

Independent Review Consulting (IRC) was founded by Erica Heath who developed and, for fourteen years, administered the University of California, San Francisco, Institutional Review Board.

IRC's IRB reviewed its first protocol, a medical device peripheral from a diagnostic clinic, in December 1984. IRC was incorporated in 1993. The company originated in San Francisco and moved to San Anselmo in 1987. In 1999, IRC moved into a larger office space in San Rafael and in 2002 IRC moved to Corte Madera.

The IRB has reviewed studies from a wide diversity of areas including vaccines, gene therapy, xenografts, in vitro diagnostics, education and behavioral studies. The IRB specializes in device studies, Phase IV studies, and social and behavioral research.

IRC has had five FDA inspections:

- August 5-6, 1992
No FDA 483. A "No Action Indicated" letter was dated June 4, 1993.
- February 9, 1993
Directed inspection to review a single, politically sensitive, device study with over 1000 sites. An FDA 483 mentioned 3 items that were reiterated in an FDA letter dated April 9. IRC responded on April 26 and a "no further questions" letter was dated June 9, 1993. Several points concerned expedited actions that were not reflected on the minutes. Corrective action was taken and the IRC minutes now contain a series of reports to the board.

The reviewers also questioned the relationship between this IRB and the local IRB listed for one investigator. Following the audit IRC modified and tightened the "Certification and Waiver Form" required to document the presence of and acknowledgment of the investigator's institutional board, if any.
- May 9-19, 1995
No FDA 483 was issued. Several observations were made.
- April 13-15, 1998
No FDA 483 was issued. A CDRH BiMO letter, dated August 27, 1998, listed 5 points. The IRC response was dated September 4 and a "no further questions" letter was received November 23, 1998.

- July 8, 10, 23, 24, 25, 30 and August 1, 2002

Three observations were noted on an FD 483. Two were simple documentation issues that were easily resolved. One noted that a non-scientist was not present in eight of the fifty meeting minutes reviewed. IRC refuted the observation arguing that the regulatory requirement is that the member's "primary concern" is as a non-scientist and that a second member, in attendance during each meeting in question, had not been professionally active in any scientific occupation for well over a decade. A response of January 18 agreed with our understanding but did not yield. The quorum count was made more specific on the agenda and minutes.

In addition, IRC has participated in multiple sponsor inspections. Sponsors are allowed access to only their own study materials.

