

Appendix V: List of Requested Changes to ICR

All changes to instruments are predominantly for clarification of instructions or questions for the participant. One de novo question was added to the Paternal Occupational History Questionnaire (see item 10 below and Appendix E.15). None of the instrument changes have a measureable impact on participant burden but do improve data quality.

1. Changed/switched order of Appendices B & C to reflect current instructions for order of attachments within an ICR.
2. Additional Instrument Coversheets were added for clarity to include: E.10.1, E.17.1-3, E.18.1, E.18.2, , R.2.1, R.2.2, S.1.1)
3. Modified Section G of *Primary Caregiver Interview* (Postnatal History section; Appendix C2) by making changes to questions G.14-15 that streamlined the respondent's answer to G13. Specifically, instead of asking the respondent to itemize every individual episode that a medication listed in G13 was taken, the respondent is asked to select an answer that indicates the frequency that the medication was taken. Based on our experience with this question in the Caregiver Interview, this approach is less burdensome and likely to be a more accurate reflection of the caregiver's memory of common medication use. The new answer choices are shown below:
 - Once a year or less than once a year
 - Less than once a month, but usually at least several times a year
 - Less than once a week, but usually at least once a month
 - Less than every day, but usually at least once a week
 - Every day or almost every day
 - RF
 - DK
4. Removed the '98 -Refused' choice from answer choices in all instruments.
5. Added a blank space for 'Study ID #' to be filled in by study staff to all data collection instruments.
6. Added a blank space for 'Date of Completion' to be filled in by the participant or study staff to all data collection instruments.
7. For purposes of clarity we added instruction sheets for each *Enrollment Packet* (Appendices E.2.1 & E.2.2)
8. Made formatting changes to instructions in *Maternal Medical History* for purposes of clarity (Appendix E.13).
9. Made formatting changes to instructions in *Paternal Medical History* for purposes of clarity (Appendix E.14)
10. Made the following changes to *Paternal Occupational Questionnaire* form (Appendix E.15) for purposes of clarity and instruction:

- a. Before question 1, asked the respondent to check off their relationship to the study child (3 answer choices: Biological father; Stepfather; Other, specify)
 - b. Added '0 LESS THAN HIGH SCHOOL' answer option to Question 3A
 - c. Made changes to instructions
 - d. Removed the first part of question 3 and moved the second part of question 3 (3b) to become 1b.
 - e. Added additional answer spaces to accommodate more jobs listed in question 4.
11. For the *3- Day Diet Diary* (Appendix H.1) added more detailed instructions and examples of a complete and incomplete diary for purposes of clarity.
 12. Per our original protocol in which we stated we would develop feedback forms for parents we have now added the *Parent Feedback Letter* (Appendix M.3) to assist parents with understanding the results of the clinical developmental evaluation.
 13. Made formatting changes to instructions in *Prenatal, Labor & Delivery, Neonatal, & Pediatric Chart Abstraction Forms* for purposes of clarity to abstractor (Appendix S.2-S.5). These forms are being developed for staff use only, not for study participants.
 14. Added this document called *List of Requested Changes to ICR* as Appendix V.
 15. Added the *301(d) Certificates of Confidentiality* for all sites (see Appendices W1 through W7) as was mentioned in the original ICR but were not provided as Appendices.
 16. Added the *Confidentiality Agreement* document that is signed by all research staff (see Appendix X) as was mentioned in the original ICR but was not provided as Appendix.
 17. Per our original protocol in which we stated we would update participants about the progress of the study we have now included an example of our *Participant Newsletter* (Appendix Y).
 18. Have added a new Appendix called *Detailed breakdown of Participant Burden Hours and Cost Burden* (see Appendix Z). This appendix provides a detailed breakdown of burden and cost for each form, a level of detail which is not possible in the single table format that is provided in Section A12 of the Supporting Statement.