

Evidence suggests that employers and health plans are reluctant to pay for care delivered as part of a clinical trial. Such denials of coverage limit patient access to trials and could impede or bias clinical research. Unfortunately, these decisions are being made in the absence of accurate information about the cost of clinical trial participation. Preliminary estimates are available; but these come from small studies at only a few institutions. The Cost of Cancer Treatment Study is an ambitious effort to measure the incremental treatment cost of cancer trials and to address limitations of previous studies. Successful implementation is predicated on the participation and cooperation of the cancer community. If successful, the study will provide generalizable results that should be of great use to insurers, the cancer research community, and policymakers as they consider ways to finance clinical trial research.

A vibrant clinical research program is necessary to ensure continual improvements in the quality of patient care. However, with the current uncertainty about what the additional costs of clinical research are, it is difficult to achieve consensus on how they might be financed. The foregoing documents the design and methods of the Cost of Cancer Treatment Study in its efforts to provide such information on the costs of clinical research.