



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

## Research Misconduct Policy

---

### BACKGROUND

The purpose of this Research Misconduct Policy (the “Policy”) is to outline the structure and process that the Patient-Centered Outcomes Research Institute (PCORI) will follow when it receives an Allegation of Research Misconduct in connection with PCORI-funded research. This Policy is not intended to supplant or preclude the submission of Allegations of Research Misconduct to an applicable research institution or other appropriate third parties, such as ethics boards overseeing the research or medical journals to which the results have been reported, or the consideration by a research institution or other appropriate third party of Allegations of misconduct under its applicable policies and procedures.

---

#### I. General

In its role as a funder, from time to time, PCORI may receive an Allegation of possible Research Misconduct relating to PCORI-funded research. PCORI requires all awardee institutions to have their own policies and procedures for the avoidance and reporting of Research Misconduct and to apply these policies and procedures to any PCORI-funded research, including by reporting to PCORI any findings of Research Misconduct.

This Policy outlines the framework that PCORI will generally follow when an Allegation of possible Research Misconduct relating to PCORI-funded research is received by a PCORI official. Particular circumstances of a case may require variation from the framework outlined in this Policy if deemed appropriate by PCORI. PCORI may in its discretion utilize this framework to consider the Allegations or complaints made to PCORI.

##### A. Definitions

*Allegation:* a disclosure to PCORI of potential Research Misconduct (defined below).

*Complainant:* the individual or group who makes an Allegation of Research Misconduct.

*Fabrication:* the making up of data or results and recording or reporting them.

*Falsification*: the manipulation of research materials, equipment or processes or the change or omission of data or results such that the research is not accurately represented in the research record.

*Person*: any individual, corporation, partnership, institution, association, unit of government or legal entity, however organized.

*Plagiarism*: the appropriation of another Person's ideas, processes results or words without giving appropriate credit.

*Research Misconduct*: Fabrication, Falsification, or Plagiarism in proposing, performing or reviewing research. Research Misconduct does not include honest error or differences of opinion.

*Review Body*: a group of PCORI senior staff assembled to conduct an initial review of reported Allegations of Research Misconduct and to make a recommendation on how PCORI should proceed. It shall be comprised of certain standing members with other members to be determined based on the nature of the Allegations.

*Respondent*: the Person who is the subject of an Allegation of Research Misconduct.

## B. Applicability

This Policy applies to all individuals engaged in research funded by PCORI, who are applying for or have received PCORI funding to engage in research, or who are otherwise affiliated by contract or agreement with PCORI.

Claims involving authorship or collaboration disputes between individuals or business disputes between organizations/institutions shall not be considered Allegations of Research Misconduct subject to this Policy.

## II. **Receipt of Allegations of Research Misconduct**

### A. Reporting Allegations

Any Person who believes that Research Misconduct has occurred or is occurring in connection with PCORI-funded research is encouraged to report such Allegations to the applicable institution's contact person or office for receipt of Allegations of Research Misconduct and/or to PCORI. Allegations should be made in good faith and should be as specific as possible and, ideally, accompanied by supporting documentation of relevant observations and facts.

Reports to PCORI may be made anonymously; however, anonymity may impact the credibility and weight of the Allegations and may limit what steps PCORI can take as a practical matter to evaluate the nature of the Allegation. While PCORI seeks to protect the confidentiality of all

Complainants bringing good faith Allegations as appropriate, consistent with this Policy and as allowed by law, there is no guarantee of confidentiality and PCORI may disclose any information necessary to conduct its review in a competent, objective and fair manner, and to take any corrective actions it deems appropriate, including communicating with the relevant funding applicant or recipient, as applicable, impacted journals, or other third parties relevant to the Allegation who have a legitimate need to know.

#### B. PCORI's Receipt of Allegations

When a report purporting to relay an Allegation of Research Misconduct is received, PCORI may conduct an initial evaluation of whether the report includes an Allegation that can be characterized as falling outside this Policy.

If PCORI determines that the Allegations may be subject to this Policy or as otherwise deemed appropriate, PCORI will convene a confidential Review Body appropriate for the nature of the Research Misconduct Allegation. The Review Body will conduct a review of the reported Allegations and will make recommendations as to how to proceed.

### III. **Protection of Involved Individuals**

PCORI is committed to maintaining the fairness and confidentiality of its review of Allegations of Research Misconduct. PCORI will treat the Complainant, Respondent, and any other parties who may have information relevant to the Allegations fairly and reasonably throughout PCORI's review and will take appropriate steps to protect the reputation of any Respondent until PCORI's review is complete. PCORI may provide the Respondent(s) with notice that it has received an Allegation of misconduct against them.

Consistent with a competent, objective and fair review of an Allegation and to the extent practicable in light of any necessary fact-finding or referrals contemplated in this Policy, knowledge of the identities of individuals involved in the review process and the Allegation, including the Complainant, the Respondent and other parties who may have information relevant to the Allegations, shall be limited to the Review Body members, the Executive Director, the General Counsel, and others with a legitimate need to know, which may include other PCORI staff and the relevant awardee institution. Further, all written materials and information with respect to the initial review process shall be kept confidential to the extent practicable and only reviewed by those individuals with a legitimate need to know.

PCORI prohibits retaliation against any individuals involved in the Allegation review process including the Complainant, other parties who may have information relevant to the Allegations and Review Body members. PCORI will take reasonable steps to ensure that PCORI staff responsible for carrying out PCORI's review under this Policy, including the members of the Review Body, do not have personal, professional or financial conflicts of interest with the

Complainant, Respondent or other parties who may have information relevant to the Allegations.

Any concerns regarding the fairness and confidentiality of the review process should be directed to the General Counsel.

#### **IV. Review by PCORI: Review Body and Executive Director**

Upon initial evaluation, if the Allegation is not dismissed as falling outside of this Policy, the Review Body will convene for the purposes of reviewing the Allegation to confirm that it is subject to this Policy, and to make a recommendation to the Executive Director about whether additional steps should be taken.

Once convened, the Review Body shall conduct a review that is tailored, impartial, fair and expeditious. The scope of the review shall be sufficient to discern whether the Allegation appears to be cognizable. The Review Body will consider whether the Allegation is sufficiently relevant, credible, and intelligible. For Allegations that the Review Body believes are cognizable, the Review Body will make a recommendation to the Executive Director which may include referral of the Allegation for an assessment, inquiry and/or investigation by the relevant applicant or awardee institution or other appropriate action. For Allegations that the Review Body believes are not cognizable, the Review Body will make a recommendation to the Executive Director as to whether any additional action is warranted, including whether an appropriate communication should be sent to the Complainant regarding the conclusion of PCORI's review and whether the awardee institution or other third party should be notified of PCORI's receipt of and response to the Allegation.

The Executive Director will be advised of the Review Body's recommendation, including the basis of the recommendation, and will be the final decision-maker. The Executive Director will make a decision about whether to accept the recommendation of the Review Body or take other action.

#### **V. Immediate Action by PCORI**

In the course of considering information relating to the Allegation (including information about risks to the rights or welfare of research study participants) the Review Body may, in its discretion, initiate immediate action as appropriate before PCORI's review of the Allegation is completed.

#### **VI. Institutional Determinations Relating to Misconduct and Notifications to PCORI**

There are circumstances where an applicant or awardee institution either discovers or is informed of an Allegation of Research Misconduct regardless of whether PCORI makes a referral. In those circumstances and as a condition of receiving PCORI funding, PCORI requires all awardee institutions to report any findings of Research Misconduct to PCORI within thirty

(30) days of the conclusion of an investigation into Research Misconduct related to any PCORI-funded research. Additionally, awardee institutions must notify PCORI, in writing, of the nature of the violation, the corrective actions that will be taken to correct the violation, and a timeline within which those corrective actions will be executed.

History:

*Approved by the PCORI Executive Staff April 3, 2017*