**REPORT FORM FOR RESEARCH CONCERNS OR COMPLAINTS**

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| Today’s Date:       Time Reported: |

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| **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**:  [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu)  Attn: Lacy Clegg, IRB Administrator | **By Fax:**  Attn: Lacy Clegg, IRB Administrator (801) 587-9138 | **By US Mail:**  Institutional Review Board  University of Utah  Attn: Lacy Clegg, IRB Administrator  75 South 2000 East, #111  Salt Lake City, UT 84112 | | |
| **There are two (2) additional ways you can submit this form:**   1. You may choose to report your concern or complaint by calling (801) 581-3655 and asking for Lacy Clegg, 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.

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| **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 |

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| **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: | | | |
| 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 more clear (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: | | | |
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| 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): |
| 1. Please estimate a date when you started this study:   (This does not have to be an exact date) | | | |
| 1. Are you still participating in the study?   Yes  No | | | |
| 1. Do you have a consent form for this study?   Yes 🡪 If yes, please provide a copy of what written documents you might have.  No | | | |
| 1. 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 | | | |

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| **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 OFFICE USE ONLY** | | | | | |
| Initial Intake / Processing: |  | | IRB# | |  |
| Date Received: |  | | Received By: | |  |
| Date Entered into ERICA: |  | | | | |
| Referred to  (if applicable): |  | 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:** | | | | | |
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