

THE ROLE OF PATIENT ADVOCATES IN MEDICAL RESEARCH

- Haavi Morreim
- Deborah Collyar
- Steve Peckman

An "Advocate" By Any Other Name ...

- Managed care utilization review clerk
- Consumer groups fighting managed care
- Hospital employee addressing patient complaints
- Groups seeking increased research funding for identified diseases
- Designated assistant for 'mentally infirm' people enrolled in research trials
- Assistant during informed consent process
- Nonparticipatory monitor of informed consent process
- Ongoing assistant for research participants

One Example of Patient Advocacy in Research:

IPAC:

**Independent Patient
Advocacy Council**

AbioCor Artificial Heart Trial

AbioCor Artificial Heart Trial

- Completely implantable bi-ventricular cardiac replacement
- Initial feasibility study:
 - 15 patients at 6 sites, nationwide
- Eligibility
 - Death 70% likely within 30 days
 - Unresponsive to maximum existing therapies
 - Ineligible for cardiac transplantation
 - (additional criteria)

IPAC

- **FUNCTIONS**
 - **CLINICAL:** Assisting prospective AbioCor candidates and enrolled patients
 - **POLICY:** Corporate advisory on ethical issues associated with the trial

IPAC STRUCTURE

- Members: site-based (6) + chair
- Independence
 - Irrevocable trust, lump-sum
 - Company can never touch funds, can not threaten withdrawal of funds to influence IPAC
 - IPAC governs all expenditures
 - Membership self-selected exc. first few; company cannot 'hire' or 'fire'
 - Self-governing
 - IPAC, not company, defines "patient advocacy"
 - IPAC chooses topics for corporate advisory

CLINICAL FUNCTION

- **INFORMED CONSENT PROCESS**
 - **Separate sessions with prospective patient, family (P/F)**
 - **Help P/F understand information, identify questions**
 - **Help P/F to think about end-of-life, quality-of-life values**
 - **Nondirective: *Not* to recommend one decision over another**
 - ***Not* to replace PI's responsibility for informed consent**
- **POST-IMPLANT: ONGOING CONTACT**
 - **Visit frequently (2-3/week or more)**
 - **Help P/F address issues arising post-implant (e.g. media issues, end-of-life issues)**
 - **Help gather information, identify resources to address concerns**