This application must be used by Rutgers Cancer Institute Investigators submitting proposed exempt research in eIRB+ through the Fast Track Exempt Review Process. The PI completes this form for SRB review. If approved, the Rutgers Cancer Institute Coordinator completes an exempt eIRB+ submission on the PI's behalf. Rutgers Cancer Institute Reviewers are selected. This document is used in place of a Rutgers IRB Protocol.

A copy of this completed document must be uploaded into eIRB+ and retained in the research record.

IMPORTANT NOTE: Due to changes as a result of the Revised Common Rule, some Exempt Research is not eligible for Rutgers Cancer Institute Fast Track Exempt Review process, they require submission to the IRB for "Limited IRB Review". These studies must be formatted using the IRBs Non-Interventional Research Protocol 15.302 (HRP-503b), or the Secondary Research With Data or Biospecimens Protocol template 15.303 (HRP-503c) template for SRB and IRB review/approval. Please contact the Rutgers Cancer Institute Scientific Review Board (SRB) Coordinator for guidance on the appropriate template to use or if you have questions about this process.

Research Not Eligible for Rutgers Cancer Institute Fast Track Exempt Review

- **Studies Requiring Limited IRB Review Under The Following Exempt Categories:**
  - **Exempt Category 2 (iii)**: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) where the information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or through identifiers linked to the subjects.
  - **Exempt Category 3 (i)(C)**: Research involving benign behavioral interventions iii in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or through identifiers linked to the subjects.
- **Studies Governed By HIPAA Regulations Which Use Identifiable Private Information Or Identifiable Biospecimens:**
  - **Exempt Category 4(iii):** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens if the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA), subparts A and E, for purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).

A. Principal Investigator Information		
Principal Investigator (PI):	*[Enter Response]*	
Institution:	☐ Rutgers Cancer Institute	
Department:	*[Enter Response]*	
Address:	*[Enter Response]*	
Telephone (daytime vs. nights & weekends):	*[Enter Response]*	
Cell:	*[Enter Response]*	
Email:	*[Enter Response]*	
B. Requestor Information (If Different From PI):		
Requestor:	*[Enter Response]*	
Telephone (daytime vs. nights & weekends):	*[Enter Response]*	
Cell:	*[Enter Response]*	
Email:	*[Enter Response]*	
C. PI MEMBERSHIP STATUS:		
Status:	☐ Rutgers Cancer Institute Full Member ☐ Rutgers Cancer Institute Associate Member	
Program Management Area:	☐ Clinical Investigations and Therapeutics ☐ Cancer Metabolism and Growth ☐ Cancer Pharmacology Cancer	☐ Other _____

	☐ Prevention and Control ☐ Genomic Instability and Cancer Genetics	

D. PROJECT INFORMATION:	
Study/Grant Title:	*[Enter Response]*
Funding Source:	*[Enter Response]*
Project Start Date:	*[Enter Response]*
Project End Date:	*[Enter Response]*
Research Staff:	Names of Individuals (Research Staff) who will be given access to the study data or specimens: Please list their names and contact information. 1. *[list name and contact information]* 2. *[list name and contact information]* 3. *[list name and contact information]*
External Collaborators:	☐ No ☐ Yes: *If yes, a Data Use Agreement and/or Material Transfer Agreement must be uploaded with this application.*
Institutional Biosafety Committee (IBC) Approval (if applicable)	☐ Attached.

E. PROJECT DESCRIPTION:

Please describe briefly the proposed research in non-technical language. If you state that participants will be anonymous, please note how anonymity will be ensured. Please attach any questionnaires, informed consent documents, or debriefing statements you plan to administer.

1. **Objectives:**
   [Enter Response]

2. **Background and Hypothesis:** (*Brief description of project rationale*)
   [Enter Response]

3. **Project Significance:**
   [Enter Response]

4. **Project Specific Aims/Goals:** (*Please use numeric or bulleted lists)*
   [Enter Response]

5. **Research Plan/Study Design:**
   [Enter Response]

6. **Procedures (If applicable):**
   [Enter Response]

7. **Study Participant Data Collection (If applicable):**
   [Enter Response]

8. **References:**
   [Enter Response]

F. Studies Involving Request for De-identified <u>Bio-Specimens</u>: ☐ N/A

1. Will de-identified specimens (and if applicable, data) be obtained exclusively from the Rutgers Cancer Institute Biospecimen Repository Services (BRS) Shared Resources?	☐ No ☐ Yes If No, explain where de-identified specimens (and if applicable data) will be obtained from:
2. Is this research limited solely to the use of FDA-regulated in vitro diagnostic (IVD) device study with left over human specimens (or specimens from an IRB approved repository) that are not individually identifiable?	☐ No ☐ Yes If yes, STOP this application is **not** acceptable for this type of review. Please see the Important Note on page 1 of this application.
3. Will any information from this project be submitted to the FDA or held for inspection by the FDA?	☐ No ☐ Yes If yes, STOP this application is **not** acceptable for this type of review. Please see the Important Note on page 1 of this application.
4. Specimens Details	☐ Number of Specimens: _____ ☐ Type of Specimens: _____

G. Studies Involving a Request for De-identified Data: ☐ N/A

1. Will this research study access (look at) identifiers or identifiable information?	☐ No ☐ Yes If Yes, STOP this application is **not** acceptable for this type of review. Please see the Important Note on page 1 of this application.
2. Will this research study or will research staff collect/receive specimens (and if applicable, data) with identifiers or identifiable information?	☐ No ☐ Yes If Yes, STOP this application is **not** acceptable for this type of review. Please see the Important Note on page 1 of this application.
3. Will this research study or will research staff record subject identifiers and link them to the specimens (and if applicable, data)?	☐ No ☐ Yes If Yes, STOP this application is **not** acceptable for this type of review. Please see the Important Note on page 1 of this application.
4. Do the specimens (and if applicable, data) have a numerical, alpha, or alpha numerical code such that a link exists that could allow the specimens (and if applicable, data) to be re-identified?	☐ No ☐ Yes If Yes, is there a written agreement that prohibits the PI and research staff from accessing the link? ☐ No ☐ Yes If yes, upload the signed agreement If No, explain:
5. In what format will medical record information be provided to this study team?	☐ De-identified (HIPAA "safe harbor"; none of the 18 HIPAA identifiers will be included). ☐ Limited Data Set (includes dates and certain geographic information) 1. Justify why dates and/or geographical information from medical record are needed to perform this study: *[Enter Response].* 2. Justify the need for each of the requested medical record data elements that are specified: *[Enter Response].* 3. Data Use Agreement for Limited Data Sets must be uploaded to application. Note: This application cannot be processed without this form, signed by the recipient: *[Enter Response].*

H. PI Certification (To be complete by Principal Investigator)

Does your study meet the following requirements:

☐ No

☐ Yes, if yes, please initial by each item below:

_____	No attempts will be made to contact subjects pertaining to this project.
_____	No attempts will be made now or in the future to identify, re-identify, link and/or re-link any data or samples used with this project.
_____	No identifiable information will be created as a result of this project.
_____	No member of the research staff has interacted, for research purposes, with the individuals whose specimens (and if applicable, data) will be studied (note: if any members of this study team are/were affiliated with a research project you will obtain specimens (and if applicable data) from, you may not qualify for this determination) AND No identifiable private information will be reviewed or recorded.

This is to certify that the procedures utilized in this study are appropriate for minimizing risks to the subjects and I take full responsibility for the conduct of the research. I certify that I and, if applicable, the students whom I am supervising, are qualified to conduct this research.

[Signature] — ***Investigator Signature***

[Date Signed] — ***Date***

[Printed Name] — ***Investigator Printed Name***