UNIVERSITY of NORTH CAROLINA ASHEVILLE

Institutional Review Board

REPORT FORM FOR RESEARCH CONCERNS OR COMPLAINTS

Today's Date:_____ Time Reported: _____

Instructions for Submitting This Form:
You may choose to use this form to report a concern or complaint. You can send us this form in one of three ways:

By E-mail:
lvtoms@unca.edu
Attn: Louis Toms, IRB Administrator

By US Mail:
Institutional Review Board
University of North Carolina at Asheville
Attn: Lacy Clegg, IRB Administrator
One University Heights, CPO 2030
Asheville, NC 28804

There are two (2) additional ways you can submit this form:

1. You may choose to report your concern or complaint by calling (828) 251-6476 and asking for Louis Toms, IRB Administrator.
2. You may send a letter to report your concern or complaint. Please mail it to the address above and use this form as a guide to include important information.

Important Note: All research complaints are taken very seriously. The information you provide will be kept confidential. We may need to share this information with others in order to follow-up with your concern or complaint.

A. Your Name

Optional (Name or Initial Only): _____

May we reveal your name to the principal investigator or other study staff regarding this complaint or concern? ___ Yes ___ No

B. Personal Contact Information (Required if you wish to be contacted regarding this complaint or concern.)

Phone:		E-mail:	
Alternate Phone:		Other Contact Info:	

Unless you agree, we will not share your personal information outside the IRB.

Are you making this report for someone else? ___ Yes ___ No If yes, please explain:

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C. Study Information

1. Please tell us about the study for which you are reporting this complaint:

Principal Investigator or Other Study Staff:	
Name or Description of Study:	
Study Phone Number: (found in your consent form)	

2. Please describe your concern or complaint:

Example: Seeing Orthopedics center as a participant and is given an iPad with 5-10 minutes of questions. No sort of cover letter. Concern is that it is appearing that it is for clinical care only. Needs to be clearer (if it's for research) that it IS for research. Doctor doesn't appear to look at this information.

3. Please explain how you would like us to help resolve this concern or complaint:

4. Have you contacted the Principal Investigator or other study staff? ___ Yes ☐ ___ No If yes, please state who you contacted:

5. Are you or were you a participant in this study? ___ Yes ☐ ___ No If yes, please respond to the following questions below (a – d):

   a. Please estimate a date when you started this study:
   (This does not have to be an exact date)

   b. Are you still participating in the study?
   ___ Yes
   ___ No

   c. Do you have a consent form for this study?
   ___ Yes ☐ If yes, please provide a copy of what written documents you might have.
   ___ No

   d. Do you have any other written information about this study?
   ___ Yes ☐ If yes, please provide a copy of what written documents you might have.
   ___ No

D. Additional Information
Please use this space to provide any additional information you wish to share. You may also attach extra sheets of paper if you need additional space.

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IRB ADMINISTRATIVE USE ONLY	
Initial Intake / Processing:	IRB#
Date Received:	Received By:
Referred to IRB Chair:	Date of Referral:
Resolution Date:	Action(s) taken (if any):
STUDY INFORMATION:	
Principal Investigator:	PI Phone:
Person to Contact:	Contact Phone:
Department:	
Study Title:	
ADDITIONAL COMMENTS:	