**Financial Interest Disclosure**

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| --- | --- | --- | --- |
| It is the responsibility of the Principal Investigator (PI) to collect the information described below from **all members of the research team and report it on this form** when submitting protocols to Yale HRPP requesting IRB review. If any information below changes, a modification must be submitted to the HRPP IRB within 30 days. If non-Yale IRB is used for review of research, the PI must also follow the policies of the reviewing IRB. | | | |
| **1.** | | | **Does the Principal Investigator (PI), the PI's immediate family (spouse or dependent children), or any other research personnel or their immediate families (spouse or dependent children), have any of the following financial interests in an entity that sponsors or provides support for the research, manufactures the product tested in this research, or owns or produces the technology/intervention investigated in this research?** |
| **YES** | | **NO** | **Any compensation or gifts from the entity in the previous twelve months that in total exceeds $5,000** *(Compensation includes salary and any payment in exchange for consulting or speaking services, payment for travel, honoraria, or paid authorship, etc.)* |
|  | |  | If “Yes” is selected, for each conflicted individual indicate the value below and describe the specific interest in detail, including the name and role of the conflicted individual in the study: |
| Details: |
| $5K or greater, but less than $10K  $10K or greater, but less than $25K  $25K or greater, but less than $50K  $50K or greater, but less than $100K  $100K or greater |
| **YES** | **NO** | | **Ownership interest (e.g., stock, stock options) in a publicly-held entity that when aggregated for the immediate family for the prior 12 months is $5,000 or greater** *(Do not include financial interest in mutual funds or similar instruments such as 401(k) plans in which you have no control over the equities held by the fund.)* |
|  |  | | If “Yes” is selected, for each conflicted individual describe the specific interest in detail, including the estimated value of interest, percentage of ownership (if applicable), name and role of the conflicted individual, and the arrangement giving rise to the potential conflict (e.g., equity purchased or provided in exchange for services). |
| Details: |
| $5K or greater, but less than $10K  $10K or greater, but less than $25K  $25K or greater, but less than $50K  $50K or greater, but less than $100K  $100K or greater |
| **YES** | **NO** | | **Any ownership interest (e.g., stock, stock options) in a privately-held entity** |
|  |  | | If “Yes” is selected, for each conflicted individual describe the specific interest in detail, including the estimated value of interest, percentage of ownership (if applicable), name and role of the conflicted individual, and the arrangement giving rise to the potential conflict (e.g., equity purchased or provided in exchange for services). |
| Details: |
| **YES** | **NO** | | **Combination of compensation and ownership interest in privately-held entity OR publicly-held entity exceeds $5K** |
|  |  | | If “Yes” is selected, for each conflicted individual describe the specific interest in detail, including the name and role of the conflicted individual and the arrangement giving rise to the potential conflict (e.g., equity purchased or provided in exchange for services). |
|  |  | |  |
| **YES** | **NO** | | **Any intellectual property rights and interests regardless of financial benefit** (e.g., patents, copyrights) |
|  |  | | If “Yes” is selected, describe the specific interest including amounts of royalties earned, if any, in detail for each conflicted individual. |
| Details: |
| **YES** | **NO** | | **Any governance or executive relationship with the entity** (e.g., board of directors, CEO) |
|  |  | | If “Yes” is selected, describe the specific interest in detail for each conflicted individual. |
| Details: |
| **YES** | **NO** | | **Other financial or non-financial interest not listed above that could appear to potentially influence the conduct or outcome of this research study or affect the protection of the participants involved in this project, the scientific objectivity of the research or its integrity** |
|  |  | | If “Yes” is selected, describe the specific interest in detail for each conflicted individual. |
| Details: |
| Complete the next section only if there is an interest indicated above. If all answers are NO, stop completing this form. | | | |
| **2.** | | | **Has there been a management plan issued by your institution for the relationship described above?** |
| **YES** | **NO** | | If yes, provide a detailed description of the human research related determinations/management plans or provide the copy of the plan: |
|  |  | | Details: |
| **3.** | | | **When reviewing potential conflict of interest, the IRB will consider a number of mitigating factors that help minimize the opportunity for undue influence created by the conflict. Please, indicate if any of the following already exist in the research plan:** |
|  | | | The informed consent form includes a disclosure of the financial interest |
|  | | | Only non-conflicted members of the study team will recruit participants |
|  | | | Only non-conflicted members of the study team will determine participant eligibility |
|  | | | Only non-conflicted members of the study team will obtain informed consent |
|  | | | A non-conflicted member of the study team will serve as the PI |
|  | | | Only non-conflicted members of the study team will perform analysis of identifiable data |
|  | | | Independent data and safety monitoring will be performed (by individuals not affiliated with the entity OR research team) |
|  | | | Interests giving rise to the COI will be reduced or eliminated prior to the individual engaging in research |
|  | | | Other: |