**Appendix G – Staff checklist and Minimum Necessary Review (MNR) for amendments or renewals**

Staff Reviewer: Mary Ann Evans

Agreement Number: 3625_APAC_PID_Public_Health

**Purpose**
The purpose of the staff checklist for amendment or renewals is to assess whether applicant completely and adequately filled out the amendment form.

**Instructions**
Complete all sections. If you check "no" on any question, please detail in the "notes" section of the same row why you checked "no" and what applicant must do in order to receive a "yes".

1.

| Task | Yes | No | N/A | Notes |
|---|---|---|---|---|
| Agreement number entered? | x | | | |
| Does agreement number and applicant listed in amendment/renewal match the agreement number and applicant in original application? | x | | | |
| Did applicant choose either "Amendment" or "Renewal"? | x | | | |
| **Section 2 – Amendment (Must go to DRC for review)** | | | | |
| Have all additional staff signed stating they have read and are bound to the terms of the original DUA? | | | x | |
| If original application included IRB approval, does the amendment fall inside the scope of the original IRB approval? | | | x | |
| Does IRB approval have more than 3 months left? (Can be either the original IRB sent with original application is valid for more than 3 months or an amended IRB is attached and is valid for more than 3 months) | | | x | |

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| If amended IRB approval is attached, does IRB application number on amendment match IRB application number on original IRB approval? | | | | |
| If requesting new/more data, is Data Element Workbook attached? | x | | | |
| Do all requested elements have a year requested, filters applied and justification response in Data Element Workbook? | x | | | |
| If requesting a limited data set, does Data Element Workbook align with response in 2.8b-c? | | | x | |
| If requesting a custom data set, is it clear what elements are being requested? | x | | | |
| Is the Payers tab completed in the Data Element Workbook? | x | | | |
| If requesting Medicare FFS data, is the project at least partially funded and directed by OHA? (Per our DUA with CMS, Medicare FFS data may be shared outside of OHA for research **only if** OHA is partially funding and directing the project.) | x | | | |
| If requesting a limited data set, does Payers tab align with response in 2.8b? | | | x | |
| If requesting a custom data set, is it clear what | x | | | |

| | | | | |
|---|---|---|---|---|
| payers are being requested? | | | | |
| If Limited data is being requested, is payment included | | | x | |
| Do 2.8b and 2.8c correspond with the files selected and the number of year input in row c of the payment table? | | | x | |
| Is cost calculated correctly? | | | x | |
| Passes Minimum Necessary Review? | x | | | |
| Adequately justified each data element requested (provide rationale and list any data elements not adequately justified in notes)? | x | | | |
| Adequately described filters and algorithms for including and excluding claim lines (provide rationale and list strengths and weaknesses of algorithms in notes)? | x | | | |
| Consider the elements requested and whether additional elements can be excluded, redacted, or additionally filtered without unreasonably impairing the ability to accomplish the project purposes. Is data requested the minimum necessary? (If no, identify data elements that may be excluded, redacted or additionally filtered in notes.) | x | | | |
| **Section 3 – Renewal (DUAs can be renewed without DRC approval)** | | | | |
| If applicant is renewing OHA agreement, does applicant include proper IRB documentation if necessary? (In notes, please state whether an amended IRB | | | x | |

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| approval is attached, the original IRB is still valid, or original application did not include an IRB approval.) | | | | |
| If applicant is renewing IRB approval, did applicant include renewed IRB approval? | | | x | |
| Does IRB application number on renewal memo match IRB application number on original IRB approval? | | | x | |
| **Signatures** | | | | |
| Is amendment signed? | x | | | |