

## Guidance Regarding the Application Professional Fees to a Clinical Research Study

### General Policy

It is Partners HealthCare policy to charge research funds for professional fees associated with research-specific clinical services performed in the course of a clinical research study. Professional Fees are applied in accordance with the study budget, sponsor agreement and applicable state and federal law. A Professional Fee is the price charged for a healthcare provider's time and professional expertise providing a clinical service to a patient or research subject. Professional Fees are typically charged per encounter or procedure at an established rate. Should an Investigator have committed effort on a sponsored research study, that Investigator may not charge Professional Fees to the fund, but, rather, their Professional Activity would be compensated through direct salary support (effort) from the corresponding research fund.

### Federally Funded Clinical Research

If a healthcare provider has committed professional effort on a federally sponsored clinical research study and he or she is performing research specific clinical services during the course of the study, professional fees **must not** be charged to the research fund for those services. Contact your institution's Research Compliance or Research Billing Compliance office to ensure that Professional Fees are not applied to your study account when a Healthcare provider has committed effort on a federally sponsored study.

If a healthcare provider does not have committed professional effort on a federally sponsored research study, then research-specific clinical services performed by the provider during the course of the study **must** be charged to the study consistent with the study budget and the terms and conditions of the award.

### Non-Federally Funded Clinical Research (including Industry, Foundation, and Departmentally Funded Studies)

If a healthcare provider has committed professional effort on a clinical research project, and he or she is performing research specific clinical services during the course of the study, professional fees **should** not be charged to the fund for those services, unless the professional effort commitment is limited to administrative for non-patient care activities. Contact your institution's Research Compliance or Research Billing Compliance office to ensure that Professional Fees are not applied to your study account when a Healthcare provider has committed effort on a sponsored study.

If a healthcare provider does **not** have committed professional effort on a clinical research study, it is appropriate to charge the study fund for professional fees associated with services rendered during the course of study. Professional fees should be applied in accordance with the study budget and sponsored research or clinical trial agreement.