Pre-Activation Eval – Study Coordinator

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| **Short Study Title**: |  |

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|  |  | Y | N | N/A |
| 1. | In a qualifying clinical trial, does ICF Benefits section align with Protocol regarding any possibility of therapeutic intent?  *(meaning ICF should not state there is NO benefit)* |  |  |  |
| 2. | Does ICF cost sections language align with the MCA? |  |  |  |
| 3. | Does the ICF cost language waive co-pays or deductibles? |  |  |  |
| 4. | Does the ICF language identify the responsible party for treatment of subject injury cost? |  |  |  |
|  | 1. Either sponsor pays OR insurance/patient is charged in usual manner |  |  |  |
|  | 1. Conditional language, where sponsor to pay after insurance, has been removed from ICF.   (*conditional language violates the Medicare Secondary Payer Rule).* |  |  |  |
| 5. | If MCA indicates a qualifying clinical drug trial, is the Medicare Advantage statement included?  *“If you belong to a Medicare Advantage Plan, the bills for your tests and services will be billed to regular Medicare first and the difference then billed to Medicare Advantage. This may result in higher copayment for you until your Medicare Advantage plan is billed while you are on the study.”* |  |  |  |
| 6. | If (or the study will) be assigned an NCT, is the ClinicalTrials.gov statement included?  ***“A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”*** |  |  |  |
| 7. | Is ICF subject compensation language in alignment with study budget? |  |  |  |
|  | 1. Does stipend match budget? |  |  |  |
|  | 1. If travel reimbursement is listed, QMC and QMC staff are not involved? (*as per QMC policies (3) on free/discounted services/transportation*): |  |  |  |