



(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§46.111\(a\)\(7\)](#).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the

1. (i) If wholesome foods without additives are consumed, or
2. (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be