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| Appendix: Children Instructions for using this Appendix:If the study will enroll children, complete this form as part of your submission to the Institutional Review Board (IRB). This form documents the information required to ensure research is performed in accordance with the NYU Langone Human Research Protections Policy and Procedure Manual, available on the Human Research Protections (HRP) website. This policy applies to all research involving human subjects if NYU Langone Health faculty, staff, students, or facilities are involved, regardless of sponsorship and/or performance site.  [Remove the instructional text above prior to submitting the appendix] | | | | | |
| Age range of the children to be enrolled | |  | | Where will the children participate? | Home  School\*  NYU Facilities\*\*  Other; specify: |
| \*≈ appropriate permission from the school is obtained and submitted to IRB  \*\*all NYU facilities are listed on the main application and should be checked off accordingly | | | | | |
| Allowable Categories Check the category below that best represents the degree of risk and benefit to which the children in this study will be exposed. Note: more than one category may be indicated such as when a protocol involves both a study group and a control group; in these cases, please specify. | | | | | |
| Category 1 | The proposed research poses risks no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk) | | | | |
| Category 2 | The proposed research poses a greater than minimal risk with the potential for direct benefit to subjects.  Specify how the benefit to risk assessment is at least as favorable as that presented by alternative approaches: | | | | |
| Category 3 | The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield generalizable knowledge about the subjects’ conditions.  Specify how is the risk of the protocol is only a minor increase over minimal risk:  Specify how the procedure presents experiences to the subject that are reasonably commensurate with those inherent in their actual or expected situations:  Specify how the knowledge to be gained of vital importance for the understanding or amelioration of the condition: | | | | |
| Category 4 | The proposed research does not meet the criteria in the above categories but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children.  Provide justification for why this research should be approved: | | | | |
| Parental Permission In general, permission from both parents is required for research involving children unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. For Categories 1 & 2, the IRB may determine that the permission of one parent is sufficient. For Categories 3 & 4, permission from both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. | | | | | |
| What permission will be obtained from the parent(s) or legal guardian(s) | | | Permission will be obtained from both parents or legal guardians, when possible.  Permission from only one parent or legal guardian is being requested.  Permission from parent(s) or legal guardian(s) will be documented.  A waiver of parental permission is being requested; the following conditions must be satisfied: submit Application for Waiver of Authorization or Consent Form (available on HRP website). | | |
| When permission will be sought from someone other than the parent of a minor child, describe the procedure for determining who is a legally authorized representative | | |  | | |
| Assent from Children Adequate provisions must be made for soliciting the assent of children when, in the judgment of the IRB, the children are capable of providing assent and for soliciting the permission of their parents or guardians. The IRB presumes that children ages 7 and older should be given an opportunity to provide assent. | | | | | |
| Indicate whether the children you will study are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved. | | | | All are capable  Some are capable; explain:  None are capable; explain: | |
| Describe how assent is will be obtained, including what information will be provided to the subjects | | | | A copy of children’s assent form is attached  Other; explain: | |
| Describe how assent will be documented | | | | A copy of children’s assent form is attached  Other; explain: | |

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| ***Re-Consent Upon Reaching Age of Majority***  The NYU Langone Health IRB requires re-consent when a research subject who was a minor and entered the study with parental or guardian permission reaches the age of majority, in accordance to local state laws and regulations, in order for research-required interactions or interventions to continue. Re-consent is also necessary if previously collected biospecimens are still being utilized or if those subjects’ medical records will continue to be accessed/reviewed. | |
| Indicate whether subjects may reach the age of legal majority during study participation | Yes; complete sections below  No |
| Indicate whether re-consent will be obtained when the subject reaches the age of legal majority during study participation | Yes  No; explain: |
| Indicate whether re-consent will be obtained if previously collected biospecimens are still being utilized or if those subjects’ medical records will continue to be accessed/reviewed | Yes  No; explain:  Not Applicable (N/A) |
| Describe how re-consent will be obtained and documented | A copy of the consent form is attached  Other; explain: |

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| Subjects/Wards & Foster Children | | | | |
| This research is greater than minimal risk with no prospect of direct benefit to subjects | Yes  No | | This study will involve children who are wards/foster children | Yes  No |
| If you answered “yes” to the previous two questions, indicate which criteria for enrolling potential subjects who are wards/foster children is met | | The research is related to their status as wards; OR  The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. | | |
| If you answered “yes” to the previous two questions, describe your plan to appoint an advocate for potential subjects who are wards/foster children | |  | | |