

WORKSHEET: Financial Interest Management

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This worksheet is used to consider management plans for financial conflicts of interests of investigators.

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1. Should the investigator be involved in:

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| 1.1 | ● Subject recruitment? |
| 1.2 | ● Determination of whether the subject meets inclusion/exclusion criteria? |
| 1.3 | ● Consent process? |
| 1.4 | ● Research interventions or procedures? |
| 1.5 | ● Clinical treatment of subjects, separate from the research interventions or procedures? |
| 1.6 | ● Clinical evaluation of subjects during the research, separate from the research interventions or procedures? |
| 1.7 | ● Adverse event evaluation and reporting? |

2. Considerations for a management plan

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| 2.1 | ● Disclosure of the financial interests to subjects |
| 2.2 | ● Public disclosure of the financial interests |
| 2.3 | ● Appointment of an independent research monitor |
| 2.4 | ● Change of personnel or personnel responsibilities |
| 2.5 | ● Disqualification of personnel from participation in all or a portion of the research |
| 2.6 | ● Reduction of the financial interest |
| 2.7 | ● Elimination of the financial interest |
| 2.8 | ● Severance of relationships that create financial conflicts |
| 2.9 | ● Modification of the research plan |
| 2.10 | ● Involvement of external individuals in key portions of the research |
| 2.11 | ● Transfer of IRB responsibilities |
| 2.12 | ● Retrospective review |
| 2.13 | ● Mitigation report |
| 2.14 | ● Monitor the implementation of the management plan |

3. Notes

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