



## ADIRONDACK HEALTH

TITLE:	Payments to Study Subjects	POLICY #: SOP-13
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 8/15	REVIEWED/REVISED: 2/16	
APPROVED BY:		
Patricia Druzba, PhD (Chair, IRB)		
Chandler Ralph (CEO/President)		

1. In the early phases of drug, device or biologic research, Phase I especially, it is not uncommon for subjects to be paid for their participation, since they are generally normal healthy volunteers and many specimens are collected over short periods of time. Since the AMC is not yet established as a Phase I unit, payments for Phase I participation will not be approved.
  
2. In the later phases of development, Phases II, III and IV, payment to subjects may be made for such items as expenses, mileage and possibly lost wages. All information concerning payment, including the amount and the schedule, must be clearly spelled out in the informed consent, not the screening consent.
  
3. Any payments to study subjects are not to be considered benefits and must be specifically outlined for the IRB, not just in the consent. If health benefits to the subject are remote or non-existent, small financial incentives may be used if approved by the IRB.
  
4. Payments to subjects must accrue as the study progresses. Partial payments, for example, after the completion of a part of a study, may be made. Complete payment must not be contingent on completion of the study. Payments must be prorated in order to be considered equitable. Payments to subjects who have withdrawn, either voluntarily or involuntarily, from the study may be made at the time they would have completed the study had they remained a participant, unless the study completion time is indeterminable. In that case, the prorated payment should be made at the time of withdrawal.
  
5. The entire payment may not be contingent upon completing the study, however a small bonus for study completion may be made provided it is not so large as to be considered coercive or as creating an undue influence. Any such bonus payments must be approved in writing by the IRB.
  
6. Non-monetary payments, such as gift cards or certificates, may be approved by the IRB, provided there is a good reason for it and the amounts are not coercive.
  
7. Study supplies, such as carrying bags, pill cutters and the like are not considered compensation and do not require IRB approval.

<b>TITLE:</b> Payments to Study Subjects	<b>DEPARTMENT:</b> IRB	<b>POLICY #:</b> SOP-13
---	---------------------------	-------------------------

8. Direct compensation to minors is a difficult issue. Money payments to a teenager, for example, may create a subtle form of coercion. Money payments to a toddler, might be meaningless. Therefore, payments to minors will be discussed at the IRB meeting on a case-by-case basis after request by the Investigator.

**REFERENCES:**

CFR (Code of Federal Regulations): 21 CFR 50.20  
C10MS Guidelines #4