FRANKLIN UNIVERSITY

PARTICIPANT CONCERNS/COMPLAINTS

The right of research participants to lodge a concern (e.g., allegation), complaint, or question and to be assured that the concern, complaint, or question is taken seriously and resolved in a timely manner is of prime importance. IRB staff are responsible for investigating concerns, complaints, and questions from participants and any improprieties involving investigators or their staff. The IRB Office handles these issues in a timely manner, assuring protection of human participants, and the IRB holds any violators accountable to the applicable regulation. A research participant (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human research study may raise concerns, complaints, or questions about a research project by telephone or in writing to the IRB Office.

PROCEDURES

Concerns/Complaints/Questions

1. A research participant or anyone with a concern, complaint, or question regarding a research study involving human participants may raise the concern, complaint, or question with the IRB Office. Upon receipt of a concern (e.g., allegation), complaint, or question, the IRB Office gathers the following information from the complainant as appropriate:

- Participant's (or complainant's) name, email address, and phone number (This information is NOT MANDATORY, and an individual may report an incident anonymously; however, a thorough review may not be possible, and, without this information, follow-up responses to the individual are not feasible.);
- Study protocol title and name of the PI;
- Date(s) of the incident; and
- An explanation of the concern, complaint, or question.

2. The IRB Office assures the individual (or complainant) that he/she will inquire into the circumstances and that the IRB/IRB Office will take appropriate measures to address the issue. Furthermore, a response to the individual will be forthcoming as rapidly as possible provided that contact information is given (e.g., if possible, within 2 to 3 weeks if the issue is a complaint). The IRB Office also explains to the individual the limits to confidentiality.

3. The IRB Office handles the concern, complaint, or question in a confidential manner to the extent allowed by law. The IRB Office limits access to information concerning the complainant to persons with responsibilities that require knowledge of the concern, complaint, or question.

4. The IRB Office conveys information regarding the concern, complaint, or question to the PI of the study at issue and the IRB Chair in a timely manner.

5. The IRB Office promptly investigates the concern, complaint, or question; evaluates the alleged impropriety on a case-by-case basis; and makes every effort to correct the issue(s) at the administrative level.

6. If the alleged impropriety involves potential harm to participants or others, the IRB Office notifies the IRB for immediate action pending formal inquiry. The IRB Office reports concerns, complaints, or

questions involving serious issues immediately to the IRB Chair and other relevant institutional leadership.

7. The IRB Office manages the inquiry, preparing related correspondence and maintaining documentation of the review for up to three years from completion of the inquiry or close out of the IRB protocol, whichever is longer.

8. The IRB Chair or his/her designee, in collaboration with the IRB Office, ensures appropriate response to each concern, complaint, or question and reports the action(s) taken to the IRB. If the complaint, concern, or question is of a minor nature such as a payment issue, the IRB Chair, IRB Office, or designee may resolve the issue without bringing it forth for an IRB committee vote. The IRB Chair, IRB Office, or designee refers major issues such as failure to obtain signed informed consent from potential participants (if required) to the IRB committee, and the IRB votes on any actions the IRB takes. All actions taken by the IRB are appropriate for the circumstances, and the final course of action is dependent on the nature, severity, and seriousness of the findings.

9. Depending on the nature of the event or circumstances, the IRB may take the following actions, but is not limited to:

- Further inquiry;
- Administrative action;
- Details and recommendations forwarded to the appropriate committee chairs for consideration in their committees;
- Details and recommendations forwarded to the appropriate department or program chair for action as appropriate;
- Details and recommendations forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up, if applicable;
- Following mandated reporting guidelines, as required, and;
- Other actions as deemed appropriate.

10. The IRB Office and the IRB monitor any concerns, complaints, or questions that an individual may lodge for issues of noncompliance. The IRB Office brings issues involving noncompliance to the attention of the IRB Chair, the IRB, and other relevant institutional officials.