# Cost Language for Drug or Device

## 1. Select Appropriate Cost Language for Drug or Device

<table>
<thead>
<tr>
<th>Selection</th>
<th>Description</th>
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| ☐ | If you choose to take part in this study, will it cost you anything?  
The study *<drug or device>* will be provided at no cost to you while you are participating in this study. |
| ☐ | If you choose to take part in this study, will it cost you anything?  
The cost of *<insert name of drug or device>* will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or co-payments for those services, and any non-covered or out-of-network services. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information. |
| ☐ | If you choose to take part in this study, will it cost you anything? (Select this option if Payment Option #1 is selected on CTA Checklist, Question #3.)  
The Sponsor will pay for all medical services provided as part of your participation in this study. There will be no cost to you. If you receive a bill related to this research study, please contact *<insert Principal Investigator’s name and phone number>* or the study coordinator at *<insert Study Coordinator’s name and phone number>*. |

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*Select Appropriate Cost Language for Medical Services*

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| ☐ | If you choose to take part in this study, will it cost you anything?  
No. There will be no extra cost to you for participating in this Research Study. |

Please note: This default costs template language is to be used for research studies that **DO NOT** require a *Billing Compliance Review* by the Research Administration and Compliance (RAC) office. For more information regarding which studies require a RAC review, see [http://rac.med.ufl.edu/preparation/rac_dsr_irb/rac/](http://rac.med.ufl.edu/preparation/rac_dsr_irb/rac/).

If your study **DOES** require a *Billing Compliance Review*, The RAC office will provide both the Costs and Subject Injury language for your consent(s) via the *Financial Language Assessment (FLA)*. You will need to ensure that the FLA language is used in your consent(s). For more information regarding the process, see [http://rac.med.ufl.edu/preparation/rac_dsr_irb/fla/](http://rac.med.ufl.edu/preparation/rac_dsr_irb/fla/).
<table>
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<th>Option</th>
<th>Description</th>
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| [ ] | **If you choose to take part in this study, will it cost you anything?** *(Select this option if Payment Option #2 is selected on CTA Checklist, Question #3.)*  
The Sponsor will pay for the medical services that you receive as part of your participation in this study as described in the question, “What Will Be Done Only Because You Are In This Research Study”. This may include some medical services that you would have received if you were not in this study. All other medical services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information. |
| [ ] | **If you choose to take part in this study, will it cost you anything?** *(Select this option if Payment Option #3 is selected on CTA Checklist, Question #3.)*  
The Sponsor will pay for all Protocol-required medical services that you receive as part of your participation in this study that are not routine, standard-of-care services. All other medical services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information. |
| [ ] | **If you choose to take part in this study, will it cost you anything?** *(Select this option if Payment Option #4 is selected on CTA Checklist, Question #3.)*  
Any medical services provided to you during your participation in this study would have been provided to you if you were not in this study. These medical services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or co-payments for those services, and any non-covered or out-of-network services. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information. |
| [ ] | **If you choose to take part in this study, will it cost you anything?** *(Select this option if Payment Option #5 is selected on CTA Checklist, Question #3.)*  
The ICF language must be drafted consistent with the description of the Payment Consideration in the CTA. The language must be written at an 8th grade level. Please have ORA review this language BEFORE submitting to the WIRB. Email drafts to regina.leonard@jax.ufl.edu or call Regina Leonard at 244-9729 for more information. |