



Clinical Research

A Day in Court

University of Tennessee Health Science Center
Office of Human Subject Protections
April 22, 2007

CJ Craig, Plaintiff

Plaintiff

A person who brings an action/lawsuit

Marcus Welby, MD

Irby Chair, MD

- Defendants

- A person defending or denying; the party against whom relief or recovery is sought in an action or suit

Dr. Marcus Welby

- Malpractice
 - Was the protocol followed properly?
- Breach of fiduciary duty
 - Conflict of interest?
 - Inclusion/exclusion criteria followed?
 - Adequate clinical assessment?
 - Was subject properly informed of risks?

Dr. Irby Chair

- Breach of fiduciary duty and negligence
 - Did the IRB confirm ethical study design?
 - Was “washout period” appropriate?
 - Was the IRB properly informed of protocol violations?
 - Did the IRB “protect the rights and welfare of the subject?”

Clara Barton, RN

- Dr. Welby's nurse
 - Not named as a defendant
 - Testimony may support plaintiff or defendant

Independent vs University IRB

- If this was a state (university) IRB, the hearing might be presented to a state commission, depending on local law. For today's trial, the IRB is not a university entity, but an independent board.

Federalwide Assurance

- Is a formal document signed by the federal Office of Human Research Protection and institutional officials, establishing the IRB and the institution's pledge to protect the rights and welfare of research subjects

Trial

- Jury selection
- Opening Statements
- Plaintiff's case
- Defendants' case
- Closing arguments
- Jury charge
- Jury Deliberation
- Verdict

The plaintiff

Has the burden of proving her cause by a “preponderance of the evidence” – generally considered to be more than 50%

Verdict

- A formal decision or finding made by a jury empaneled and sworn for the trial for a cause of action or lawsuit

Discussion

- Please write your questions on the cards enclosed and turn in to the judge for discussion following the verdict.