

Clinical Research Billing Top 10 List

The Top 10 Things You Do NOT Want to do Related to Clinical Research Billing



Number 10 . . .



- **Do not bill insurance for anything that is not “reasonable and necessary.”**
 - Experimental and investigational items/services are generally not reasonable and necessary.
 - Items/services solely for data collection or screening are generally not reasonable and necessary.
- Items/services billed to insurance related to clinical research should generally be those items routinely provided to patients not in a study.



Number 9 . . .



- **Do not get paid by a sponsor more than “fair market value” especially if the sponsor is someone from which UMHS also buys products or services.**
 - Compensation in excess of “fair market value” can be construed as “kick back” if one purpose is to generate business between the parties.
 - Consider the payments outlined in your sponsor budgets and assess if they seem fair for the work and services being provided.



Number 8 . . .



- **Do not back into a sponsor research budget.**
 - Create your own internal budget to identify how much it will cost you to do a particular study before you review a sponsor budget.
 - Make sure you use appropriate billing codes and the associated research charges when creating your budget. Use the institutional research discount rates and codes should not be selected based on the budget.
 - Assess the feasibility of completing the research and know how much money you need before you negotiate with a sponsor or make funding requests.



Number 7 . . .



- **Do not bill Medicare for items/services associated with an investigational device research study without prior approval from the local Medicare contractor.**
 - Submission must be made to Medicare contractor if anything related to a FDA category A or category B IDE research study is to be billed to Medicare.
 - Contact the CRBU if you need guidance on this.



Number 6 . . .



- **Do not bill Medicare for any items/services provided within the context of a research study if it does not meet the “qualifying” criteria.**
 - This includes items/services considered standard of care or routine for the patients enrolled in the study.



#6 continued

CMS Centers for Medicare & Medicaid Services

- **“Qualifying” clinical trials must meet the following criteria as established in the CMS NCD.**
 - Subject or purpose of trial must be evaluation of an item or service that falls within a Medicare benefit category.
 - Have therapeutic intent (not designed exclusively to test toxicity or disease pathophysiology)
 - Enroll patients with a diagnosed disease (trials of diagnostic interventions may enroll healthy patients as “controls”)
 - Meet the seven desirable characteristics. Some studies have been deemed by CMS to meet these characteristics



#6 continued

CMS Centers for Medicare & Medicaid Services

- **“Deemed” clinical trials are those studies:**
 - Funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
 - Supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
 - Conducted under an IND or drugs trials that are exempt from having an IND



Number 5 . . .



- **Do not use money from a sponsor provided to pay for patient-specific items or services to cover research effort.**
 - Read your clinical trial agreement and review the budget in the agreement to see for which items the sponsor has agreed to pay.
 - (HINT: You don’t have to be a lawyer to understand the agreement.)
 - Do not assume that the sponsor is giving you money to use for any purpose associated with the research.



Number 4 . . .



- **Do not bill insurance or the subject for any item or service that the informed consent says will be provided.**
 - If the patient signed a consent that says this *even if the language was written in the consent by mistake*, it must be followed.



Number 3 . . .



- **Do not bill insurance or the subject for any item or service for which someone else has agreed to pay.**
 - This includes complications or adverse events. Look for language related to this in your contract/clinical trial agreement.



Number 2 . . .



- **Do not bill insurance or the subject for any item that you received for free.**
 - If a sponsor provided a device or product for free, you must ensure that no bill is sent out related to that item.



Number 1 . . .



- **Do not keep money to which you know the institution is not entitled.**

- Reconcile your research accounts and identify any items/services that should have hit your research account and did not.
- If these missing items were billed out, the insurance company and patient need to be given the money back including any co-pays and deductibles.



What Should I Do . . .



- **Do** make sure all study documents are consistent with each other.
- **Do** work with your billing manager and the Budget & Rate Setting Office to make sure you are coding items/services correctly and to get accurate charge amounts.
- **Do** contact the CRBU or the Grant Review and Analysis Office for assistance.



For More Information . . .



Clinical Research Billing Unit:
CRB-Unit@umich.edu or 998-6880

Grant Review & Analysis Office:
msgrants@umich.edu or 763-4272

Information on clinical research billing
is also available at:

<http://www.med.umich.edu/u/compliance/areas/crb/index.htm>



Institutional Review Board Top 10 List

*The Top 10 Things the IRB
Wants You to do with the
Informed Consent Document
Related to Clinical Research
Billing*



Number 10 . . .



Section 4. Information About Study Participation

4.1 What will happen to me in this study?

- **Do include everything outlined in the study protocol.**

- Distinguish the research-only/investigational procedures and/or treatment from routine/regular care
- Note clinical tests/procedures that may be repeated (e.g. CXR)
- List eligibility procedures
- List data collection (e.g. blood samples (PK's), office visits, survey, etc.)
- Describe any wash-out periods or other deviations from the subjects' regular regimen
- Explain if research-only tests will be analyzed or assessed in a different way to the standard of care (e.g. results analyzed at the end of the study and then made known to the subject)



4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Comment [UpdateCRB11]: Explain in lay terms, *usually* in chronological order, what will happen to subjects during the study. If appropriate, describe medical care or other procedures that would be performed whether or not the subject participated in the study. In this case, be sure to distinguish the research-only or experimental procedures from routine or regular care.

ALL research-only/experimental procedures and treatments must be listed in this section, including any clinical tests or procedures that may have to be repeated in order to conform to the study protocol (e.g., repeat CT scan that was done 6 months ago because protocol requires CT scan within last 4 weeks).

The following should always be addressed, as applicable:

- Eligibility Testing (e.g., blood tests, CT Scan, office visit, EKG, etc.),
- Experimental intervention/interaction (e.g., study drug or device, experimental neuropsychological test, etc.)
- Data collection (e.g. blood samples, CT scan, office visit, EKG, survey, etc.)
- Other research procedures or activities

Be sure to describe:

- any wash-out periods or other deviations from the subjects' regular regimen.
- if research-only tests will not be analyzed or assessed in a timely manner for clinical care purposes



Number 9 . . .

Section 5. Information About Risks and Benefits

5.1 What risks will I face by taking part in the study?
What will the researchers do to protect me against these risks?

- Do include the items/services being completed for the study in order to minimize risks to the subject.



5. INFORMATION ABOUT RISKS AND BENEFITS


5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:
The researchers will try to minimize these risks by:
As with any research study, there may be additional risks that are unknown or unexpected.

Explain the risks and discomforts in clear, simple, concise terms (consider using bulleted format). Please note that "none" or "not applicable" are not considered appropriate for this section, since even studies involving minimal risks do have foreseeable risks, such as discomfort or inconvenience, or risk to confidentiality.

- Note that federal regulations require that research consent documents list ALL reasonable foreseeable risks, stresses, and discomforts of ALL aspects of participation in a study, not just the most serious or common side effects of a research intervention or procedure (e.g., study drug or device). Avoid statements like "The main risks are..." or "Side effects include..." as these statements would not comply with the federal requirement to list all foreseeable risks. However, investigators are encouraged to stratify the risks by categories such as
 - "The most common side effects (occurring in more than 10% of patients) are..."
 - "Less common side effects (1% - 10% of patients) are..."
 - "Rare side effects (less than 1% of patients) are..."
- Remember to include the risks of any research-related monitoring procedures such as biopsies, blood draws, or radiological tests, as well as the risks of allergic reactions and adverse drug-drug interactions, as applicable. Include risks to a fetus if women of child-bearing potential may participate in the study. It is not necessary to list risks associated with non-research procedures.

When appropriate, also note here that in order to minimize risk, those procedures already being performed on subjects for diagnostic or treatment purposes will be used for the research. List the procedures these include. This list can be general or specific, as appropriate. For example: "To avoid extra blood tests we will use the results of blood tests you are having for your clinical care."



Number 8 . . .

Section 5. Information About Risks and Benefits

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

- Do explain the items/services being completed per protocol in order to monitor the subject for study complications.



Number 7 . . . 5.2 cont'd

- Do make sure there is no payment information for first-aid or emergency care in Section 5: "Information on Risks and Benefits".
 - Payment information should be listed in Section 8. "Financial Information".



5. INFORMATION ABOUT RISKS AND BENEFITS

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. *(You should also tell your regular doctors.)*

COMMENT [UpdateCRB16]: Explain how risks are monitored and reduced. For example, explain that the subject will receive a physical examination and blood test once a week after beginning treatment with the new drug or device. Also explain what steps will be taken if complications or adverse effects are detected (e.g., "first aid will be provided" or "the drug dose will be lowered or stopped altogether").

Information about payment for first aid or emergency care should be provided in Section 8 "Financial Information" and not here in Section 5 "Risks and Benefits." Make sure there is no promise for the University of Michigan to pay if insurance does not.



Number 6 . . .

Section 8. Financial Information

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

- Do include what the internal or external sponsor will pay for.
 - Reconcile this against what procedure/treatment items and services are listed in 4.1.
 - If there are no costs for the study state "There are no costs or billing for this study".



Number 5 . . . 8.1 cont'd



- Do include information on what the subject will pay if the internal or external sponsor will not cover the study-related items and services.

– E.g. “The study will not cover the cost of the follow-up chest x-ray after the second cycle of treatment”.



Number 4 . . . 8.1 cont'd



- Do include information if the sponsor has agreed to pay for study-related complications, monitoring side effects/problems, health care given as part of SOC and items/services to provide a drug or device.

– List any known or expected insurance coverage problems.



Number 3 . . . 8.1 cont'd



- Do make sure there are no promises in the informed consent that the University of Michigan will cover the costs if the sponsor, third-party payor (insurance company) or subject cannot.

– For Co-pays and deductibles don't make promises regarding how much or how little the subject must pay – amount varies.
 – If sponsor promises payment it should be consistent with the Clinical Trial Agreement (CTA)/Contract. Don't always assume the sponsor will pay for items not otherwise covered.



8. FINANCIAL INFORMATION

8.1. Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

If you or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Treatment of complications
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

Comments:

- Comment [1] (b) (6) (CR24): If there is no cost for the study, delete all of the language under 8.1 EXCEPT FOR THE LAST PARAGRAPH and add "There is no cost for being in this study."
- Comment [1] (b) (6) (CR25): "The study will pay for" means the internal or external sponsor.
- Comment [1] (b) (6) (CR26): The discussion in section 4 will have made clear what items or services are research-related. The final approved language may seem a good idea to provide to subjects.
- Comment [1] (b) (6) (CR27): If complications are paid for by the internal or external sponsor, you should say so here. For example, "the sponsor will pay for..."
- Comment [1] (b) (6) (CR28): If the internal or external sponsor has explicitly agreed to pay for the items or services in this list, edit this section.
- Comment [1] (b) (6) (CR29): If the internal or external sponsor has agreed to provide limited payment for complications that occur as a result of...
- Comment [1] (b) (6) (CR30): If appropriate, identify any specific known or expected insurance coverage problems for the study, and modify the language.
- Comment [1] (b) (6) (CR31): DO NOT DELETE THIS last paragraph (i.e., "By signing this form...").

Number 2 . . .

- Do make sure the information listed in the informed consent document match the

- Protocol
- Internal Budget
- External Budget
- Contract (signed/executed)
- Billing calendar (final)
- Recruitment documents



Number 1 . . .

- Do notify the IRBMED and CRBU if there are any changes to the informed protocol, consent document, contract or budget (as applicable) after you receive IRB approval.



Do NOT . . .

- Wait until the IRBMED is ready to review the project before consulting with the Clinical Research Billing Unit.
- Wait until DRDA approves the clinical trial agreement (CTA)/contract



For More Information . . .



Institutional Review Board Office:
irbmed@umich.edu or 763-4768

Information on IRBMED
is also available at:
<http://www.med.umich.edu/irbmed>

