

Date

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:
[UW Oshkosh IRB Website](#)

Email Form to:

irb@uwosh.edu

By US mail:

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?		<input type="checkbox"/> Yes <input type="checkbox"/> 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?		<input type="checkbox"/> Yes → <input type="checkbox"/> 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?	<input type="checkbox"/> Yes → <input type="checkbox"/> No	<i>If yes, please let us know whom you contacted:</i>	
5. Are you or were you a participant in this study?	<input type="checkbox"/> Yes → <input type="checkbox"/> No	If yes, please answer questions A-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 <input type="checkbox"/> No		
c. Do you have a consent form for this study?	<input type="checkbox"/> Yes → <input type="checkbox"/> 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.)	<input type="checkbox"/> Yes → <input type="checkbox"/> No		

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

Office Use Only	
<u>Intake/Initial Processing</u>	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: _____
Principal Investigator(s): _____	PI Phone#: _____
Department Contact _____	Contact Phone #: _____
Title of Study: _____	
IRB Approval #: _____	Date of Approval: _____