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|  | **Investigator’s Progress Report**  Form version July 29, 2019 | **irb - forms** |

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| **Continuing Review (Complete Items 1-12)**  **—OR—**  **Final Report—all protocol-related activities are complete, including data analysis (Complete Items 1-11, and Item 13)** | **—FOR—** | **Expedited Review**  **—OR—**  **Convened (Full) Review** |

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| **1. Dates** | | |
| **Today’s Date** |  | To help avoid delay, respond to all required items in the format provided, and include requested materials. |
| **Starting Date of Project** |  | If previous approval expires before approval is officially re-issued by the Office of the IRB, all work on the protocol must cease. |
| **Current IRB Expiration Date** |  | The IRB recommends applying for continuing review *4-6 weeks* before expiration of current approval. ([See schedule.](http://www.uab.edu/irb/schedule)) |

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| **2. Principal Investigator (PI)** | | | |
| **Name (with degree)** |  | **Blazer ID** |  |
| **Department** |  | **Division** |  |
| **Office Address** |  | **Office Phone** |  |
| **E-mail** |  | | |
| **PI Contact who should receive copies of IRB correspondence (Optional)** | | | |
| **Name** |  | **E-mail** |  |
| **Phone** |  | | |

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| **3. UAB IRB Protocol Identification** | | |
| **Protocol Number** |  | |
| **Protocol Title** |  | |
| **Study Sponsor(s)** |  | |
| **OSP Assigned Number (9 digits)** |  | |
| **Note.** *If the source or amount of funding for this project has changed or a new OSP # has been assigned to the protocol, include the new or revised funding application and/or provide the new OSP Assigned Number:* | |  |

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| **4. Purpose** |
| **In two or three sentences, briefly summarize the purpose of this protocol, and related studies if applicable. Please use non-technical language, and write for adults with general knowledge rather than for specialists.** |
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| **5. Screened, entered, or otherwise accessed by the UAB Investigator(s). Include numbers for individuals, specimens, data records, charts, etc., as applicable to the protocol.** | |
| **5.a. Number screened for study entry since the start of the project?** |  |
| **5.b. Number entered in study since the start of the project? (See Total in 5.e.)** |  |
| **5.c. Number entered in study since the last IRB review?** |  |
| **5.d. What is the age range for all participants entered in the study since the start of the project (e.g., 18-65)?** |  |

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| **5.e. Complete the table below for cumulative enrollment for each racial and ethnic category. Copy/paste the entire table for additional groups (e.g., controls, sub-studies) if needed.** | | | | | | | | | | |
| **Racial Categories** | **Ethnic Categories** | | | | | | | | | **Total** |
| **Not Hispanic or Latino** | | | **Hispanic or Latino** | | | **Unknown/Not Reported Ethnicity** | | |
| **Female** | **Male** | **Unknown/**  **Not Reported** | **Female** | **Male** | **Unknown/**  **Not Reported** | **Female** | **Male** | **Unknown/ Not Reported** |
| American Indian/ Alaska Native |  |  |  |  |  |  |  |  |  |  |
| Asian |  |  |  |  |  |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |  |  |  |  |  |
| Black or African American |  |  |  |  |  |  |  |  |  |  |
| White |  |  |  |  |  |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |  |  |  |  |  |
| Unknown or Not Reported |  |  |  |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |  |  |  |
| Check the box at the left if demographic information is not available (e.g., not collected for screening; collecting only specimens or data records and did not have access to the information). | | | | | | | | | | |

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| **6. Conflict of Interest Review Board (CIRB)** | |
| **Does the Principal Investigator, the institution, or any other person listed on this protocol have a financial conflict of interest,** [**as defined by the UAB CIRB**](http://www.uab.edu/cirb)**, related to this research?**  **If No, continue with Item 7.**  **If Yes, in the space below, provide the names of the individuals who have a conflict and indicate whether or not a management plan is in place for each person listed.** | Yes No |
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| **7. Information Since the Date of Last IRB Review**   * Mark at least one checkbox to indicate the type(s) of information received since the Date of Last IRB Review. * Please summarize each type of information, and provide details and copies as requested. | |
| **7.a. You received multi-center trial reports that you have not previously forwarded to the IRB.** Attach a copy and, in the space below, provide the date and source of the report, and summarize the findings and any recommendations: | Yes No  Multi-Center Trial Report |
|  | |
| **7.b. You received data and safety or other monitoring reports (e.g., DSMB, sponsor site visit) not previously forwarded to the IRB.** Attach a copy and, in the space below, provide the date and source of the report, and summarize the findings and any recommendations: | Yes No  Data Safety or  Other Monitoring Report |
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| **7.c. You learned of literature published about this research.** Attach the publication or provide its web address, and summarize the published findings here: | Yes No  Published Literature |
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| **7.d. You learned of other relevant information regarding this research, especially about risks associated with the research.** Attach a copy of the source and/or summarize below, and check “Other Information” at right. Also check “Affects Willingness” if this information might affect a participant’s willingness to continue in the research, and describe the effects on participants here: | Yes No  Other Information |
| Yes No  Affects Willingness |
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| **7.e. You have received another type of information. Summarize the information, including details relevant to participants here:** | Yes No  Other Type of Information |
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| **8. Reportable and Non-reportable Problems** | |
| **8.a. Have there been any “reportable events” since the IRB’s last continuing review of the project? “Reportable events” are those that may constitute unanticipated problems involving risks to participants or others.**  Attach the [UAB Problem Summary Sheet](http://www.uab.edu/irb/forms/problem-summary.doc) completing Table A;  Provide brief narrative summary (2-3 sentences) of any trends or increases in frequency or severity noted for all events over the life of the project, or enter “None noted” here: | Yes No  Reportable Events since last continuing review (Table A) |
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| **8.b. Have participants experienced harms (expected or unexpected, serious or not serious) that do not meet the UAB IRB criteria for “reportable events” since the IRB’s last continuing review of the project?** Attach [UAB Problem Summary Sheet](http://www.uab.edu/irb/forms/problem-summary.doc) completing Table B; provide brief narrative summary (2-3 sentences) of any trends or increases in frequency or severity noted for all events over the life of the project, or enter “None noted” here: | Yes No  Other Events since last continuing review (Table B) |
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| **8.c. Have there been any reportable or non-reportable events over the life of the project?** Attach [UAB Problem Summary Sheet](http://www.uab.edu/irb/forms/problem-summary.doc) completing Table A and/or B as appropriate. Note the UAB Problem Summary Sheet is a cumulative report for all events over the life of the project. Provide brief narrative summary (2-3 sentences) of any trends or increases in frequency or severity noted, or enter “None noted” here: | Yes No  Any reportable or non-reportable events over the life of the project |
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| **9. Events Since the Date of Last IRB Review**  Mark at least one checkbox to show event(s) that have occurred since the Date of Last IRB Review. Please summarize all events, and provide specific details and/or copies as requested. | |
| **9.a. You have had one or more problems obtaining informed consent.** Briefly describe the problem(s) here: | Yes No  Consent Problems |
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| **9.b. You have received complaints about the research.** Briefly describe the number and nature of the complaints: | Yes No  Complaints |
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| **9.c. One or more participants withdrew, or were withdrawn from, the research.** Indicate here the number of withdrawals and the reason for each: | Yes No  Withdrawals |
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| **9.d. Participants have experienced research-related benefits.** For example, “60% of participants in the treatment group appear to have reduced symptoms or reduced severity of symptoms, compared with 10% in the placebo group.” Briefly describe the benefits here: | Yes No  Benefits |
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| **9.e. The risks, potential benefits, or both of this research have changed.** Briefly describe the changes here: | Yes No  Change in Risk or Benefit |
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| **9.f. Does the research involve minors (<18 years of age)?**  If the study is still open to accrual or the participants are still receiving protocol driven intervention, the PI must either (a) confirm the previously assigned Children’s Risk Level (CRL) number or (b) reassign a new CRL and give the reason it has changed in the space provided below: | Yes No |
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| **9.g. Events have occurred that relate to participant safety but do not fit into the categories listed above.** Briefly describe the events here: | Yes No  Other Events |
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| **10. Protocol and/or Informed Consent Modifications**  **Check the applicable boxes to indicate modifications made since Date of Last IRB Review (Yes to 9.a.) or requested with this renewal (Yes to 9.b. or 9.c.). Please provide the details and materials requested.** | | |
| **10.a. Previous Modifications** | | |
| **Since the last IRB review, have you made modifications to the protocol, consent process, consent document or change in personnel?** | | Yes No |
| **If Yes, have the modifications been approved by the IRB?** | | |
| Yes  No—In the space below, justify making the modification without prior IRB approval: | | |
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| **10.b. Modifications To Protocol Requested With This Renewal** | | |
| Are you requesting IRB review of changes to the protocol (e.g., procedures, personnel, recruitment)? If so, check “Yes” and describe them in the space below.  **Changes to personnel may not be made with the continuing review application. To change personnel concurrently with a continuing review, create a Personnel Amendment and complete the IRB PERSONNEL eFORM to add or remove study personnel.** | Yes No  Protocol Changes | |
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| **10.c. Modifications To Consent Requested With This Renewal** |  | |
| **Are you requesting IRB review of changes to the consent process and/or form(s)? If so, check the applicable “Yes” box and, in the space below, describe the changes.** | Yes No  Consent Process Changes  Yes No  Consent Document Changes | |
| **If the changes affect the consent form(s), indicate the number of consent and/or assent forms used for this protocol, and describe the changes to each form:**  **(a) describe all changes to IRB-approved forms and the reasons for them;**  **(b) describe the reasons for the addition of any materials (e.g., addendum consent); and**  **(c) indicate either (1) how and when you will reconsent enrolled participants or (2) why reconsenting is not necessary.**  **Also, indicate the number of forms changed or added. For new forms, provide 1 copy. For revised documents, provide 3 copies:**  **• a copy of the currently approved document (showing the IRB approval stamp, if applicable),**  **• a revised copy highlighting all proposed changes with “tracked” changes, and**  **• a revised copy for the IRB approval stamp.** | | |
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| **11. Gene Therapy, Gene Transfer, Recombinant DNA** | | | | | |
| **If this study involves** | Gene therapy | Gene transfer | Recombinant DNA | | N/A – go to item 12. |
| **Complete this item, and include memorandum with original signatures of Gene Therapy Review Panel addressing the risk-benefit ratio, any recommendations, and the CRL if applicable.** | | | |  |
| **11.a. Has the Panel's assessment of the risk-benefit ratio of this project changed? If yes, please explain below.** | | | | Yes No  Risk-Benefit Change | |
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| **11.b. Does the Panel have any recommendations regarding the protocol or the consent form? If yes, please explain below.** | | | | Yes No  Panel Recommendations | |
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| **12. Continuing Review—Complete only if you want to renew IRB approval so that protocol-related activities can continue.** | |
| **12.a. Accrual Status—Indicate whether the study is “NOT YET OPEN,” “OPEN,” or “CLOSED” (described below)   and provide the details requested for that accrual status.** | |
| **NOT YET OPEN: No individuals have been screened or entered.** | Not Yet Open |
| **OPEN: The study could still enroll more individuals, add more specimens, review more records, etc.**   * **Attach a copy of the most recently approved consent form(s) OR note in the space below that the IRB has waived informed consent and/or use of a consent form (waiver of documentation of informed consent).** * **Describe plans for future accrual, enrollment, or recruitment here:** | Open |
|  | |
| **CLOSED: No more individuals will be enrolled, no more specimens or records will be added.** | Closed |
| **If the study is closed, is a consent form being submitted for review? If “Yes,” explain why in the space below.** | Yes No  Closed & Consent Form |
|  | |
| * **Indicate the date closed to accrual:** | Date Closed: |
| * **Choose one status to describe accrued participants, specimens, records:** | Check **ONE** Status Below: |
| **One or more is/are still receiving procedures as defined in the protocol (therapy, intervention, follow-up visits, etc.)** | On protocol procedure |
| **All are off protocol-driven procedures, in long-term follow-up only** | In long-term follow-up |
| **All are off protocol-driven procedures, in data analysis only** | In data analysis |
| **12.b. Describe any interim findings from this research. Please note that the IRB expects to receive findings on any protocol approved for 5 years.** | |
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| **13. Final Report—Complete only if you want to end IRB approval after all protocol-related data analyses are complete and no further work on the protocol will be done.** | | |
| **13.a. On what date were the final data analyses completed?** | | Final Date: |
| **13.b. Summarize the final findings from this protocol and provide copies of any publications:** | | |
|  | | |
| **13.c. Who will be responsible for managing and storing the data records, including any and all research-related electronic files and paper documents?** | | |
| **Name** |  | |
| **UAB Dept/Div, or Employer** |  | |
| **Work Address** |  | |
| **Daytime Telephone** |  | |
| **13.d. Describe the storage plan. How will data records be stored—on paper, computers, or both? How will they be protected from damage, unauthorized release, loss, and theft? How long will the data be stored? Where will the records be stored?** | | |
|  | | |
| **13.e. At the end of the storage period, will the data records be destroyed, archived, or transferred? Describe the plan in detail.** | | Destroy  Archive  Transfer |
|  | | |
| **Note. Specimens may be stored only if/as described in the IRB-approved protocol. Data records must be stored as described in the sponsor’s protocol or contract if applicable, and/or in the** [**UAB Health System Record Retention Policy**](http://www.hipaa.uab.edu/pdffiles/HS_Retention_Policy.pdf)**. Anyone wishing to use these data or specimens for secondary research purposes or for purposes preparatory to secondary research must obtain prior IRB review and approval.** | | |

**Signature of Principal Investigator: Date:**

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| FOR IRB USE ONLY – Expedited Review  Change to Expedited Category Y / N  No change to IRB’s previous determination of approval criteria at 45 CFR 46.111 or 21 CFR 56.111    Signature (Chair, Vice-Chair, Designee) Date |