



THE UNIVERSITY OF TEXAS  
**MD ANDERSON**  
**CANCER CENTER**

*Making Cancer History®*

# Insurance Coverage for Clinical Trials: Patient and Ethical Perspectives

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# National Patient Advocate Foundation

- Non pro-fit organization
- Improve access to health care services through policy reform
- Informed by experience of Patient Advocate Foundation
  - Counseling and case management to patients
  - 6.2 M patients
  - 25% Medicare beneficiaries
  - 78% patients with cancer

# Importance of Clinical Trials

- Advance scientific knowledge
- Improve treatment
- Cure or control disease
- Relieve symptoms and toxicities of disease and treatments

# Factors Influencing Participation in a Clinical Trial

- Understanding of importance of clinical trials
- Belief that treatment in clinical trial offers as good a chance as any of disease cure/control
- Willingness to accept potential side effects of investigational or experimental treatment
- Financial cost of clinical trial participation

# Treatment Coverage Only Through Clinical Trial

- Patient only wants treatment on one arm of randomized trial
- Treatment is not available to all patients
- Patients may not report side effects of treatment for fear of being taken off study
- Patient age as criteria

# Patient Only Wants Treatment on One Arm of Randomized Trial

- Voluntariness of consent is questionable
- Patient may withdraw consent if randomized to “wrong” arm of trial
- Patient may seek treatment at different institution in effort to achieve desired randomization
- May bias research sample and compromise trial results

# Treatment Is Not Available to All Patients

- Patients may not perceive that treatment is available even when it is
- Patients may decline participation in a clinical trial for fear of losing all or part of coverage
- Patients may decline participation in a clinical trial for fear of additional expenses associated with participation
- Physicians may not offer all treatment options to a patient if insurance coverage is not available
- Patients are often aware of therapies being investigated in clinical trials
- Patients may be aware that they are not offered the same treatment options as other patients

# Patients May Not Report Side Effects for Fear of Being Taken off Study

- Many new cancer therapies are:
  - Very effective
  - Very expensive
  - Must be taken for extended period of time
- Patients may be able to receive a therapy only on a clinical trial when the medication is provided for free
- Patients may be reluctant to report side effects for fear they will be removed from the trial and lose the free medication



# Patient Age as Criteria

- May be specified by investigator or payor
- Concerned with harm treatment may cause to older patient
- Alternate method of determining eligibility
  - Functional status
  - Co-morbidities that relate to treatment



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