**DESCRIPTION:** IRBs must review studies at regular intervals to determine if – in light of any changes in the study or the world around it – it remains approvable. This is also a good time to review your files to make sure all your documentation is in order.

If you can attach an electronic signature, we will accept it. If not, we will accept the form electronically but a signed copy must be sent.

**MAKE A COPY FOR YOUR STUDY CORRESPONDENCE FILE.**

|  |  |  |  |
| --- | --- | --- | --- |
| E&I Approval Number |  | IRB Expiration Date |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. Study and Personnel - Updates and Information | | | | | |
| A.1. The Study | | | | | |
| Study Title | |  | | | |
| Study Number | |  | | | |
| Protocol date/version | |  | | | |
| A.2. The Investigator | | | | | |
| Investigator |  | | Title |  | |
| Agency |  | | Phone |  | |
| Address |  | | Fax |  | |
| City |  | | E-mail |  | |
| State Zip |  | |  | | |
| A.3. Conflicts of Interest – Screening question | | | | | |
| Have you declared any conflict of interest to the sponsor?  Are you (including your family and any key personnel and their families) receiving stocks, bonuses, gifts, titles, honors, or other benefits that could affect subject recruitment or study outcome? Are there any promises of such? | | | | | No  Yes:  If “***yes***, please complete the supplemental **E&I Form 31** that has more precise questions |

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| --- | --- | --- |
| 1. Places - Updates and Information | | |
| B.1. Acquisition Sites: List all sites from which you received Data or biological specimens | | |
|  | Site 1 | Site 2 |
| Facility Name |  |  |
| Address |  |  |
| Phone |  |  |
| Fax |  |  |
| What kind and number of specimens? |  |  |
| B.2. Study Sites: List all sites where the specimens were used in your studies. | | |
|  | Site 1 | Site 2 |
| Facility Name |  |  |
| Address |  |  |
| Phone |  |  |
| Fax |  |  |
| What kind and number of specimens? |  |  |

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| 1. Study Activity – Updates and Information | | | | |
| Continuing review is intended to assess whether anything has happened that would alter the original decision to approve. The major change in this area might be a change of source material, consent at acquisition, or measures to assure protection of privacy. | | | | |
| C.1. Protocol Changes | | | | |
| 1 | | Describe any changes made in this protocol after the last complete review. |  | |
| 2 | | Describe any changes requested at this time. |  | |
| C.2. Consent and Privacy Evaluation | | | | |
| 1 | | What information is available about the consent of the donor? | | None or N/A or |
| 2 | | Do you have a (sample) copy of the consent document? | | None or N/A or |
| C.3. External Events: Summarize here or attach information | | | | |
| 1 | Any changes in this field that impact your work? | | | None or N/A or |
| 2 | Any social, legal, economic or other change that would alter donor perception (if they knew)? | | | None or N/A or |
| C.4. RISK AND DISCOMFORT EVALUATION Summarize here or attach information. A frequency table can be very useful. | | | | |
| 1 | Has it been necessary to break any code to return any information to a donor? | | | No or N/A or |
| 2 | Have any results had an impact on the group the donor represents? | | | None or N/A or |
| C.5. Benefit Evaluation Summarize here or attach information. | | | | |
| 1 | What benefit has come from your work? | | | No or N/A or |
| 2 | Has any publication resulted?  If ***yes***, attach it. | | | None or N/A or |
| C.6. Review Evaluation Summarize here or attach information. | | | | |
| 1 | Has this study been submitted to any other IRB? Is there something we can learn from that review? | | | No or N/A or |
| 2 | Please use one or two adjectives to describe your views of E&I and of the IRB. (Add an evaluation if you wish.) | | |  |

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| --- | --- | --- |
| Signatures | Principal Investigator | Person who prepared the form |
|  | Everything on this is true and complete. |  |
| Signature |  |  |
| Printed name |  |  |
| Title |  |  |
| Date |  |  |