**USE OF A NCI INFORMED CONSENT TEMPLATE**

**EAST CAROLINA UNIVERSITY INFORMATION SHEET**

In November 2018 the NCI issued more specific guidance on the use of boilerplate language in their informed consent templates. Click here to review the [NCI’s Guidelines for Permitted Boilerplate Language Additions](https://www.ncicirb.org/announcements/new-guidelines-permitted-boilerplate-language-additions). This revised information sheet reflects the current guidance from the NCI.

 If your human research study does not involve ECU, reference to ECU requirements/contacts should not be included and you should verify that site-specific appropriate language is included instead. The permitted additions to the NCI informed consent template for local boilerplate language are limited to the information below.

**REQUIRED INSTITUTIONAL LANGUAGE/INSTRUCTIONS:**

1. **The following identifying information must be present at the top of the first page of the consent document.**

Title of Research Study:

Sponsor/Funding Source:

Sponsor Protocol #:

Principal Investigator:

Institution/Department or Division***(As Applicable)***:

Address:

Telephone#:

Study Coordinator ***(If Applicable)***:

Telephone #:

1. **Patient Identification as a Research Participant**

For all study consents where the target population consists of patients a name and date of birth line must be inserted on the first page of the consent document. You may cut and paste from the block below.

Participant Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Please PRINT clearly**

1. **Local Contact Information**

The CIRB-approved consent template provides blank areas for contact information regarding the local study doctor (questions or concerns about the study) and the IRB (rights while in the study). In addition, you will find instructions in the template that say, “contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.” This would be the location where, if ECU Health Medical Center is a study site, you would list contact information for ECU Health Center for Research and Grants and/or ECU Health Medical Center’s Risk Management Office.