CASE STUDIES

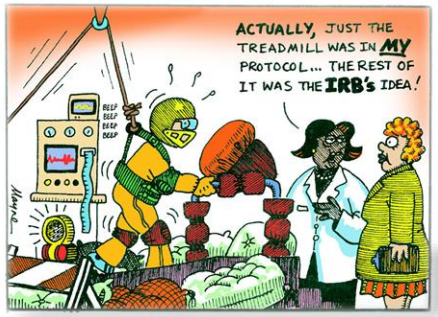
MOCK IRB MEETING

Criteria for Approval

Risks are reasonable

Risks and benefits that may result from the research.

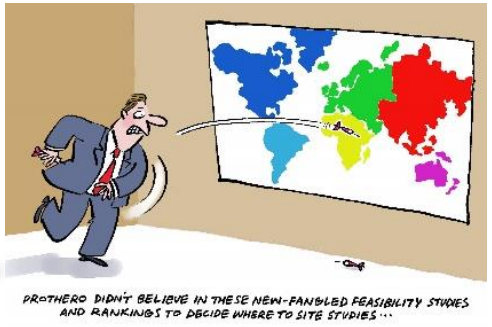
Do not consider possible long-range effects of applying knowledge gained in the research as among those research risks.



Risks are minimized

Evaluate if the research design is sound.

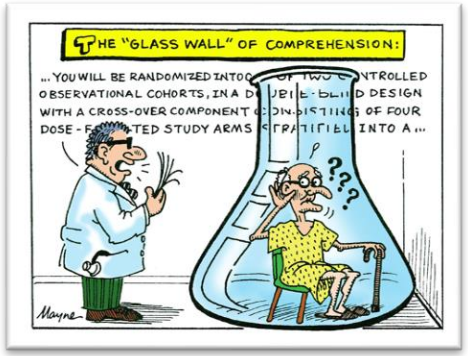
Evaluate if subjects will be exposed to unnecessary risks.



Subject selection is equitable

Review eligibility criteria.

Consider if research burdens and benefits are distributed fairly.



Informed Consent

Consider if information provided is adequate.

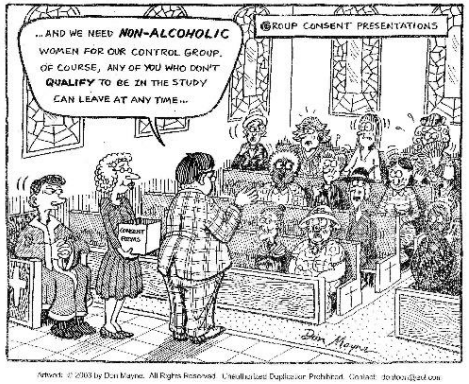
Consider who is giving consent and who is obtaining consent.

Consider documentation of consent.

Adequate provisions for confidentiality

Consider if only minimum necessary data is collected.

Evaluate plan for access control, security – electronic and physical.



Adequate provisions for privacy

Privacy refers to persons and their interest in controlling access to themselves.

Consider recruitment strategy.

Data and Safety Monitoring

DSMP for all studies greater than minimal risk.

Consider if safety and efficacy data will be reviewed, frequency of review and who will review this.

Additional protections for vulnerable populations.

Children – parental permission – one or both parents, assent. Risk category – no greater than minimal risk (404), greater than minimal risk with prospect of direct benefit to participant (405), minor increase over minimal risk with no prospect of direct benefit (406).

Pregnant women – is there a prospect of biomedical benefits?

Prisoners- specific regulatory criteria – refer to policy.

IRB OUTCOME

Approve

Pending Modification

Defer

Disapprove

Table

Assess Cancer in Ovarian Tumors With Biomarkers

- Purpose: Evaluate novel proteomics-based blood test to differentiate benign from malignant ovarian tumor.
- Enrolling: Women with ovarian tumors scheduled for surgery. N= 1000 participants
- Method: Whole blood collection for analysis.
- Primary outcome: Proportion of actual ovarian cancer cases among OvaRl positive patients is higher than the proportion of actual ovarian cancer cases .

https://clinicaltrials.gov/ct2/show/NCT00436189

Infusion of Panobinostat (MTX110) Into the Fourth Ventricle in Children and Adults With Recurrent Medulloblastoma

- Purpose: Safety and efficacy of panobionstat
- Enrolling: Children with recurrent medulloblastoma, N=5
- Method: Ventricular access device placed in fourth ventricle. 4 infusions per week X 6 consecutive weeks = 24 infusions.
- Primary outcome: Number of participants with grade 3 through grade 5 new neurological adverse events that are related to study drug 4 months post intervention

https://clinicaltrials.gov/ct2/show/NCT04315064

MATCH Precision Medicine Cancer Trial

- Purpose: Determine whether matching certain drugs or drug combinations in adults whose tumors have specific gene abnormalities will effectively treat their cancer, regardless of their cancer type
- Enrolling: Adults with any solid tumor, lymphoma, or myeloma OR a type of cancer for which no standard treatment exists that has been shown to prolong overall survival
- Method: Lab identifies tumor gene abnormalities being studied in NCI-MATCH. If the patient matches to the trial, the lab contacts the patient's physician. Patient and physician decide whether to join.
- Primary outcome: Objective response, overall survival, progression free survival.

https://clinicaltrials.gov/ct2/show/NCT02465060

An Online Initiative to Understand the Experiences of Those Impacted by a Cancer Diagnosis

- Purpose: To better understand the psychosocial experiences and needs of people who have been impacted by cancer, including patients, survivors and caregivers.
- Enrolling: Adults who have received a cancer diagnosis or who are caring for someone with cancer. N=15,000
- Method: Web-based platform to distribute cross-sectional and longitudinal surveys - focus on the social, emotional, physical, financial and decision-making experiences of those who have been diagnosed with cancer and their caregivers.
- Primary outcome: Self-reported quality of life measures

https://clinicaltrials.gov/ct2/show/NCT02333604

Early Palliative Care With Standard Care or Standard Care Alone

- Purpose: To better understand the psychosocial experiences and needs of people who have been impacted by cancer, including patients, survivors and caregivers.
- Enrolling: Adults with newly diagnosed incurable lung or non-colorectal gastrointestinal cancer. N= 400 patients, 300 family caregivers
- Method: Patients randomized to receive early palliative care and standard oncology care vs standard oncology care.
- Primary outcome: To determine the efficacy of early integrated palliative care on patient reported quality of life at 12 weeks using the FACT in patients

https://clinicaltrials.gov/ct2/show/NCT02349412

Xenograft Mouse Model of Solid Tumors

- Purpose: To develop mouse xenograft models of cancer using fresh biopsy tissues. NGS analysis using commercial cancer panels. Correlate molecular alterations with drug response/resistance.
- Enrolling: Adults with newly diagnosed incurable lung or non-colorectal gastrointestinal cancer. N= 400 patients, 300 family caregivers
- Method: Samples collected from patients with solid tumors. Quarterly data collection from medical records.
- Primary outcome: Mouse models will be created by commercial partner.

https://clinicaltrials.gov/ct2/show/NCT02349412

References

- OHRP Regulations - 45 CFR 46
- OHRP Guidance for Investigators
- FDA Regulations - 21CFR 50 ; 21 CFR 56
- FDA Information Sheets – IND
- FDA Information Sheets - IDE

COVID-19 Vaccine Challenge Trial

- Controlled Human Infection Model - a well-characterized strain of an infectious agent is given to carefully selected adult volunteers in order to:
  - better understand human diseases,
  - how they spread,
  - find new ways to prevent them,
  - find new ways to treat them.
- These studies play a vital role in helping to develop vaccines for infectious diseases.

https://clinicaltrials.gov/ct2/show/NCT04865237/