
REPORTING FORM FOR HUMAN SUBJECT RESEARCH CONCERNS OR COMPLAINTS

Instructions:

You may use this form to report a concern or complaint regarding human subjects research. You can send us this form in one of two ways:

By email:

sleming@capefearvalley.com

By US Mail:

Research Subject Advocate HRPP/IRB
Office/Medical Education
Cape Fear Valley Health System
1638 Owen Drive
Fayetteville, NC 28304

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 office at (910) 615-5839 and speaking with the Research Subject Advocate.
- 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.

NOTE: All human subject 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. The Human Research Protection Program and the Institutional Review Board adhere to Cape Fear Valley Health System's Whistleblower Policy.

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|--|---|-------------------------|--|
| Part I: Your Name | | Date: | |
| Name (optional or initials only): | | | |
| May we reveal that you are the source of the concern or complaint to the study's Principal Investigator and other study staff? | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Part II: Personal Contact information (REQUIRED if you wish to hear back from us regarding this complaint) | | | |
| Phone: | | Email Address: | |
| Alternate Phone: | | Other Contact Info: | |
| <i>Unless you authorize us to do so, your personal contact information will not be release to anyone outside the HRPP/IRB.</i> | | | |
| Are you making this report for someone else? | <input type="checkbox"/> Yes <input type="checkbox"/> No | If yes, please explain: | |
| Part III: 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 (if available) | | | |
| 2. Please tell about the research concern or complaint you are reporting: | | | |
| 3. Please tell us how you would like to see your concern or complaint resolved: | | | |
| 4. Have you discussed this concern or compliant with the Principal Investigator or other study staff | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | If "Yes", please let us know who you contacted: | | |
| 5. Are you or were you a participant in this study? | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | If "Yes", please answer the following: | | |
| a. When did you start participating the study? (Please guess if you cannot remember) | Date: | | |
| b. Are you still in the study? | <input type="checkbox"/> 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? | <input type="checkbox"/> Yes <input type="checkbox"/> No | | |

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