TABLE 1. A Comparison of Standard IRB Review Practice vs. a Local Consideration

Example	Standard IRB Review Practice	Local Consideration
Research study includes experimental drugs that could adversely affect a pregnancy	Determining how to minimize reproductive risks from drugs that can affect pregnancy, such as what forms of contraception would be acceptable.	Any limits a Relying Institution may impose on what contraception it would be willing to provide to research subjects enrolled at its site (e.g., because of religious beliefs or practices) and what language it requires to be included in the informed consent about contraception.
Informed consent content	When informed consent is required, determining the information that must be provided to research subjects, as well as the format and method of presentation.	Specific language required by institutional policy (e.g., compensation for injury language) or state law (e.g., California Experimental Participants Bill of Rights).
Subject selection and enrollment	Ensuring subject selection is equitable and that informed consent documents and forms provide information in a language understandable to the subject or the legally authorized representative. Determining whether vulnerable subjects are likely to be enrolled in the study and additional safeguards that may be needed to protect the rights and welfare of these subjects.	Participants or populations who might not be identified explicitly in a research protocol or IRB application and who could be enrolled at a site or whose records or biospecimens might be used for the research, such as those who: ▸ May have relevant ethical, cultural, or religious standards, ▸ May be vulnerable to coercion or undue influence, ▸ Are from discrete and insular communities, or ▸ May have unique legal status (e.g., American Indian/Native Alaskan tribes).