IRB sends information/documents that were

disclosed to the study sponsor

documents to FDA for inclusion

in Public Docket

informed consent to the IRB. (Submission includes study protocol, informed consent

family members, and plans for community

CI/Sponsor revise materia1

consultation & public disclosure.*)

Sponsor/CI revise

Community Cons. Plan

Sponsor notifies FDA and other IRBs and CIs involved in this or

substantially similar studies

CI/Sponsor revise plans for

CI/sponsor complete additional

DMC established; CI begins enrolling

subjects; eventually study is completed

CI/Sponsor provide plans for public

disclosure of study results to IRB

CI/Sponsor revise plans for public

consultation/public disclosure process.

sequential.

**IRB review of community consultation and public

disclosure plans may be concurrent, rather than

disclosure of study results.

activities.

public disclosure and resubmit