

Guidance on the Inclusion, in Research Consent Forms, of Appropriate “Cost Language” When a Research Study Includes Any Use of UPMC Clinical Services

Goals

1. To provide research subjects with information about their responsibility for any costs associated with research study participation when UPMC clinical services are used.
2. To describe those subjects’ financial responsibility accurately and understandably without being overly detailed.
3. To identify an office or individual who can provide the participant with more information about their financial responsibility.

Definitions

Routine Clinical Services: Patient care services (diagnostic and/or therapeutic procedures, drugs, devices, laboratory assays, other services) that individuals would ordinarily receive for their medical treatment, regardless of whether they are participating in the study. Sometimes these services are described in the research protocol and included in the consent document. There is no requirement that they be described in the consent form, but if they are, investigators must make it clear that those specific procedures are not research, but are part of routine clinical care.

Note: Although the term ‘*conventional care*’ has been used by Medicare in the National Coverage Decision (NCD), ‘*routine clinical services*’ is the preferred term, as indicated in the proposed revision to the policy. The term ‘*Standard of Care*’ should be avoided as it has different meanings in different situations.

Example: an oncology patient is enrolled in a study and receives a new chemotherapeutic agent as part of a research protocol, along with a standard chemotherapeutic agent. Because the standard chemotherapy and related monitoring are routine clinical services, these are the patient’s financial responsibility and may be covered by insurance. The new chemotherapeutic agent is research and because it is unlikely to be covered by insurance, the subject must be informed that either (a) the research project will cover the costs, or (b) costs will be the responsibility of the subject.

Research Only Services: Procedures, drugs, devices, services, interventions or interactions (including questionnaires and interviews) that are described in the research protocol and are occurring solely for research purposes.

Example 1: If conventional treatment for the patient’s medical condition includes a CT scan every eight weeks during the 16 week treatment period (i.e., 3 CT scans), but the research protocol requires additional monitoring and

specifies that CT scans are done every four weeks (i.e., 5 CT scans), the two additional CT scans are not routine clinical care but are research-related. Because research services are generally not covered by health insurance, the cost of the two additional scans are usually covered by the study. If not, study participants must be informed that they will be responsible for those costs.

Example 2: a research subject participating in an MRI study that has no relationship to their routine clinical care comes to the UPMC Neuroimaging Center and has 2 scans and a blood sample that is analyzed at a UPMC laboratory. This is a research procedure and as a consequence, the subject will not be charged. However, because these research procedures are conducted at UPMC, a medical record may be generated, a cost center will be charged, and the possibility exists that the subject may inadvertently receive a bill. The consent form must include language informing subjects who to contact if they receive a bill in error.

Suggested Consent Form Language In Response to the Question:

“Are there any costs to me or my insurance carrier if I participate in this study?”

For Studies in which Research Subjects are In- or Outpatients and Receive Both Routine Clinical Services and Research Only Services:

Some of the services you will receive are being done only because you are participating in this research study. Examples of these ‘research only’ services include [*insert significant **study drug, device or procedures** (e.g., additional CT scans; interview)*]. Those services will be paid for by the study and will not be billed to you or your health insurance company.

In addition, some of the services you will receive during this research study are considered to be “routine clinical services” that you would have received even if you were not participating in the research study. Examples are [*insert significant **conventional care drug, device, or procedures***]. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs. To obtain more detailed information about what routine clinical services your health insurance is likely to pay for, contact a UPMC financial counselor [**NOTE: Research Team must provide information on who to contact. This can be included in the consent, or perhaps better, on a separate information sheet, since it may vary, depending on the facility**].

For In- or Outpatient Studies Limited to the Collection of Data Related to Routine Clinical Services

This research study is limited to the collection of information about you that is obtained during your regular clinical care. All of the services you receive during this study are considered to be "routine clinical services" that you would have received even if you were not participating in the study. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

For Studies Involving Research-Only Services at UPMC

You will not be charged for any of the research activities [*insert procedure* (e.g., *blood sample and MRI scans*)] that are administered to you during this study. If you think that you or your health insurance has been charged, please contact a member of the research team and the UPMC billing office that sent the bill.

NOTE: when including procedures or services in the consent form, it is *not* necessary nor is it advised to list and enumerate *every* procedure; the goal is to provide the subject with a limited number of examples of the sorts of procedures that will be undertaken for research and/or clinical purposes.