

# National Public Forum on Payment Policy

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- Volunteering study subjects are the lifeblood of clinical & translational research.
- Refusal to participate, or the decision to abandon an ongoing clinical study, are often based on intangible factors.

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- No where else is the subject's perception so near to reality as when a study subject makes the decision to participate OR withdraw from a clinical study based on their perceived “ease” of participation.
- Thus, short of inducement or coercion, study subject enrollment and retention ought to be ‘facilitated’ to the largest possible extent by institutions, sponsors, funding agencies, investigators, and research staff alike.

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- Thematic fears or concerns on the part of research study subjects usually relate to study costs and treatment coverage policies:
  - ‘I could be refused Medicare benefits because my medical care is being taken care of through a research study’.
  - ‘Medicare could refuse to pay for any medical care thought to be related to a complication of my participation in a research study’.
  - ‘Prior partial requests for medical supplies or medications to Medicare prevent coverage of additional items in the future’.
  - ‘I could get stuck with medical bills that Medicare or the study sponsor refuse to cover’.

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The missing link is a quantitative assessment of how often these concerns play a critical role in the decision to consent to participate or to leave a study prematurely.

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- Recommendations:
  - The final policy ought to be easily applicable and unambiguous.
  - It should be broadly communicated across the healthcare and clinical research environments so as to pre-empt misconceptions by patients about clinical study payments.
  - Appropriate policy language should be included in the study consent form to educate and reassure study subjects.