

A. Participant questions, concerns and complaints to PI

The Rutgers University IRB requires the Informed Consent procedure to include informing subjects about their rights, including how to reach the investigator with questions, concerns, or complaints. The Informed Consent document must also include the following contact information for the IRB:

Rutgers University Institutional Review Board for the Protection of Human Subjects
Office of Research and Sponsored Programs
3 Rutgers Plaza
New Brunswick, NJ 08901-8559
Tel: 732-932-0150 ext. 2104
Email: humansubjects@orsp.rutgers.edu

For studies that involve more than minimal risk, it is necessary to inform participants in the consent document that they should call the Sponsored Programs Administrator if they are injured or otherwise harmed at the number listed above.

For research involving more than minimal risk, the RU IRB requires that the consent document include an explanation as to whether any compensation is available, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Investigators should state precise amounts of financial compensation, if applicable. For example, "If you are harmed by being in this study, we will provide or arrange care as needed. Payment will be your responsibility, or that of your health insurance carrier (or Medicaid, etc.)."

REFERENCE:

AAHRPP V-1.A. Rutgers University has and follows written policies and procedures that require each protocol to provide a procedure for research participants to ask questions and voice concerns or complaints to the Investigator.

B. Confidential channel for participant concerns independent of protocol

The IRB requires that the Informed Consent document provide the contact information for the Sponsored Programs Administrator who serves as a confidential recourse for subjects or their families. The Administrator is the informed individual unaffiliated with the specific research protocol, with whom they can discuss problems, concerns, and questions; obtain information; or offer input. All of the consent documents must provide the Sponsored Programs Administrator's phone number (732-932-0150 ext. 2104) and the following email address: humansubjects@orsp.rutgers.edu; which participants can use to contact an individual anonymously who is unaffiliated with the research protocol.

REFERENCE:

AAHRPP V-1.B. Rutgers University has and follows written policies and procedures that establish a safe, confidential and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who may be unaffiliated with the specific research protocol.

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