Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date Study Expires: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please select/initial **one** course of action:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ **I do not wish to renew my study.** All data collection and analysis are complete. The study has been completed.

**OR**

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Future use is only analysis of de-identified data and paper preparation.** **All data has been collected and completely de-identified** such that all information that appears alone or in combination with other information would not reveal anyone’s identity and anonymity is assured. All links to the identities of the subjects have been completely removed. For example: There are no names, no addresses, no phone numbers, no email addresses, no Web Universal Resource Locators (URLS), no Internet protocol (IP) addresses, no fax numbers, no school identification numbers, no employee numbers, no social security numbers, no birth dates, or other identifiable information that could possibly connect the data to an individual.

If a medical chart or record is involved, the De-identification and Confidentiality Forms are required for submission to the Louisiana Tech IRB. Data should not include biometric identifiers, including finger and voice prints or photographs. No biologic specimens, whether “de-identified” or not, are involved. For guidance on biologic specimens see the following URL: <http://www.hhs.gov/ohrp/policy/cdebiol.html>. Information not required in or approved for the approved study has been expunged.

1. The only continuation of research is analysis of de-identified data and article preparation as previously approved.

Data that is to be reanalyzed for a purpose other than that originally approved should be resubmitted for expedited review or exemption. Any use of data is subject to the approval of all of the original investigators. Note: Consent forms will be required to be kept on file for a minimum of 3 YEARS after data usage is complete.

**My signature certifies data has been de-identified and will only be used for previously approved purposes.**

**Researcher’s Signature Date**

 **Or**

1. \_\_\_\_\_\_\_\_**I wish to renew the research**. (Continued on Page 2)

|  |
| --- |
| List Current P.I. (s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |
| Phone: Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |

Attach Training Certificates for all P.I.’s.

 See <https://about.citiprogram.org/en/homepage/>

 to take the training & print out your certificates

|  |  |
| --- | --- |
| 1.  | The number of subjects accrued: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
| 2. | Have additional risks been identified? \_\_\_\_\_\_\_Yes or No\_\_ \_\_\_\_ (Check one, if so specify). |
|  |  |
| 3. | Is research permanently closed to the addition of subjects? \_\_\_\_ \_\_\_\_\_Yes or No\_\_\_\_\_\_\_\_ |
|  |  |
| 4. | Have all subjects completed all research-related interventions? \_\_ \_\_\_Yes or No\_\_\_\_Is the research remaining active only for long-term follow-up subjects? \_\_\_\_\_\_\_Yes or No\_\_\_\_\_\_ |
|  |  |
| 5. | Is the remaining research activities limited to data analysis? \_\_\_\_\_\_Yes or No \_\_\_\_\_\_ |
|  |  |
| 6. | Summarize adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review. If none please check \_\_\_\_\_\_NA. (You may attach pages if necessary to summarize).  |
|  |  |
| 7. | Summarize any relevant recent literature, interim findings, and amendments or modifications to the research since the last review that would alter your procedure. If none please check \_\_\_\_\_NA. (You may attach pages if necessary to summarize). |
|  |  |
| 8. | Summarize any relevant multi-center trial reports. Check \_\_\_\_\_\_\_\_NA if not applicable. (You may attach pages if necessary to summarize). Summarize any other relevant information, especially information about risks associated with the research: changes in location, facility, P.I.’s, or design. |
|  |  |
| 9. | Please attach the following:  |
|  | 1. A copy of the current informed consent document and any newly proposed consent documents.
 |
|  | 1. A copy of the complete protocol including any modifications previously approved by the IRB.
 |
|  | * Is the currently approved or proposed consent document still accurate and complete?

\_\_\_\_ \_\_\_\_\_\_Yes or No \_\_\_\_\_\_\_\_\_\_\_  |
|  |  |
|  | * Are there any significant new findings that may relate to the subject’s willingness to

continue participation provided to the subject in accordance with HHS regulations at 45 CFR 46.116 (b) (5)? \_\_\_\_\_\_Yes or No\_\_\_ \_\_\_(The link to regulations available on Tech research web site). |
| 10.  | Are copyrighted materials involved? \_\_\_\_\_\_ Do you have permission to use copyrighted materials? \_\_ \_\_\_\_\_ |
|  |  |
| 11. | If prior permission was required from another institution, please indicate if that approval is still valid. YES\_\_\_\_\_\_approval still valid NO\_\_\_\_\_\_will need to update approval. |