

# What stumps SCROs?

---

**Bernard Lo, M.D.**

**UCSF**

**Nov 8, 2006**

# Is researcher responsible for actions of collaborators?

---

- **Collaboration essential to research**
  - Outsource work considered unethical at home
  - Take advantage of lax standards or oversight?
- **“Appropriation of evil”**

# Is researcher responsible for actions of collaborators?

---

- History of SCNT scandal
- Fervent opponents of hESC attack  
weakest link

# What responsibilities?

---

- **Approval in other country necessary but not sufficient**
- **Researcher has burden of evidence**
  - Cannot claim ignorance
  - Cannot accept declaration of collaborator
- **Institution, SCRO address dilemma**
  - Justify decision to public

# Compliance with universal ethical standards

---

- **Acceptable medical risk**
  - Risk of ovarian hyperstimulation at site?
- **Informed and free consent**
  - Assess consent process as well as consent form

# Compliance with universal ethical standards

---

- **Absence of undue influence**
  - Level of payment justified?
- **Review by IRB or REB** □
  - Quality of review?

# Concerns about payment

---

- **Undue influence**
  - Can address concerns about risk and consent
- **Payment per se unethical?**

# Payment policies in other jurisdictions

---

- **Explicit policy to allow**
  - After deliberation, public input
  - Persuasive rationale?
  - Reflect values of country
- **No specific policy**

# Import hESC line

---

- **Universal ethical standards**
- **Jurisdictional requirements**
  - Payment to donors explicitly justified

# SCRO process and procedures

---

- **Cannot copy IRB procedures**
- **Full, expedited, administrative review**
- **Coordination with other reviews**
- **Conflicts of interest on SCRO**
- **Nonaffiliated members**

**Establishing procedures for institutional oversight of stem cell research. Acad Med, in press.**