

Human Subjects Issues in Quality of Care Surveys

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Background

- Federal agencies adopted Common Federal Policy for Protection of Human Subjects
- Requires IRB approval for research involving human subjects
- Exemption for (some) survey research

General Survey Research Concerns

- Biomarkers
- Special populations
- Sensitive subject matter
- Observation of clinical consultations

Issues for Quality of Care Surveys

- Informed consent
- Protection of confidentiality
- Protocols for intervening during observation
- Consent for client follow-up studies

Who are the Subjects?

- Client (exit interview and observation)
- Provider (observation)
- Informed consent required from both clients and providers

Informed Consent

- Purpose of study
- Procedures involved
- Risks and benefits
- Right to withdraw consent/refuse questions
- Confidentiality
- Documentation (signed)
- Appropriate language (potential conflict)

Other Issues - Confidentiality

- Names of clients not collected
- Names of providers not recorded on observation forms
- No provider number on provider consent form
- Training

Other Issues

- Female nurses used for observation
- Some distance between observer and consultation
- Protocol for intervening during an observation