

Item 2.1.4 addresses client responsibilities. This document lists IRC responsibilities.

**INDEPENDENT REVIEW CONSULTING (IRC)** is a business entity that fulfills the role of an institution as defined in the Common Rule, and FDA regulations. This institution provides IRB services for research regulated by other agencies.

- IRC is the contracting institution.
- IRC assures sufficient staff and resources for the IRB's operation.
- IRC receives the application package and submits it to the IRB for review.
- IRC may authorize exemption from IRB review or may allow submission of a grant.
- IRC maintains communication with the relevant federal agency and shall respond to all valid requests for IRB inspection.
- IRC may "monitor" the ongoing investigation. IRC also expects industry clients to monitor sites as required under Title 21, sections 312 and 812 and to report to IRC and the FDA any serious or continuing non-compliance.
- IRC retains the authority to terminate or suspend a study regardless of the decision of the IRB; it may not approve a study disapproved by the IRB.
- IRC retains expert consultants when the IRB requests outside assistance.
- The President of IRC will usually be designated the "impartial third party" to whom subjects can turn.

**THE INSTITUTIONAL REVIEW BOARD (IRB)** is a standing committee of IRC, Inc.

- The IRB is charged with conducting an objective review of applications.
- The IRB must act as defined in its operating policies and procedures.
- When issues arise that members recognize go beyond its expertise, the IRB may request consultation with specialists.
- The IRB may request that IRC arrange for a site visit to any investigator.
- The IRB may approve, approve with conditions or contingencies, request modifications or may disapprove an application.
- The IRB has the authority to terminate or suspend approval of a study.
- While the IRB will seek to confirm facts contained in the submission, the IRB must presume that all information is truthful and honest. IRC will take appropriate and immediate action should it learn that this faith is misplaced.
- The IRB has the authority to observe the consent process.

