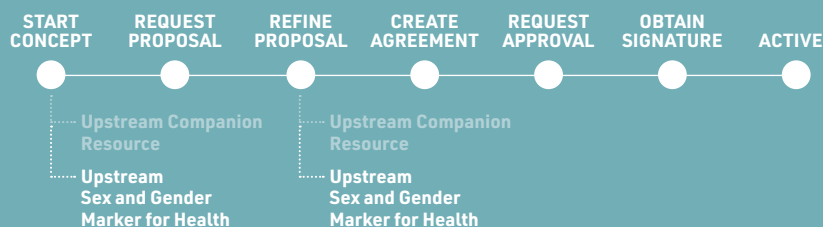


UPSTREAM SEX AND GENDER MARKER FOR HEALTH



This Upstream Sex and Gender Integration Marker is a learning tool for the foundation’s upstream health investments. It is intended to be used by investment owners when designing and refining an investment and to spark conversation with grantees.

The purpose of this tool is to enable investment owners and teams to more intentionally integrate relevant considerations on:

- » **Sex** as a biological variable—anatomy, physiology, genetics, hormones, etc.—and/or
- » **Gender**—social variables such as roles, norms, relations, and power.

For additional information on how to answer questions in this tool, please see the **Upstream Sex and Gender Integration Companion Resource**.

Sex and Gender Considered	Sex and Gender Responsive	Addresses Gender Disparities in R&D
Possible sex and gender elements and their consequences are considered in investment design.	Sex and gender elements are accounted for, and representativeness is reflected in R&D plans.	Investment is sex and gender responsive AND explicitly addresses a systemic gender-related disparity or structural inequity in the R&D field.

For non-upstream investments, use the downstream Gender Integration Marker [here](#).

HOW TO USE THE UPSTREAM SEX AND GENDER INTEGRATION MARKER

- STEP 1** Input your general information.
- STEP 2** Answer Questions 1–5 and explain your responses.
- STEP 3** Count the number of ‘YES’ answers. If the count is 2 or less, the investment is *‘sex and gender considered’*; skip to Step 6. If the count is 3 or more, the investment is likely *‘sex and gender responsive’* or *‘addresses gender disparities in R&D’*. Continue to Step 4.
- STEP 4** Answer Question 6 and explain your response.
- STEP 5** If you answered ‘YES’ to Question 6, the investment *‘addresses gender disparities in R&D’*. If you answered ‘NO’ to Question 6, the investment is *‘sex & gender responsive’*.

This tool is informed by, and draws language from: the Sex and Gender Equity in Research (SAGER) Guidelines , the WHI Opportunity Map, and internal and external subject matter experts.

General Information

STEP 1 Input your general information

INVEST ID	
Is this a supplement	<input type="checkbox"/> YES <input type="checkbox"/> NO
PO Completing Assessment	

Sex and Gender Integration Assessment

STEP 2 Answer Questions 1 – 5 and explain your responses.

Design incorporates end-user perspectives	
Question 1	<p>Will the design of the research, product, platform, or process be informed by gender-specific perspectives, needs, and preferences of end-users?</p> <p>End-users are defined as individuals who will use or receive the end-result of the product, platform, device, or policy, or will be subjects of research, including but not limited to: patients/target population, health care workers, caregivers who are responsible for or influence health behaviors and decisions, manufacturing/laboratory personnel, and regulators.</p> <p><i>For example:</i></p> <ul style="list-style-type: none">» Include a gender analysis when developing the iTPP with teams and the cTPP with partners to surface important distinctions in gender preferences for trade-offs between efficacy and tolerability, perceived barriers to access, preferred formulation, and other attributes that are critical to uptake and adherence.» In modeling investments, addressing differential exposure to a pathogen due to gendered norms, roles, and behaviors, such as through labor migration or mobility constraints, which can be linked to sex-specific outcomes.» Ensuring that informed consent for participation is structured on local context and researchers use appropriate methods to communicate the study to participants.
<input type="checkbox"/> YES <input type="checkbox"/> NO	<p>Please explain your response:</p>

Sampling is inclusive and representative of the target or reference populations

Question 2

Will the investment ensure that research samples, subjects, and/or participants are representative of the target or reference population? This could include sex*, gender, and/or other sociodemographic characteristics (e.g., age, socioeconomic status, or other characteristics).

*Select YES for single sex conditions (e.g., women’s contraceptive technologies, maternal health). When possible, for single sex focused studies, ensure the diverse needs, preferences, and voices of women and girls are included.

*In discovery investments, sex representativeness along cell lines may not be relevant. If not relevant, select no and describe why.

For example:

- » In preclinical investments, consider sex-representative human tissue and/or animal models included in the design and testing based on the target/reference population. If sex-representative tissue/models are not used, explain why.
- » In clinical and epidemiological research investments, are study samples reflective of the target or reference population and are sex, gender, and other relevant sociodemographic characteristics adequately represented in the sample? If not, what are the reasons for any exclusion, such as pregnancy and lactation, or study design interventions, contraception requirements?

YES

NO

Please explain your response:

Data management and analysis plan	
Question 3	<p>Does the investment's data management and analysis plan include collection and reporting on data disaggregated by sex* and/or gender and, if relevant, other sociodemographic characteristics, such as age?</p> <p>*Select YES for single-sex conditions-i.e., women's contraceptive technologies, maternal health, etc. When possible, for single sex focused studies, ensure the diverse needs, preferences, and voices of women and girls are included.</p> <p><i>For example:</i></p> <ul style="list-style-type: none"> » For cell biological, molecular biological, or biochemical experiments, the origin and sex chromosome constitutions of cells or tissue cultures are stated and, if unknown, the reasons are stated. » For in-vivo and in-vitro studies, the sex of the subjects or source donors is stated (except for immortalized cell lines, which are highly transformed). » For example, in vaccine trials, will data on adverse reactions be disaggregated by sex in order to understand sex-specific outcomes, such as effects on menstruation. » For disease modelling and epidemiology studies, are the effects of other exposures on health problems examined with sex and gender considered.
<input type="checkbox"/> YES <input type="checkbox"/> NO	<p><i>Please explain your response:</i></p>

Mitigating unintended consequences	
Question 4	<p>Has the investment identified potential gender-related negative consequences that may arise during implementation, and have appropriate mitigation strategies been developed?</p> <p><i>For example:</i></p> <ul style="list-style-type: none"> » Safeguard against retribution for participants' involvement/participation in research studies. Ensure confidentiality and privacy for participants to protect against stigma or backlash related to gender power dynamics between couples/within households or the potential to reveal sensitive information, such as STI diagnosis or use of contraception. » Women's participation in research can lead to increased time and financial burden. Identify and include measures that compensate and support women to participate. » For non-human investments, consider any potential future gender-related harms associated with this investment
<input type="checkbox"/> YES <input type="checkbox"/> NO	<p><i>Please explain your response:</i></p>

Gender diversity and equity in the R&D workforce

Question 5

Will the investment include efforts to meaningfully address barriers and promote equity in the workforce of the partner institution and, where relevant, other aspects of the investment (e.g., sub-grantees/sub-contractors, investment activities related to learning/knowledge exchange, or ecosystem strengthening)?

The following are non-exhaustive examples of how a grantee may be addressing gender diversity and equity gaps:

- » Implement strategies to promote the entry, recruitment, retention, and sustained advancement of women in science and research careers.
- » Include supportive measures, such as access to mentoring programs and gender advisory committees.
- » Institutionalize policies that help close gender disparities in the workforce, such as equal pay, higher minimum wage, paid sick days, paid family leave, quality and affordable childcare, flexible work arrangements, and improved health and benefits packages.
- » Create training and professional development approaches that are gender-intentional, such as virtual or hybrid courses or flexible schedules, financial support to offset costs of travel or care arrangements, and content and resources that support women’s advancement in the field.

YES

NO

Please explain your response:

STEP 3 Count the number of 'YES' answers. If the count is 2 or less, the investment is *sex and gender considered*; skip to Step 6. If the count is 3 or more, the investment is likely *sex and gender responsive* or *addresses a gender disparity in R&D*. Continue to Step 4.

YES	
NO	

STEP 4 Answer Question 6 and explain your response.

Addresses gender disparities in R&D	
Question 6	<p>Does this investment explicitly address a systemic gender-related disparity or structural inequity in the R&D field or does this investment contribute to an overarching portfolio that makes progress toward this goal?</p> <p><i>For example:</i></p> <ul style="list-style-type: none">» Investing in solutions for women’s health and improved quality of life that address conditions across the life course and across disease areas.» Contribute to developing sex as a biological variable (SABV) best practices, or advance R&D methodologies that help standardize sex and gender approaches.» Updating and expanding burden of disease metrics to better account for sex and gender-related conditions, long-term sequelae, and sociocultural gender biases (including input data gaps, disability weighting, and duration assumptions) in order to more accurately measure and assess conditions for women and girls.» Designing studies to address gaps in information for specific sub-populations (e.g., adolescent girls, women living with HIV, pregnant people).
<input type="checkbox"/> YES <input type="checkbox"/> NO	<p><i>Please explain your response:</i></p>

STEP 5 If you answered ‘YES’ to Question 6, the investment is *sex and gender responsive and explicitly addresses a systemic gender-related disparity or structural inequity in the R&D field*. If you answered ‘NO’ to Question 6, the investment is *sex and gender responsive*.

FINAL ASSESSMENT

STEP 6 Mark the correct category based on this assessment.

<input type="checkbox"/>	Sex and Gender Considered
<input type="checkbox"/>	Sex and Gender Responsive
<input type="checkbox"/>	Addresses Gender Disparities in R&D

Note for clinical trials

The GF Design Analyze Communicate (DAC) Team is a service available to all PSTs: DAC reviews clinical trial protocols and other types of clinical research studies to ensure sex, gender, and other considerations have been integrated and optimized for an informative outcome. Contact dactrials@gatesfoundation.org to learn more or request a review

Legal disclaimer

This is a learning tool designed to support and inform integrating sex and gender considerations into an investment. Resourcing decisions are not contingent upon the responses in this document. Data collected from this tool are for internal use only.