# Management Plan Builder ****Algorithm(pulls data from the Reviewer Checklist to suggest a management plan based on an algorithm)****

**CODING FROM REVIEWER CHECKLIST**

**Investigator: [**Investigator]

**Department:** [Investigator.company]

**Title:** [title]

**Project ID:** [CRV ID]

The discloser has provided this additional information about the project:

* **Project description-**

[Conflict Review.CRV Form.2-1 Documents Read-only]

[Conflict Review.CRV Form.2-2 Abstract Read-only]

* **Additional information-**

[Conflict Review.CRV Form.Other Information Read-only]

* **Preferred contact information-**

[Conflict Review.CRV Form.Contact Information Read-only]

**1-SFI)** Does the investigator (or family member) have a significant financial interest related to the study? (Y/N)

**A-Rem)** Remuneration (Y/N)

**a)** Name of Business Entity (TEXT)
**b-Range)** Compensation Amount/Range

**B-Equity)** Equity (Y/N)

**a)** Name of Business Entity (TEXT)
**b-Traded)** Publicly Traded?
**c-Range)** Compensation Amount/Range

**C-IP)** IP (Y/N)

**a)** Name of IP w/ University Tech ID, if possible (TEXT)
**b-Commercialization)** Is the technology imminent of commercialization? (Y/N)
**c)** Is the technology licensed?
**d)** Royalties in the last 12 weeks

**2-Role)** What is the role of the investigator?

⚪ **A)** Principal Investigator
⚪ **B)** Co-Investigator
⚪ **C)** Other (Please Indicate Below)
[\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]

The discloser has provided this additional information about their responsibilities in the project:

[\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]

**3)** Will students or subordinates work on the study? (Y/N)

**3.1)** Please Specify:

**A-Students)** ☐ Students
**B-Subordinate)** ☐ Subordinates

**4-Blinded/Collection)** Can the data be blinded during collection? (Y/N)

**5-Blinded/Analysis)** Can the data be blinded during analysis? (Y/N)

**6-NonConflicted/Collection)** Can a non-conflicted individual, other than the investigator, collect the data? (Y/N)

**7-NonConflicted/Analysis)** Can a non-conflicted individual, other than the investigator, analyze the data? (Y/N)

**8-PossibleNewIP)** Is it possible that new IP could be generated from the results of this study? (Y/N)

**9-ProcurementAuthority)** Does the investigator have procurement authority in the company causing the conflict (Y/N)

**10-PHS)** Is the project funded by a U.S. Public Health Service (“PHS”) agency or the Department of Energy? (Y/N)

**11-HSR)** Is the project human subjects research? (Y/N) – (if it’s an IRB being reviewed in the CRV then prepopulate as Yes. Data from the IRB)
[Only show sections below if 9 is yes]

* **A)** Is this a multicenter trial? (Y/N) (data from the IRB)
	+ Participants from the U: [\_\_\_\_\_] (text)
	+ Total Participants: [\_\_\_\_\_] (text)
* **B-StudyDesign)** What is the study design? (data from IRB)
	+ [checkbox] **Non-Experimental and/or Descriptive Research Design:** collection and assessment of the participant's data and information without prospective manipulation of the participant's body, environment, or treatment.
		- [checkbox] Secondary/Archival Data Analysis or Retrospective Chart Review
		- [checkbox] Survey/Questionnaire Research
		- [checkbox] Interviews and Focus Groups
		- [checkbox] Oral History
		- [checkbox] Observational Research
	+ [checkbox] **Experimental and/or Interventional Research Design:** prospectively manipulating the participant's body, environment, treatment, or strategies for receiving information in order to observe a resulting effect or outcome.
		- [checkbox] Prospective Biomedical Intervention or Experiment
		- [checkbox] Blinded Trial (Single or Double Blinded)
		- [checkbox] Placebo Controlled Trial
		- [checkbox] Randomized Trial
		- [checkbox] Prospective Social/Behavioral Intervention or Experiment
		- [checkbox] Phase I Clinical Trial
		- [checkbox] Phase II Clinical Trial
		- [checkbox] Phase III Clinical Trial
		- [checkbox] Phase IV Clinical Trial
		- [checkbox] Open Label Trial
	+ [checkbox] **Development of a research resource (repositories, databases, etc.)**
	+ [checkbox] **Other**
		- **If Other, describe:** [Show if Other is selected]
		[text area]

**a-SecondaryArchivalDataAnalysis)** Secondary/Archival Data Analysis or Retrospective Chart Review
**b)** Survey/Questionnaire
**c)** Interviews and Focus Groups
**d)** Oral History
**e)** Observational Research

**f)** Prospective Clinical Research
**g)** Blinded Trial (Single or Double Blinded)
**h)** Placebo Controlled Trial
**i)** Randomized Trial
**j)** Prospective Social/Behavioral Intervention or Experiment
**k)** Phase I Clinical Trial
**l)** Phase II Clinical Trial
**m)** Phase III Clinical Trial
**n)** Phase IV Clinical Trial
**o)** Open Label

# ****MANAGEMENT PLAN STANDARD OPTIONS FOLLOWED BY ALGORITHM RULES****

If COI CM checklist motion = “Eliminate the Conflict” then ignore all the other rules and set clause of “eliminate your financial interest or your role on the study”

### ****Annual Compliance report, Transparency, Business Transaction Disclosures****

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ID** | **Simple Name** | **Header** | **Component** | **Action** | **Guidance** |
| ID00000001 | ACR1 | Annual compliance report | Annual CMR | I will provide annual reports of my compliance with this management plan to the Conflict of Interest Office for review. | For all management plans  |
| ID00000049 | T1 | Transparency | Disclosure in Publications | I will disclose my financial conflict of interest to the editors of all publications (journals, books, etc.) when submitting manuscripts or other reports of the results of this research. | For all research management plans |
| ID00000050 | T2 | Transparency | Disclosure in Public Presentations | I will disclose my financial conflict of interest in all public presentations of this research. | For all research management plans |
| ID00000051 | T3 | Transparency | Disclosure on the Public Website | The University of Utah Conflict of Interest Office will disclose my financial conflict of interest on a publicly available website. The publicly available disclosures will include my name, the name of the business entity, the nature of the financial interest and the dollar ranges or value of the financial interest as available. | Applicable when the study is active human subjects research or funded by the US Public Health Service / Department of Energy |
| ID00000052 | T4 | Transparency | Disclosure to the Research Team | I will disclose my financial conflict of interest in writing to all members of the research team. Members of the research team will be informed that any concerns about my conflict of interest should be discussed with the Individual Conflict of Interest Committee. | For all research management plans |
| ID00000048 | Business Transactions | Business Transactions | Business Transactions | I have disclosed a Financial Relationship in a Business Entity that may transact business with the University of Utah ("University"). I am aware that the Utah Public Officers' and Employees' Ethics Act ("Ethics Act," Utah Code Ann. § 67-16-1 et seq.) creates legal obligations for me as a public employee, including prohibiting my participation in any transactions between the University and this Business Entity. Violations of the Ethics Act may result in prosecution and criminal penalties. Consistent with the Ethics Act, I agree to the following management plan:* I will advise my immediate supervisor of the existence of my Financial Relationship.
* If the University transacts business with the Business Entity, I will not participate in any aspect of the transaction process on behalf of the University. This includes, but is not limited to, preparation, deliberation, negotiation, and execution of: purchases (including the purchase of supplies, equipment, or services), subcontracts, subawards, material transfer agreements, data sharing agreements, term sheets (whether binding or non-binding), option agreements, licensing agreements, agreements for sponsored research, grants, lease agreements, etc. If my University responsibilities require me to provide input regarding the transaction with the Business Entity, at the time of providing such input, I will clearly disclose my conflict of interest in writing to the University decision-makers, and ensure that the minutes of the relevant committee meetings reflect my recusal from the decision-making process.
* I will not disclose or use any of the University's controlled, private, or protected business information (1) to further my, or another's, business interests or (2) to secure special privileges or exemptions for myself or others.
 | Applicable for all management plans when the conflict is caused by a financial relationship with a business entity (ie not intellectual property only) |

***Annual Compliance report, Transparency, Business Transaction Rules***

|  |  |  |
| --- | --- | --- |
| 1 | 10-**PHS/DOE** = Yes | **T3** |
| 2 | 10-**PHS/DOE** = No &11-**HSR** =yes & unless\* 11.B.a-**StudyDesign.SecondaryArchivalDataAnalysis** is only option selected* If human subjects research, we want disclosure unless it is only retrospective chart review.
 | **T3** |
| 3 | 1-**SFI** = Yes | **ACR1, T1, T2, T4, Business Transactions** |
| 4 | 9-**ProcurementAuthority** = Yes | **Business Transactions** |

### ****Student & Subordinate Disclosures****

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ID00000053 | SSP/D | Subordinate and Student Protections | Disclosures to Subordinates/Students | I will disclose my financial conflict of interest in writing to all subordinates and students working on this project. I will inform them that any concerns about my financial conflict of interest should be discussed with the department chair or the Individual Conflict of Interest Committee. | Applicable when the Investigator Information Form indicates subordinates or students will be involved |
| ID00000054 | SSP/E | Subordinate and Student Protections | Evaluation of Subordinates/Students | My evaluation of University subordinates and students will not be based, in whole or in part, on their participation (or refusal to participate) in non-University activities involving any business entity in which I have significant financial interest as defined by the University Individual Financial Conflict of Interest Policy. Their participation in non-University activities involving such business entities will not be expected or required. | Applicable when the Investigator Information Form indicates subordinates or students will be involved AND the conflict is with a business entity |
| ID00000010 | SSP/P | Student and Subordinate protection | Publications of Students/Subordinates/Other Investigators | Publication of student, subordinate, or other investigator's work on the project will not be delayed beyond the standard University agreement for review of intellectual property issues. | Applicable when the Investigator Information Form indicates subordinates or students will be involved |

***Student & Subordinate Rules***

|  |  |  |
| --- | --- | --- |
| 1 | 3.B-**Subordinate** = Yes | **SSP/D, SSP/P** |
| 2 | 3.B-**Subordinate** = Yes & 1.B-**Equity** = Yes | **SSP/E** |
| 3 | 3.A-**Students** = Yes | **SSP/D, SSP/P** |
| 4 | 3.A-**Students** = Yes & 1.B-**Equity** = Yes | **SSP/E** |
| 5 | 3.B-**Subordinate** = Yes & 1.A-Rem = Yes | **SSP/E** |
| 6 | 3.A-**Students** = Yes & 1.A-Rem = Yes | **SSP/E** |

### ****IP Disclosures****

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ID00000011 | IP1 | Intellectual Property | Intellectual Property Disclosures to PIVOT | I will promptly disclose any and all new intellectual property arising from this research to the University of Utah Partners for Innovation, Ventures, Outreach & Technology (PIVOT) Center. | Applicable when IP is being used in the study or new IP could be generated from the research |
| ID00000012 | IP2 | Intellectual Property | Recusal from Licensing Negotiations for IP | I will recuse myself from negotiating licensing agreements on behalf of the University for any new intellectual property arising from this research. | Applicable when new IP could be generated from the research (PIVOT also independently enforces this based on their own policy) |
| ID00000055 | IP3 | Intellectual Property | Recusal from Licensing Negotiations (SFI) | I will recuse myself from negotiating licensing agreements on behalf of the University with any business entity in which I have significant financial interest as defined by the University's Individual Financial Conflict of Interest Policy. | Applicable when the conflict is with a business entity |

***IP Rules***

|  |  |  |
| --- | --- | --- |
| **1** | 1.C.b-**IP.Commercialization** = Yes | **IP1, IP2** |
| **2** | 8-**PossibleNewIP** = Yes | **IP1, IP2** |
| **3** | 1.B-**Equity** = Yes & 1.B.b-**Equity.Traded** = No | **IP3** |
| 4 | 1.A-Rem = Yes | **IP3** |

### ****Data Integrity Disclosures****

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ID00000056 | DI6 | Data Integrity | Blinding during Collection | I will blind the data during the collection phases of this research. | Applicable when the Investigator Information Form indicates this is possible |
| ID00000057 | DI7 | Data Integrity | Blinding during Analysis | I will blind the data during the analysis phases of this research. | Applicable when the Investigator Information Form indicates this is possible |
| ID00000058 | DI8 | Data Integrity | Non-conflicted Data Collection | I will identify a non-conflicted member of the research team or third party to collect all data for this research. | Applicable when the Investigator Information Form indicates this is possible |
| ID00000059 | DI9 | Data Integrity | Non-conflicted Data Analysis | I will identify a non-conflicted member of the research team or third party to analyze all data for this research. | Applicable when the Investigator Information Form indicates this is possible |
| ID00000060 | D10 | Data Integrity | Non-conflicted CRFs with PI Review | I will identify a non-conflicted member of the research team to abstract all data for the case report forms. The principal investigator will review and sign off on the case report forms. | Applicable when the discloser is participating in the collection of data (for example, performing routine physical exams) but not abstracting research data from those records |
| ID00000023 | DI3 | Data Integrity | Peer Review Prior to Publication | I will identify a non-conflicted peer (not a subordinate), subject to the approval of the Individual Conflict of Interest Committee, to review the research and results prior to publication. | The most commonly used data integrity clause |
| ID00000014 | DI4 | Data Integrity | Peer Consultation | I will identify a non-conflicted peer (not a subordinate), subject to approval of the Individual Conflict of Interest Committee, to consult and advise on all major research decisions. | Prepopulates when the SFI is valued between $40-100K; there is a lower threshold ($20-40K) for PIs and cases when other data integrity measures (blinding, non-conflicted collection/analysis of data) aren’t possible |
| ID00000017 | DI5 | Data Integrity | Peer Monitor | I will identify a non-conflicted peer (not a subordinate), subject to approval of the Individual Conflict of Interest Committee, to review this research and results at least annually and submit reports to the Conflict of Interest Office for review. | The strictest data integrity clause, which prepopulates when the SFI is valued over $100K; there is a lower threshold of $40K for PIs and cases when other data integrity measures (blinding, non-conflicted collection/analysis of data) aren’t possible |

***Data Integrity Rules***

\***Note**: If DI5 is criteria is met by any condition, DI4 should not be triggered regardless of the criteria below.

|  |  |  |
| --- | --- | --- |
| **1** | 4-**BlindingCollection** =Yes | **DI6** |
| **2** | 5-**BlindingAnalysis** =Yes | **DI7** |
| **3** | 2.A-**Role** = PI & 1.A.b-**Rem.Range** <20k | **DI3** |
| **4** | 2.A-**Role** = PI & 1.A.b-**Rem.Range** >20k & <40k | **DI4** |
| **5** | 2.A-**Role** = PI & 1.A.b-**Rem.Range** >40k | **DI5** |
| **6** | 2.A-**Role** = PI & 1.B.b-**Equity.Traded** = No | **DI3** |
| **7** | 2.A-**Role** = PI & 1.B.c-**Equity.Range** <40k | **DI3** |
| **8** | 2.A-**Role** = PI & 1.B.c-**Equity.Range** >20k & <40k | **DI4** |
| **9** | 2.A-**Role** = PI & 1.B.c-**Equity.Range** >40k | **DI5** |
| **10** | 2.A-**Role** <>PI & 1.A.b-**Rem.Range** <40k | **DI3** |
| **11** | 2.A-**Role** <>PI & 1.A.b-**Rem.Range** >40k & <100k | **DI4** |
| **12** | 2.A-**Role** <>PI & 1.A.b-**Rem.Range** >100k | **DI5** |
| **13** | 2.A-**Role** <> PI & 1.B.b-**Equity.Traded** = No | **DI3** |
| **14** | 2.A-**Role** <> PI & 1.B.c-**Equity.Range** <40k | **DI3** |
| **15** | 2.A-**Role** <> PI & 1.B.c-**Equity.Range** >40k & <100k | **DI4** |
| **16** | 2.A-**Role** <> PI & 1.B.c-**Equity.Range** >100k | **DI5** |
| **17** | 6**-NonConflictedCollection =** Yes | **DI8** |
| **18** | 6-**NonConflictedCollection =** No & 7-**NonConflictedAnalysis =** No & 4-**BlindingCollection**= No & 5-**BlindingAnalysis**= No & 1.A.b-**Rem.Range** <20k | **DI3** |
| **19** | 6-**NonConflictedCollection =** No & 7-**NonConflictedAnalysis =** No & 4-**BlindingCollection**= No & 5-**BlindingAnalysis**= No & 1.A.b-**Rem.Range** >20k & <40k | **DI3, DI4** |
| **20** | 6-**NonConflictedCollection =** No & 7-**NonConflictedAnalysis =** No & 4-**BlindingCollection**= No & 5-**BlindingAnalysis**= No & 1.A.b-**Rem.Range** >40k | **DI3, DI5** |
| **21** | **7-NonConflictedAnalysis =** Yes | **DI9** |
| **22** | 6-**NonConflictedCollection =** No & 7-**NonConflictedAnalysis =** No & 4-**BlindingCollection**= No & 5-**BlindingAnalysis**= No & 1.B.c-**Equity.Range** <20k | **DI3** |
| **23** | 6-**NonConflictedCollection =** No & 7-**NonConflictedAnalysis =** No & 4-**BlindingCollection**= No & 5-**BlindingAnalysis**= No & 1.B.c-**Equity.Range** >20k & <40k | **DI3, DI4** |
| **24** | 6-**NonConflictedCollection =** No & 7-**NonConflictedAnalysis =** No & 4-**BlindingCollection**= No & 5-**BlindingAnalysis**= No & 1.B.c-**Equity.Range** >40k | **DI3, DI5** |

### ****Human Subjects Disclosures****

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ID00000061 | HSP/CD | Human Subject Protections | Disclosure in the Consent Documents | I will disclose my financial conflict of interest to all potential research participants in the informed consent documents. | Applicable for human subjects research (unless only secondary/archival or retrospective chart review) |
| ID00000062 | HSP/CP | Human Subject Protections | Disclosure in the Consent Process | A member of the research team who does not have any conflicts of interest related to this research or an appropriate third party will inform potential research participants of my financial conflict of interest during the informed consent process. | Applicable for human subjects research (unless only secondary/archival or retrospective chart review) |
| ID00000020 | HSP R | Human Subject Protections | Recusal from Obtaining Consent | I will recuse myself from participation in the process of obtaining informed consent from all potential research participants for this study. Informed consent for all potential research participants will be obtained by a member of the research team who does not have any conflicts of interest related to this research or by an appropriate third party approved by the Individual Conflict of Interest Committee. | Applicable for human subjects research (unless only secondary/archival or retrospective chart review), even if the investigator isn’t initially planning on participating in consenting |

***Human Subjects Rules***

|  |  |  |
| --- | --- | --- |
| 1 | 11-**HSR** =yes & unless\* 11.B.a-**StudyDesign.SecondaryArchivalDataAnalysis** is only option selected\*If 11 is yes do the consent clauses unless only secondary/archival or retrospective chart review is selected) So if one of each or both is selected only it does not run. If any other choices are selected in the list, it will run. | **HSP/CD, HSP/CP, HSP R** |