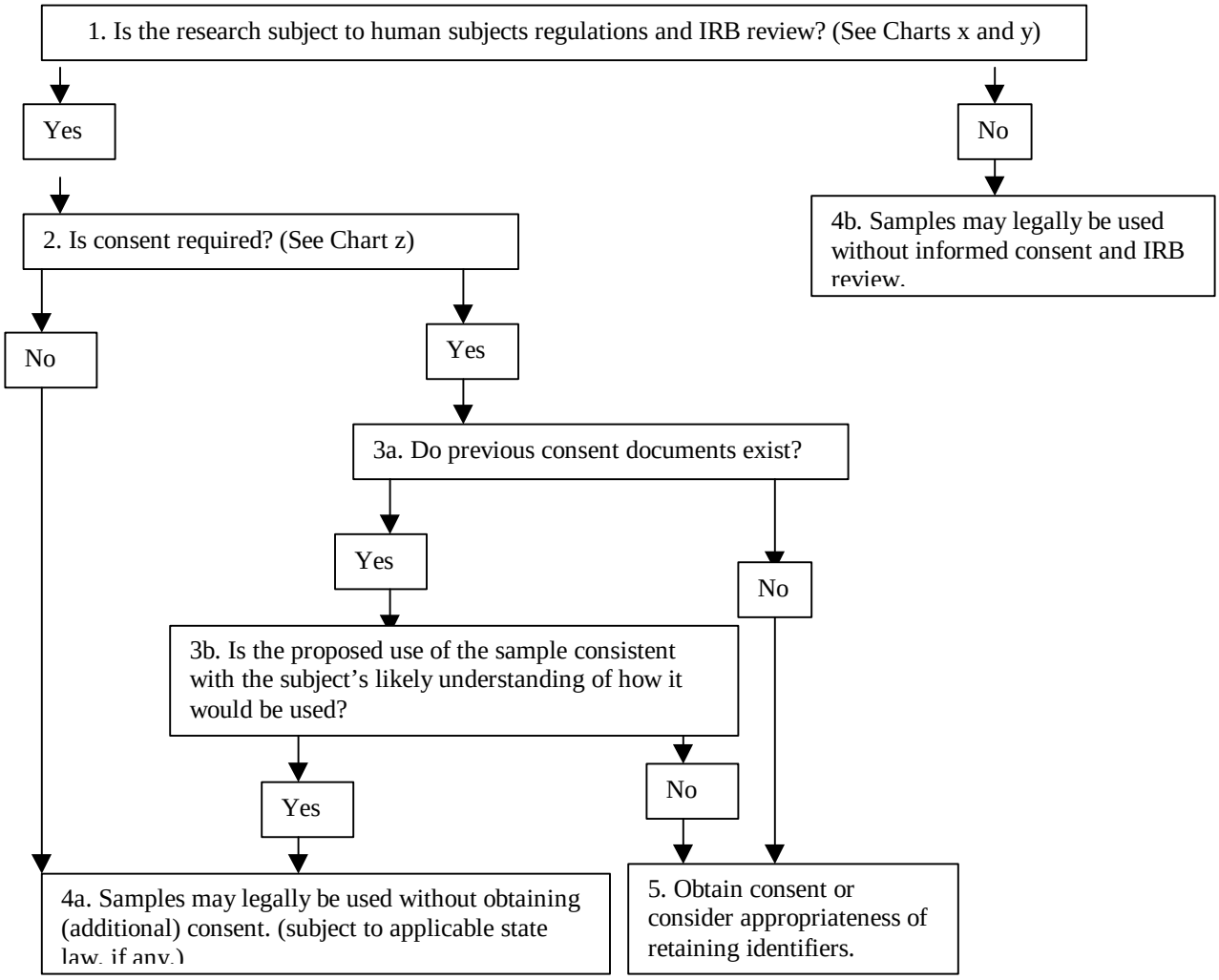
November 10, 1998: This is a staff draft report developed for the National Bioethics Advisory Commission. It does not represent conclusions and should not be cited or referenced as such.

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)

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
- "Collection of Human Biological Materials in the Future" (p. 207)