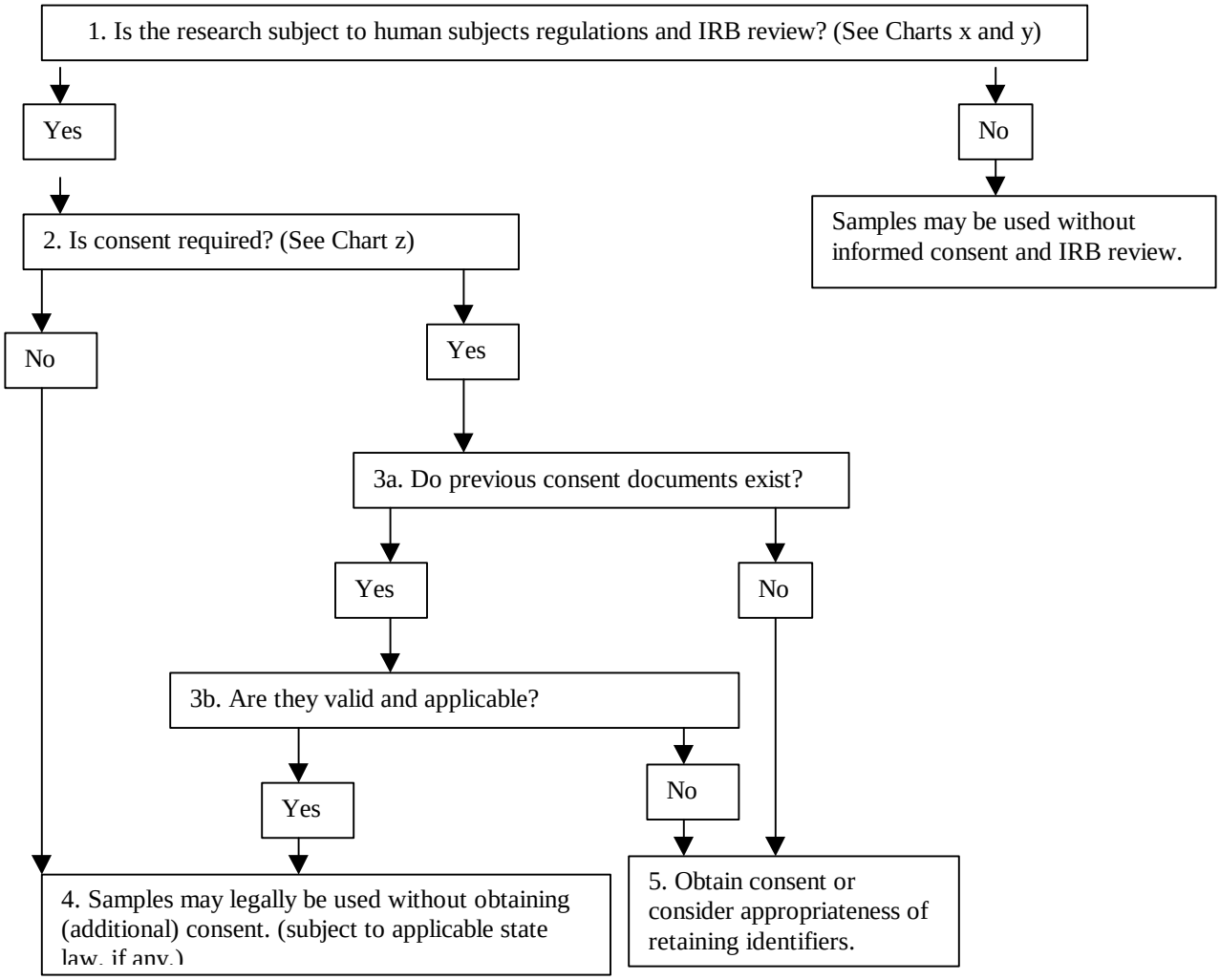
September 4, 1998: This is a staff draft report developed for the National Bioethics Advisory Commission. It does not represent conclusions and should not be cited or referenced as such.

Chart a: **Proposed Process for Research Using Human Biological Materials**



1) What research is subject to IRB review
   a) "research"
   b) "identifiability"
   c) consideration of harm to others

2) Is consent required?
   a) "Minimal risk"
   b) "Practicability"
   c) **rights and welfare**

3) Existing consent
   a) Do previous consent documents exist?
   b) **Do previous consent documents apply?**

   How should IRBs evaluate previous consent documents?

4) Use of existing samples where consent is not legally required
   a) How should research be carried out using these samples?
   - Is "disclosure" sufficient?
   - Should specific consent be obtained only for certain "special scrutiny" classes of research?

5) How and when should subjects be re-contacted to give consent?
How should consent forms be designed to provide adequate protections for human subjects?
Under what conditions is it appropriate to remove identifiers from existing samples?