

IRB APPLICATION

Email the completed IRB application, informed consent and other consent documents, locator forms, measurement forms, and all other documents that participants will be asked to complete to Kelli Wright at kwright@chestnut.org.

If you have any questions regarding the completion of this form, email Kelli Wright at kwright@chestnut.org.

Respond to all items. Type “NA” if not applicable.

**SECTION A: GENERAL INFORMATION**

1. Project Title:

2. Funding Source(s):

3. Estimated Project Duration:

4. Estimated Start Date:

5. Principal Investigator Information

 a. Last Name:

 b. First Name:

 c. Degree:

 d. Organization:

 e. Street Address:

 f. City/State/Zip:

 g. Telephone:

 h. Email:

6. Co-Investigator Information

 Co-Investigator #1

 a. Last Name:

 b. First Name:

 c. Degree:

 d. Telephone:

 e. Email:

 Co-Investigator #2

 a. Last Name:

 b. First Name:

 c. Degree:

 d. Telephone:

 e. Email:

**SECTION B: RESEARCH DESCRIPTION**

7. Hypotheses/Objectives:

8. Intervention (if applicable):

9. Sample Size and Characteristics:

10. Setting:

11. Instrumentation (list all instruments and tools to be used and submit with this form):

12. Measurement Frequency:

13. Research Design:

14. Statistical Analysis Plan:

**SECTION C: HUMAN SUBJECT PROTOCOL**

15. Study Design (check all that apply):

 [ ]  Retrospective (data already exist; e.g., record review)

 [ ]  Prospective (data do not currently exist)

 [ ]  Randomized

 [ ]  Subjects blinded

 [ ]  Other – please explain:

16. Subject Identification (check all that apply):

 [ ]  The data used for this research is free of identifying information (such as name, pseudonym, treatment record number, linked code)

 [ ]  The data is coded but not linked to a subject identifier

 [ ]  The data is coded but the subjects’ identities could be obtained if needed

 [ ]  The data contains references to the subjects’ identities

 [ ]  Other – please explain:

17. Data Source (check all that apply):

 [ ]  Information in the public domain (e.g., newspaper)

 [ ]  Treatment records

 [ ]  Questionnaire/survey or interview

 [ ]  Laboratory samples (e.g., urine)

18. Describe procedures to keep collected data confidential:

19. Special Subject Groups (check all that apply):

 [ ]  Pregnant

 [ ]  Children/adolescents

 [ ]  Prisoners

20. Source of Subjects (check all that apply):

 [ ]  Chestnut Health Systems patients

 [ ]  Other – please explain:

21. Who will pay for treatment costs? (check one)

 [ ]  Funding agency

 [ ]  Participant/insurance

 [ ]  Other – please explain:

 [ ]  Not applicable

22. Explain plans for participant recruitment:

23. Total participant payment amount:

24. Are alternative treatments available to the patients/subjects? (check one)

 [ ]  Not applicable

 [ ]  No

 [ ]  Yes – please explain:

25. List the names and titles of all persons obtaining informed consent:

26. Describe training for persons obtaining informed consent:

27. List any potential risks involved (e.g., unauthorized disclosure of confidential data, drug reaction):

28. Describe steps taken to minimize risk (e.g., certificate of confidentiality, ID codes, record security):

29. Describe how the subjects and/or society will benefit from this study:

30. Good Clinical Practice (GCP) Certification: Is this study a clinical trial funded by NIH and/or is this study a clinical trial of medication or a medical device?

 [ ]  No

 [ ]  Yes – List the names and titles of all investigators and personnel responsible for clinical study coordination, data collection, and data management. All individuals listed must have completed the GCP certification program at National Drug Abuse Treatment Clinical Trials Network (<https://gcp.nihtraining.com/>) within the past 3 years. GCP certification documentation must be included as part of the IRB submission for this project.

31. Adverse Event Reporting: All studies are to report unanticipated events to the IRB’s Human Protections Administrator within 2 business days of PI notification. Unanticipated events are events that are not consistent with the foreseeable risk associated with research procedures or are not expected in the natural progression of any underlying condition of the sample. All deaths are considered unanticipated events. Reports should be made to the Human Protections Administrator by sending a copy of a completed Adverse Event Report (Adverse Event report forms for a DSMP may be used or the Adverse Event Form Template located at Y: <http://chestnut.org/LI/Institutional-Review-Board>).

a. Is there is a Data Safety and Monitoring Plan (DSMP) for this study?

[ ]  No

[ ]  Yes – Include a copy of the DSMP with your IRB application

32. (For Drug Studies Only) Test Article Summary:

 a. Drug (check all that apply)

 [ ]  Drug is FDA-approved to use for any indication

 [ ]  Drug is FDA-approved to use for this research study indication

 [ ]  Drug is FDA-approved to test in this research study

 a1. If any of the above boxes are checked, provide IND#:

 b. Device (check all that apply)

 [ ]  Device is FDA-approved to use for any indication

 [ ]  Device is FDA-approved to use for this research indication

 [ ]  Device is FDA-approved to test in this research study

 b1. If any of the above boxes are checked, provide IND# or IDE#:

 c. Radioactive substances

 [ ]  Yes

 [ ]  No

33. Financial interests: Indicate below if any investigators or any members of their immediate families have any relationships, commitments, or activities with the sponsor of this research that might present or appear to present a conflict of interest with regard to the outcome of the research. If you have questions about conflict of interest, contact Dr. Mark Godley, Human Subjects Protections Administrator, at 309-451-7800.

 [ ]  Ownership, equity, or stock options

 [ ]  Has been disclosed to Chestnut Health Systems

 [ ]  Has not been disclosed to Chestnut Health Systems

 [ ]  Personal compensation such as royalties, consulting fees, etc.

 [ ]  Has been disclosed to Chestnut Health Systems

 [ ]  Has not been disclosed to Chestnut Health Systems

 [ ]  Intellectual property such as patents, trademarks, copyright, licensing, etc.

 [ ]  Has been disclosed to Chestnut Health Systems

 [ ]  Has not been disclosed to Chestnut Health Systems

 [ ]  Other conflict of interest – please explain:

 [ ]  Has been disclosed to Chestnut Health Systems

 [ ]  Has not been disclosed to Chestnut Health Systems

 [ ]  No conflicts exist

Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_