Study Group Working Notes #11: Compensation & Access to Therapies

Study Group: NA

Background: Two issues that have been raised in Working Group deliberations and Public Comments are (1) compensation for research participants who are injured as a result of participation in biomedical research and (2) access to therapies.

With regard to compensation of research participant, there have been recommendations by national task forces to develop a national compensation program for care and compensation patterned after the federal worker's compensation system. To date there is no California or federal program to compensate injured research participants.

Access to therapies will likely depend on the clinical efficacy of a particular treatment. There is good reason to believe that efficacious therapies for chronic disease already covered under national insurance or private insurance would potentially be eligible for funding even during the clinical trail stage. Consider the example of islet cell transplants. Under federal law, for services performed on or after October 1, 2004, Medicare will cover islet cell transplantation for Medicare beneficiaries with Type I diabetes who are participating in a NIH clinical trial. The islet cell transplant may be done alone or in combination with a kidney transplant. Medicare also covers the costs of immunosuppressive therapy to prevent rejection of the transplant islet cells and routine costs. As the islet cell transplant example suggests, clinical efficacy is a primary determinant for therapy funding.

All California insurers, including the State Medi-Cal program, must cover routine patient care services for research participants provided in connection with Phase 1, Phase II, Phase III, or Phase IV cancer clinical trials meeting certain requirements. This law sets a precedent for funding participation in research trials. This model could be expanded to other health outcomes.

Recommendation and/or Proposed Language:

There is no model policy for injury compensation. CIRM could *permit but not require* such a program in funded institutions.

Demonstration of clinical efficacy appears to be the most effective means of enhancing access to therapies as evidenced by this islet example. Access can be further enhanced by mandating compensation in trails. These remedies appear to be beyond the scope of the CIRM and its working groups.