



## MATRIX FINANCIAL DISCLOSURE/CERTIFICATION FORM – 42 CFR 50

<p><b>Please complete all of the information below, including providing your signature and date where indicated. Once complete, scan the document and email it as instructed. Retain the original form in your central files.</b></p>	
<p><b>1. Name and Address of Project Prime:</b> Magee-Women’s Research Institute and Foundation 204 Craft Avenue Pittsburgh, PA 15213 USA</p>	
<p><b>2. Project Name:</b> MATRIX: A USAID Project to Advance the Research and Development of Innovative HIV Prevention Products for Women</p>	
<p><b>3. USAID Cooperative Agreement Number:</b> #7200AA22CA00002</p>	
<p><b>4. Your Name:</b></p> <p><b>Institution Name and Address (including phone number):</b></p>	
<p><b>5. Indicate by marking YES or NO if any of the financial interests or arrangements of concern to MATRIX (as described below) apply to you, your spouse, or dependent children.</b> If you respond “yes” to any of the items, please provide the details of the interest or arrangement. Attachments to this document are permitted. Your disclosure must cover the previous 12 months. As a MATRIX collaborator in a decision-making position, you must report any significant financial relationships that you or your immediate family members have with any pharmaceutical, diagnostic, biologic, software, assay, medical device, or similar company whose products or services are relevant to MATRIX’s scientific agenda. <b>Additional details and instructions can be found in Pages 2 and 3 of this form.</b></p>	
<p><b>YES</b> <input type="checkbox"/> <b>NO</b> <input type="checkbox"/></p>	<p>Anything of monetary value from a relevant entity(ies) that, when aggregated for you and your immediate family members, exceed \$5,000 annually. This is <i>per entity</i> and not the sum of financial interests in numerous entities combined. If yes, please describe: _____</p>
<p><b>YES</b> <input type="checkbox"/> <b>NO</b> <input type="checkbox"/></p>	<p>All stock options in a relevant entity(ies). If yes, please describe: _____</p>
<p><b>YES</b> <input type="checkbox"/> <b>NO</b> <input type="checkbox"/></p>	<p>A significant equity interest in the sponsor(s) of a relevant clinical study(ies) that amounts to more than a five percent ownership interest or, when aggregated with family members’ interests, exceed \$5,000 annually. This is <i>per entity</i> and not the sum of equity interests in numerous entities combined. If yes, please describe: _____</p>
<p><b>YES</b> <input type="checkbox"/> <b>NO</b> <input type="checkbox"/></p>	<p>Any reimbursed or sponsored travel paid by a relevant entity(ies). If yes, please describe: _____</p>
<p>In accordance with 42 CFR § 50.601 to 50.607, I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, <b>if my financial interests and arrangements, or those of my spouse and dependent children, change from the information provided above during my involvement in MATRIX R&amp;D activities, I will complete a new Financial Disclosure/Certification Form to document this change and notify the Project Prime within 60 days of discovery.</b></p>	
<p><b>6. Signature:</b></p>	<p><b>7. Date:</b></p>

Dear MATRIX Colleague:

As an applicable member of the MATRIX Prime, Clinical Trials Hub (CTH) or Design to Delivery (D2D) Hub Pillar 2, and/or other lead/key persons responsible for the design, conduct, analysis and/or reporting of MATRIX-funded human subjects research (e.g., Protocol Chair/Co-Chair, site Investigator of Record [IoR]/key staff, Product Developer Principal Investigators (PI)/key staff, study statistician, safety physician, etc.), you are required to complete, sign and date the following financial disclosure statement. These statements are not study specific and cover your participation across all MATRIX-funded human subjects research activities.

Everyone to whom the description above applies is required by the U.S Federal Code of Regulations and MATRIX policy to:

- Complete the form before starting MATRIX-funded research activities involving human subjects.
- Update the form annually thereafter until one year after completion of their participation in MATRIX-funded research activities involving human subjects.
- Update the form within sixty (60) days of discovering or acquiring a relevant, new significant financial interest.
  - **IMPORTANT:** Per federal regulation and MATRIX policy, this requirement remains effective throughout your participation in MATRIX-funded research activities involving human subjects and until one year after your participation ends.

Your disclosure statement will allow project leadership to identify and manage financial conflicts of interest (COI) to minimize the potential for bias in research design, conduct, reporting and analysis.

Once completed, you will send the signed and dated form to the MATRIX Clinical Trials Hub regulatory team at [matrixregulatory@lists.matrix4prevention.org](mailto:matrixregulatory@lists.matrix4prevention.org) and (if applicable) to the Investigational New Drug (IND)/Investigational Device Exemption (IDE) sponsor.

**NOTE:** Submission of the 42 CFR 50 financial disclosure statement to MATRIX does not release collaborators from their own institutions' COI submission requirements nor the requirement for collection of financial disclosures from site staff for FDA-regulated (i.e., IND/IDE) studies.

**What does your financial disclosure statement need to include?**

Your disclosure must cover the previous 12 months. As a MATRIX collaborator in a *decision-making position*, you must report any significant financial relationships that you or your immediate family members have with any pharmaceutical, diagnostic, biologic, software, assay, medical device, or similar company whose products or services are relevant to MATRIX's scientific agenda.

Relevant entities are those whose product or service:

- Is involved in a MATRIX clinical study.
- Is being considered for inclusion in a MATRIX clinical study.
- Competes with a product or service included in a MATRIX clinical study.
- Will benefit a lead/key MATRIX collaborator (as described above) on a matter and thereby potentially influence them and directly and significantly affect the design, conduct, or reporting of MATRIX human subjects research.

Significant financial interests include:

- Anything of monetary value from a relevant entity(ies) that, when aggregated for you and your immediate family members, exceed \$5,000 annually. This is *per entity* and not the sum of financial interests in numerous entities combined.

- Intellectual property rights (e.g., patents, copyrights, licensures, and royalties) related to a relevant product must be declared upon receipt of income from rights and interests if those payments, in aggregate with all other stipulated sources, shall exceed \$5,000 annually, and upon execution of a licensing or equivalent agreement that creates a right to receive income in the future that is directly and significantly related to a relevant entity.
- Pharmaceutical, diagnostic, biologic, software, assay, or similar products or equipment.
- Teaching fees, honoraria, or consultant fees, including lecture/seminar fees.
- Service grant, contract, direct salary support, or other direct benefits from industry-sponsored research.
- Membership on scientific/clinical advisory board.
- All stock options in a relevant entity(ies).
  - A "stock option" is an option to buy stock in a company at a future date at an agreed price ("strike price"). All stock options in relevant entities with significant financial interests must be disclosed. Stock options must always be disclosed, regardless of the shares' strike price or whether the company concerned is being publicly traded.
- Any equity interest in the sponsor(s) of a relevant clinical study(ies) that amounts to more than a five percent ownership interest or, when aggregated with family members' interests, exceed \$5,000 annually (per entity) as determined by fair market value.
  - For example, any ownership interest, stock options or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding \$5,000 in annual income.
- Any reimbursed or sponsored travel paid by a relevant entity(ies).

Whether made directly or indirectly (except as noted below), all payments made on behalf of a company (including its agent or contractor reimbursements) must be considered in determining the aggregated total of the monetary interest in an entity. This applies to financial interests in a single entity and not a total of financial interests in numerous entities combined. In instances where a clinical study may have more than one sponsor for financial disclosure purposes, MATRIX interprets the regulation to mean that the dollar amounts triggering reporting apply separately to each sponsor.

**DO NOT INCLUDE THE FOLLOWING:**

- Salary, royalties, other remuneration provided by your institution to you or your immediate family members (e.g., salary support from an industry grant or contract that is given to and/or administered by your institution and that pays a portion of your salary as compensation for your time and effort spent on a specific clinical trial or research project).
- Anything of monetary value given to your institution or to you exclusively in support of research or a clinical study.
- Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Income from investment vehicles (e.g., mutual funds and retirement accounts) if you or your immediate family members do not directly control these vehicles' investment decisions.
- Sponsored travel where expenses are paid by MATRIX, a Clinical Research Site, a federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

**Need assistance or have questions?**

If you have any questions or need assistance, contact the MATRIX Clinical Trials Hub regulatory team at [matrixregulatory@lists.matrix4prevention.org](mailto:matrixregulatory@lists.matrix4prevention.org).