How to Evaluate Human Subjects Protections

PCORI requires that research involving human subjects include adequate safeguards. Institutional Review Boards selected by awardees have authority for ensuring the protection of human subjects. PCORI asks merit reviewers to assist with identifying any issues with protection of human subjects that PCORI staff should review with potential funding awardees.

Human subjects protections concerns should not be factored into the application's score, but they should be flagged for PCORI staff by checking the appropriate box and providing written comments in PCORI Online.

The four bullets below provide guidelines that may be helpful to merit reviewers in identifying concerns that PCORI staff should be aware of for any potential awardee. Please note any concerns regarding human subjects protections in your review.

- **Risks to Human Subjects**
  Does the application adequately describe human subjects involvement, characteristics, and design; sources of materials; and potential risk, including:
  - Description and justification for the proposed involvement of human subjects
  - Characteristics of subject population (number, age range, and health status, e.g., physical and cognitive functioning)
  - Inclusion/exclusion criteria
  - Rationale for involvement of vulnerable populations (e.g., fetuses, pregnant women, children, prisoners, institutionalized individuals)
  - Role of collaborating sites where research will be performed
  - Description and justification of research procedures (including dosage and frequency of intervention)
  - Description of what research material, data, and information will be collected
  - Access to personally identifiable information collected and retained
  - Management and protection of materials and information
  - All potential risks to subjects (e.g., physical, psychological, financial, legal) including likelihood and seriousness
  - Any alternative treatments or procedures available to subjects in lieu of participation

- **Adequacy of Protection against Risks**
  Does the application adequately describe recruitment, informed consent, and protections against risk, including:
  - How subjects will be recruited
  - Description of informed consent and parental permission and assent
  - Waiver for any elements of consent
  - How risks described previously, including privacy and confidentiality, will be minimized

- Additional protections for vulnerable populations
- Ensuring necessary medical/professional intervention for adverse events

- **Potential Benefits of the Proposed Research to Human Subjects and Others**

  - Does the application adequately describe how potential risks to subjects appear reasonable in relation to anticipated benefits?

- **Importance of the Knowledge to Be Gained**

  - Does the application adequately describe how potential risks to subjects appear reasonable in relation to the importance of the knowledge that may result from the study?