Consent/Assent Form(s)

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| ESSENTIAL ELEMENTS OF INFORMED CONSENT YES NO | | | |
| 1 | Statement that the study involves research  Explanation of the purpose of the research  Expected duration of participation  Description of the procedures  Identification of *research* procedures v. *non-research* |  |  |
| 2 | Description of any reasonably foreseeable risks or discomforts |  |  |
| 3 | Description of any benefits to the subject or to others that might be reasonably expected from the research |  |  |
| 4 | Disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject |  |  |
| 5 | Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the research staff, IRBs, sponsor, their representatives, and possibly the FDA or OHRP. |  |  |
| 6 | For research involving more than minimal risk, a statement that emergency medical care will be arranged for a study-related illness or injury, and an explanation of whether funds are set aside to pay for this care and/or compensation, and if so by whom (e.g., sponsor, subject, insurer). Language must not be exculpatory. |  |  |
| 7 | Identification of funding source(s). |  |  |
| 8 | Identification of whom to contact (a) on research team with questions, concerns, complaints or about a research-related injury; and (b) at the IRB for same issues and information about research subjects' rights. |  |  |
| 9 | Statement that participation is voluntary and that the subject may discontinue at any time. Refusal to participate or withdrawal will not involve a penalty or loss of benefits to which the subject is otherwise entitled. |  |  |
| ADDITIONAL ELEMENTS ONE OR MORE OF WHICH MAY BE APPROPRIATE YES NO | | | |
| 1 | A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable. |  |  |
| 2 | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. |  |  |
| 3 | Any additional costs to the subject that may result from participation in the research. |  |  |
| 4 | The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. |  |  |
| 5 | A statement that significant new findings developed during the course of the research that may affect the subject's willingness to continue to participate will be provided to the subject. |  |  |
| 6 | The approximate number of subjects involved in the study. |  |  |
| 7 | If monetary payment will be given, a statement informing the participant that their personal information (name, address, and social security number) will be collected for tax purposes and will be reported to the IRS if they receive over $600 in one year from Emory. |  |  |
| 8 | All information concerning payment, including the amount and schedule of payments |  |  |