University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 8 Effective Date: May 18, 2017 Last Reviewed: May 18, 2017 Attachment: Page 1 of 6 Prepared By: Anca Miron, Kelly Schill	Title: **Participant Concerns or Complaints**

I. Policy Goals

The University of Wisconsin Oshkosh is committed to protecting the rights and welfare of human subjects in research. Complaints from research participants must be addressed by members of the institution to ensure that suitable resolutions can be identified to protect the rights and welfare of research participants. A participant may voice a concern or complaint directly, or a representative of the participant may voice the concern or complaint on behalf of the participant. When addressing participant complaints, appropriate privacy and confidentiality protections must be in place throughout the process to ensure protection of the participant.

II. Participant Complaint Chain of Command

A. Participant complaints should be reported in the following manner:

1) Concerns may be reported directly to Principal Investigator (PI) and study team. Contact information for PI is located on the IRB Consent Form.

2) If a participant would like to contact someone outside of the PI or study team with a concern or complaint, or if the issue is not resolved after communicating with the PI, then the IRB Chair may be contacted:
   Phone: (920) 424-3215
   Email: irb@uwosh.edu
   Anonymous Online Submission: Participant Concerns or Complaint Form
   U.S. Mail:
   Attn: IRB Chair
   University of Wisconsin Oshkosh
   Department of Sponsored Programs and Faculty Development
   800 Algoma Blvd.
   Oshkosh, WI 54901

3) If the IRB chair has a conflict of interest or is unable to resolve the issue, then the IRB Administrator may be contacted:
   Phone: (920) 424-3215
   Email: irb@uwosh.edu

U.S. Mail:
Attn: IRB Compliance Administrator
University of Wisconsin Oshkosh
Department of Sponsored Programs and Faculty Development
800 Algoma Blvd.
Oshkosh, WI 54901

III. Participant Complaint Procedure

A. Participant complaints received by the PI and/or study team

If a participant complaint is received by the investigator or study team (any individuals directly involved with participants or the informed consent process), the investigator must ensure that the complaint is addressed and resolved in a method that protects the rights and welfare of the participant and is consistent with the IRB-approved study. If the complaint results in the need for the investigator to amend the IRB-approved study, an IRB Modification Request Form must be submitted to the IRB for approval.

All complaints received by the PI and/or study team should follow these reporting guidelines:

1) If the complaint is resolved by the PI and does not meet the criteria of an unanticipated problem, then no further action is required.
    - The phrase "unanticipated problems" involving risks to subjects or others" is found but not defined in the HHS regulations at 45 CFR part 46. OHRP considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:
        a. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
        b. related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
        c. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
    - OHRP guidance on unanticipated problems and examples
2) If the complaint meets the criteria of an unanticipated problem, the investigator must report the complaint promptly to the IRB using the Unanticipated Report Form. If the PI is uncertain if an event meets the criteria of an unanticipated problem, they should contact the IRB Chair for clarification. Unanticipated problems are reviewed by a convened IRB.
    - It may not be possible for the investigator to completely resolve the complaint prior to the prompt reporting deadline (within 72 hours of event); however, the investigator must still report the incident and should describe the current status of

the complaint resolution in the Unanticipated Report Form as well as a plan for future action toward resolution.
    - If a complaint involves non-compliance with the IRB-approved protocol, procedures outlined in SOP #9: Noncompliance will be followed.
3) If the investigator is unable to resolve the complaint satisfactorily with the participant, the complaint should be reported by the investigator to the IRB Chair. The IRB Chair should be notified promptly at such a time as it is determined that the problem cannot be resolved without additional help from the institution.

B. Participant complaints received by the IRB Chair

If a participant complaint is received by the IRB Chair, the chair takes necessary steps to address the complaint. If the complaint identifies a specific study of concern, the investigator of the study may be contacted to assist in addressing the complaint. The IRB chair will complete the Reporting Form for Participant Concerns or Complaints (Appendix A) or ask the complainant to complete the form. The form is used to document receipt of the complaint as well as any actions taken to address the complaint. The IRB chair may engage the IRB (or a subcommittee of the IRB) if assistance with a corrective action plan for resolving the issue is necessary.

C. Participant complaints received by head of IRB: an institutional official outside of the study team

Any participant complaints received that have not been resolved by the PI, study team, or IRB Chair are directed to the head of the IRB. If necessary, the head of the IRB will consult with the Institutional Official for Research to develop a corrective plan to resolve the issue.

References:

1. University of Utah: https://irb.utah.edu/participant-resources/complaints.php
2. UCLA OHRPP; Policy and Guidance: Complaints, Concerns and Suggestions, and reports of undue influence regarding the conduct of human participants' research. http://ora.research.ucla.edu/OHRPP/Documents/Policy/11/Complaints.pdf
3. Tulane IRB Complaints and Non-compliance policy. http://www2.tulane.edu/asvpr/irb/upload/Section-10-Complaints-and-NonCompliance.pdf
4. USC HSPP Policies and Procedures (2016). Chapter 22. Complaints regarding human subjects research. https://oprs.usc.edu/files/2012/11/Chapter-22-Complaints-Regarding-Human-Subjects-Research.pdf

APPENDIX A: **Please Date Form:** _____

UWO Institutional Review Board

REPORTING FORM FOR PARTICIPANT CONCERNS OR COMPLAINTS

Participant concerns or complaints may be reported in the following manner:

1) Concerns or complaints may be reported directly to PI and study team.
2) If a participant would like to contact someone outside of the PI or study team, this form may be submitted.

Instructions for submitting this form:

You may choose to use this form to report a concern or complaint. You can send this form in one of three different ways:

Submit Online Anonymously:	**Email Form to**:	**By US mail:**
UW Oshkosh IRB Website	irb@uwosh.edu	Attn: IRB Chair University of Wisconsin Oshkosh Sponsored Programs & Faculty Development 800 Algoma Blvd Oshkosh, WI 54130

There are two additional ways you can choose to report a concern or complaint:

- You may choose to report your concern or complaint by phone by calling the IRB Chair, Dr, Anca Miron, at (920) 424-2328.
- You can also send a letter to the above address to report your concern or complaint. If you send us a letter, you may find it helpful to use the questions in this form as a guide for the content of your letter.

Important Note: All research concerns and complaints are taken very seriously. The information you provide on this form will be kept as confidential as possible. However, we may need to share this information with others in order to follow-up with your concern or complaint. If you wish to report anonymously, you will may submit the form online.

A. Your Name			
Name (Optional or Initials Only):			
May we reveal that you are the source of this concern or complaint to the study's Principal Investigator and other study staff?	☐ **Yes** ☐ **No**	**Today's Date:**	

B. Personal Contact Information (REQUIRED if you wish to hear back from us regarding this complaint)			
Phone:		Email Address:	
Alternate Phone:		Other Contact Info:	
Are you making this report for someone else?	☐ **Yes** → ☐ **No**	If yes, please explain:	

C. Study Information			
1. Please tell us about the study for which you have a concern or complaint:			
Study Name or Description:			
Name of Study Investigator(s):		Study Phone Number:	

2. Please tell us about the research concern or complaint you are reporting:

3. Please tell us how would like to see your concern or complaint resolved:			
4. Have you discussed this concern or complaint with the Principal Investigator or other study staff?	☐ **Yes** → ☐ **No**	*If yes, please let us know whom you contacted:*	
5. Are you or were you a participant in this study?		☐ **Yes** → ☐ **No**	If yes, please answer questions a to d below:

a. When did you start participating in the study? (Please guess even if you can't remember):	Date:	
b. Are you still participating in the study?	☐ **Yes** ☐ **No**	
c. Do you have a consent form for this study?	☐ **Yes** → ☐ **No**	If yes, please attach a copy of the consent form or other written information that you have.
d. Do you have any other written information about this study? (e.g., debriefing document, study forms, etc.)	☐ **Yes** → ☐ **No**	

If you have additional comments or need additional space, please attach additional sheets.

Office Use Only

Intake/Initial Processing

CASE # _____

Date Received: _____ Received By: _____

Date Entered to Tracking Log: _____ Date IRB File Requested: _____

Resolution Date (Document Resolution in Tracking Log and QIU case file): _____

Referred to: _____ Date of Referral: _____

Study Information

Principal Investigator(s): _____ PI Phone#: _____

Department Contact _____ Contact Phone #: _____

Title of Study: _____

IRB Approval #: _____ Date(s) of Approval: _____