

# Criteria for Evaluating the INTEGRATION OF SEX & GENDER [BIOMEDICAL RESEARCH]

## LETTER OF INTENT STAGE

### 1. Quality of the proposed research program

- Statement of any known sex differences in the biology or epidemiology of the disease under study
- Brief discussion of the influence of sex on the mechanism under study (e.g. genetic, sex hormone receptors, immune response)
- Clear articulation of whether or not the research question intends to examine sexual dimorphism
- Sample size considerations with respect to sex
- Description of additional ways in which sex and/or gender will be accounted for in research programs involving cells, tissues, animals and humans

- If sex and gender considerations are being omitted, a scientifically sound justification should be provided

### 2. Strength of the team

- Evidence that one or more of the applicants has credibility and research experience in sex and/or gender science as relates to the field of study

Examples may include:

- graduate training;
- publication history; or
- IGH core competency certificate in sex- and gender-based analysis.

## FULL APPLICATION STAGE

### 1. Vision, rationale and added value

- Clarity of the vision regarding the analysis and expected results/outcomes as they relate to sex and/or gender
- Evidence of explicit consideration being given to achieving equitable health impacts across diverse patient/population sub-groups

### 2. Quality and appropriateness of research approach with respect to sex and/or gender

#### Literature review

- Clear articulation that the phenomenon/condition/disease under study has or does not have a different incidence or prevalence based on sex or gender
- Literature review describing known mechanisms explaining sex or gender differences, or lack thereof, in research area under study

#### Research question

- Clear articulation of the type of research question being considered with respect to sex and/or gender, including:
  - Identifying and explaining sex and/or gender differences;
  - Establishing sex and/or gender similarities in the mechanism under study;
  - Investigating sex-specific pathways underlying a common phenotype; and
  - Studying sex/gender as a confounder or interaction variable while testing the main study hypothesis.

#### Study Design and Methods

- Scientifically sound justification for proposing a single-sex study, if applicable
- Identification of the sex of the cells, tissues or animals being used, if applicable
- Description of the method for documenting/controlling the hormonal status of experimental female animals, if applicable
- Description of the method for including equal numbers of male and female human participants for translational research, if applicable

#### Analysis & Reporting

- Description of the analysis and reporting plan for sex-disaggregated data, if applicable
- Sample size calculations to show adequate power for a sex-disaggregated analysis, where appropriate
- Inclusion of a statement that negative findings with respect to sex will be reported

### 3. Knowledge Translation Plan

- Description of how the knowledge translation strategies intend to maximize uptake by men, women, boys, girls or gender-diverse people (e.g. will the content, messages or products vary by sex or gender?)