

Complaints and Concerns			
Document	Version #	Effective Date	Page
SOP 032	1.0	11-08-2021	Page 1 of 2

1 PURPOSE

- 1.1 This SOP describes the process followed when research participants or other individuals express concerns or complaints regarding involvement in or the conduct of WVU research involving human participants.

2 OVERVIEW

- 2.1 The WVU IRB is committed to the protection of research participants. As such, research participants are encouraged to express any concerns or complaints regarding a WVU research project.
- 2.2 Consent documents must include the investigator's contact information (email address and phone number) for any questions, complaints, and/or concerns the participant or the legal representative may have about the research or related matters. Consent documents must also include contact information for the WVU OHRP. This contact information is made available for submitting questions, complaints, and/or concerns. Concerns and complaints may be submitted anonymously if preferred. Information about how to report complaints is also provided on the WVU OHRP website (<https://human.research.wvu.edu/about/participants>) (LINK TO THIS). This link includes the option to submit a concern or complaint with complete anonymity.
- 2.3 The WVU IRB will investigate all complaints or concerns received regarding human subject research conducted under its jurisdiction. All complaints and/or concerns will be handled confidentially, including the reporting of alleged violations of investigator compliance.

3 PROCEDURES

- 3.1 Complaints received by an investigator or members of the research staff must be reported to the IRB following the guidelines of the WVU OHRP policy regarding research-related events. (See SOP 031: Reporting Research-Related Events.)
- 3.2 Complaints directly reported to the IRB will be documented following the Reporting Research-Related Events policy (SOP 031).
- 3.3 The OHRP Director or designee will attempt to find a suitable resolution and respond to the complaint or concern in a timely manner. As necessary, complaints may be brought to the WVU IRB Chairs for discussion and recommendation.
- 3.4 If the concern or complaint involves possible noncompliance or research misconduct, the complaint will be handled according to WVU OHRP's Noncompliance and Research Misconduct Policy (SOP 034).

Complaints and Concerns			
Document	Version #	Effective Date	Page
SOP 032	1.0	11-08-2021	Page 2 of 2

4 REFERENCES

WVU Policies:

SOP 031: Reporting Research-Related Events

SOP 034: Noncompliance

Federal Regulations:

21 CFR 56.108(b)(1)

AAHRPP:

Standard I-4

Element III.1.G

History of Revisions to SOP

Effective Date	Nature of Revision(s)