***National Institutes of Health/Office of Extramural Research***

# *era_tag_new*

***Type 333,666,777 requirements for Human Subject and Clinical Trials Form***

***Version: 1.1***

***Date: 11/16/2018***

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# Revision History

| Version Number | Revision Date | Author | Summary of Changes |
| --- | --- | --- | --- |
| 1.0 | 1/26/2018 | Seema Verma | Excluded Types 333, 666,777s from HSCT rules as applicable |
| 1.0 | 1/30/2018 | Seema Verma | Removed validation 034.4.7, as it is mandatory in schema |
| 1.0 | 11/16/2018 | Seema Verma | Rule 034.8.12 requiring Phase III Clinical Trial response updated to trigger for Type 7 applications |

# Global Validation

|  | **Rule #** | **Mandatory (Y/N)** | **Shared(Y/N)** | **Agency Specific (List Agencies)** | **Form Version** | **FOA or special conditions** | **Activity Specific**  **Lists Activity Code (Inclusion & Exclusion)** | **Applies to Single Project/Multi Project or Both** | **Applies to Overall, Other Components or Both** | **Cross COmponents (MUlti Projects only)** | **Validation** | **Message** | **Error/Warning** | **Type 3** | **Type 6** | **Type 7** |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Global Validation  **If Yes to Human Subjects on Other Project Information form**  Add New Study/Delayed Onset Study on Human Subjects and Clinical Trial Information form | 000.40 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE = “R" or "I" | Excl : 333,666 | Multi |  | Y | Provide error if a Clinical Trial Study Record, or a Delayed Onset Study that is marked as ‘Anticipated Clinical Trial’, is not provided on the entire application for a FOA that is set to R or I, and answered yes to questions 1.4a through 1.4d | At least one Clinical Trial Study Record or a Delayed Onset Study that is marked as ‘Anticipated Clinical Trial’ must be provided. | E | Rule should not fire | Rule Should not fire | E | New Rule  October 2017 Release  Note: This rule is parallel to 034.5.5 for Single Projects. |
| Global Validation  **Human Subject and Clinical Trial Information**  **Section 1 – Basic Information**  1.1 Study Title | 000.41 | N | N | NIH,  AHRQ | 1.0 |  | Excl : 333,666 | Both | Overall | Y | Provide error if same Study Record or Delayed Onset Study title is duplicated in an application.  Note: Study Record and Delayed Onset Study Record cannot have the same titles i.e. all study titles must be unique within an application | Study Record and Delayed Onset study titles must be unique and cannot be duplicated in an application. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |

# PHS Human Subject and Clinical Trial Information

| **Form** | **Field** | **Rule#** | **Rule Categories** | | | | | | | | | **Validation** | **Error Message** | **Error/**  **Warning** |  |  |  | **Comments** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mandatory  (Y/N) | Shared (Y/N) | Agency Specific  (Lists Agencies) | Form Version | FOA or special conditions | Activity Specific  Lists Activity Code (Inclusion & Exclusion) | Applies to Single Project, Multi Project or Both | Applies to Overall, Other Components or Both | Cross Components  (Multi Project Only) | Type 3 | Type 6 | Type 7 |
| PHS Human Subject and Clinical TrialInformation | **If No to Human Subjects**  Human Subject/Delayed Onset Study | 034.1.1 | N | N | NIH,  AHRQ | 1.0 |  | Excl : 333,666 | Both | Both |  | Provide error if response to “Are Human Subjects Involved”’ question is “No” on the Other Project Information form, and a Study Record or or Delayed Onset Study Record is provided. | In order to attach a Study Record or Delayed Onset Study to the PHS Human Subjects and Clinical Trials Information form, you must answer “Yes” to the question “Are Human Subjects Involved” on the Other Project Information form. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **If No to Human Subjects**  Does the proposed research involve human specimens and/or data? | 034.2.1 | N | N | NIH,  AHRQ | 1.0 |  | Excl : 333,666 | Both | Both |  | Provide error if response to “Are Human Subjects Involved” question is “No” on the Other Project Information form and a response to the question “Does the proposed research involve human specimens and/or data?” has not been provided. | If you answered “No” to the question “Are Human Subjects Involved?” on the Other Project Information form, you must answer the “Does the proposed research involve human specimens and/or data?” question. | E | Rule should not fie | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **If No to Human Subjects**  If yes, provide an explanation of why the application does not involve human subject research | 034.2.2 | N | N | NIH,  AHRQ | 1.0 | Excl : 333,666 |  | Both | Both |  | Provide error if response to “Does the proposed research involve human specimens and/or data is “Yes” and an explanation detailing why the proposed study does not constitute human subject research has not been provided. | If you answered “Yes” to the question “Does the proposed research involve human specimens and/or data?”, you must provide an explanation why the application does not involve human subject research. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **If Yes to Human Subjects**  Does the proposed research involve human specimens and/or data and/or explanation attachment | 034.2.3 | N | N | NIH,  AHRQ | 1.0 |  | Excl : 333,666 | Both | Both |  | Provide error if response to “Are Human Subjects Involved” question is “Yes” on the Other Project Information form and a “Yes” response is also given to the question ‘Does the proposed research involve human specimens and/or data’ is provided with or without an explanation | If you answered “Yes” to the question “Are Human Subjects Involved” on the Other Project Information form, a “Yes” a response to the question “Does the proposed research involve human specimens and/or data” is not a valid response. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **If Yes to Human Subjects**  Add new study | 034.3.1 | N | N | NIH,  AHRQ | 1.0 |  | Excl : 333,666 | Single |  |  | Provide error if response to “Are Human Subjects Involved” is “Yes” on the Other Project Information form and a Study Record or Delayed Onset study has not been included. | If you answered “Yes” to the “Are Human Subjects Involved” question on the Other Project Information form, you must provide at least one Study Record or Delayed Onset Study. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **If Yes to Human Subjects**  Add new study | 034.3.2 | N | N | NIH,  AHRQ | 1.0 |  | Excl : 333,666 | Multi | Component |  | Provide error if response to “Are Human Subjects Involved” is “Yes” on the Other Project Information form and a Study Record, Delayed Onset study or Other requested information has not been provided | If you answered “Yes” to the question “Are Human Subjects Involved” on the Other Project Information form, you must provide at least one Study Record or Delayed Onset Study or an Other Requested Information attachment. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017  Release |
| PHS Human Subject and Clinical TrialInformation | **If Yes to Human Subjects**  Add new study | 034.8.75 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE = O | Incl: D43, K12  Excl : 333,666 | Single |  |  | Provide error if a Study Record is provided | This Funding Opportunity Announcement only allows Delayed Onset Studies. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Add New Delayed Onset Study**  Anticipated Clinical Trial | 034.4.6 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE = N |  | Both | Both |  | Provide Error if response to “Anticipated Clinical Trial” is checked for at least one delayed onset study when the FOA does not support Clinical Trial. | The ‘Anticipated Clinical Trial’ box cannot be checked for Delayed Onset Study titled <study title> since this Funding Opportunity Announcement does not allow clinical trials. | E | Rule should not fire  Note: The FOA will never be CT-N for type 3/6/7, so it will never fire | Rule should not fire  Note: The FOA will never be CT-N for type 3/6/7, so it will never fire | Rule should not fire  Note: The FOA will never be CT-N for type 3/6/7, so it will never fire | New Rule  October 2017 Release |
| ePHS Human Subject and Clinical TrialInformation | **Section 1 – Basic Information**  1.3 Exemption number | 034.5.2 | N | N | NIH,  AHRQ | 1.0 |  | Excl**:** D43, K12 | Both | Both |  | Provide error if Exemption number is not provided when response to “Is this Study Exempt from Federal Regulations” is “Yes” | Exemption number is required for Study Record <Study Title>, since you selected “Yes” to the question “Is this Study Exempt from Federal Regulations” | E | E | E | E | New Rule  October 2017 Release |
| tidyPHS Human Subject and Clinical TrialInformation | **Section 1 – Basic Information**  1.3 Exemption number 7 -8 | 034.5.6 | N | N | NIH, CDC, FDA, AHRQ, USU | 1.0 |  |  | Both | Both |  | Provide error if Exemption 7 and/or 8 is selected on the Human Subject Clinical Trial form | Exemption 7 and/or 8 are not valid selections for study title< study title> | E | E | E | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 1 – Basic Information**  1.4 Clinical Trial Questionnaire  1.4.a – 1.4.d | 034.5.3 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE = “N” | Excl**:** D43, K12  Excl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Excl K’s**:** K01,  K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76,K43,K38 | Both | Both |  | Provide error if responses to questions 1.4.a through 1.4.d are “Yes”, but the Funding Opportunity Announcement does not support clinical trials. | You cannot answer “Yes” to all questions 1.4a-1.4.d in the Clinical Trial Questionnaire since this Funding Opportunity Announcement does not allow clinical trials. | E | Rule should not fire  Note: The FOA will never be CT-N for type 3/6/7, so it will never fire | Rule should not fire  Note: The FOA will never be CT-N for type 3/6/7, so it will never fire | Rule should not fire  Note: The FOA will never be CT-N for type 3/6/7, so it will never fire | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 1 – Basic Information**  1.4 Clinical Trial Questionnaire  1.4.a – 1.4.d | 034.5.4 | N | N | NIH,  AHRQ | 1.0 |  | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error if responses to questions 1.4.a through 1.4.d are “Yes” but the only exemption selected is E4. | You’ve answered Yes to questions 1.4.a through 1.4.d in the Clinical Trial Questionnaire. Clinical trials are not allowed when E4 is the only exemption selected. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 1 – Basic Information**  1.4 Clinical Trial Questionnaire  1.4.a – 1.4.d | 034.5.5 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE = “I" or “R” | Excl:D43, K12 | Single |  |  | Provide error if Clinical Trial Study Record or a Delayed Onset with Anticipated Clinical Trial is not provided for a Clinical Trial FOA. | You must answer “Yes” to all questions 1.4a through 1.4d on at least one study record OR provide a Delayed Onset Study with Anticipated Clinical Trial for this Funding Opportunity Announcement | E | Rule should not fire  Note: The FOA will never be CT-“I” or “R” for type 3/6/7, so it will never fire | Rule should not fire  Note: The FOA will never be CT-“I” or “R” for type 3/6/7, so it will never fire | Rule should not fire  Note: The FOA will never be CT-“I” or “R” for type 3/6/7, so it will never fire | New Rule  October 2017 Release  Note: This rule is parallel to 000.40 for Multi Projects. |
| PHS Human Subject and Clinical TrialInformation | **Section 1 – Basic Information**  **1.5 ClinicalTrials.gov Identifier (NCT number) – Initial Submission** | 034.5.7 | N | N | NIH,  AHRQ | 1.0 |  | Excl : 333,666 | Both | Both |  | Provide error if the submitted NCT# is not a valid ClinicalTrials.gov identifier. | The submitted NCT# is not a valid ClinicalTrials.gov identifier. A ClinicalTrials.gov identifier references a clinical trial that has been registered with ClinicalTrials.gov and must be in the format "NCT" followed by eight digits (e.g. NCT12345678). | E | Rule should not fire | Rule should no fire | E | New Rule  December 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 1 – Basic Information**  **1.5 ClinicalTrials.gov Identifier (NCT number) – Initial Submission** | 034.5.8 | N | N | NIH,  AHRQ | 1.0 |  | Excl: D43,K12  Excl : 333,666,777 | Both | Both |  | Provide warning (for Initial Submission) when the CT elements in a study record do not match CT elements from the protocol definition in a trial registered on ClinicalTrials.gov. | Some of the Information provided in study<study title> (list of elements that do not match) does not match the information registered at ClinicalTrials.gov for the provided Clinical Trials.gov identifier <NCT #>. | W | Rule should not fire | Rule should not fire | Rule should not fire | New Rule  December 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Study Population Characteristics**  2.1 Conditions or Focus of Study | 034.6.1 | N | N | NIH,  AHRQ | 1.0 |  | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial Study Record if Condition or Focus of Study is not provided and the study is exempt from federal regulations (1.2 is yes) and E4 is not the only exemption number selected | Conditions or Focus of Study is required for study titled <Study Title>. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Study Population Characteristics**  2.2 Eligibility Criteria | 034.6.2 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is Not = “I” | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial Study Record if Eligibility Criteria is not provided and the study is exempt from federal regulations (1.2 is yes) and E4 is not the only exemption number selected. | Eligibility Criteria is required for study titled < Study Title>. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Study Population Characteristics**  2.3 Age Limits  Minimum Age | 034.6.3 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is not = “I” | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial Study Record if Minimum Age limit is not provided, the selection is not NA and the study is exempt from federal regulations (1.2 is yes) and E4 is not the only exemption number selected. | Minimum Age is required for study titled <Study Title> | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Study Population Characteristics**  2.3 Age Limits  Minimum Age –  N/A (No limits) | 034.6.11 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is not = “I” | ExclD43, K12  Excl : 333,666 | Both | Both |  | Provide error if N/A (No limits) has been selected as Minimum Age unit and a number for Minimum Age is provided and the study is exempt from federal regulations (1.2 is yes) and E4 is not the only exemption number selected. | A number for Minimum Age cannot be provided on Study titled <study title> since N/A (No limit) has been selected as the unit of a time. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Study Population Characteristics**  2.3 Age Limits Maximum Age | 034.6.4 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is not = “I” | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial StudyRecord if Maximum Age limit is not provided and the selection is not NA and the study is exempt from federal regulations (1.2 is yes) and E4 is not the only exemption number selected | Maximum Age is required for study titled <Study Title> | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Study Population Characteristics**  2.3 Age Limits  Maximum Age –  N/A (No limits) | 034.6.12 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is not = “I” | ExclD43, K12  Excl : 333,666 | Both | Both |  | Provide error if N/A (No limits) has been selected as Maximum Age unit and a number for Maximum Age is provided and the study is exempt from federal regulations (1.2 is yes) and E4 is not the only exemption number selected. | A number for Maximum Age cannot be provided on study titled <study title> since N/A (No limit) has been selected as the unit of time. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2- Study Population Characteristics**  2.4 Inclusion of Women, Minorities, and Children | 034.6.5 | N | N | NIH,  AHRQ | 1.0 |  | Excl: D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial Study Record if Inclusion of Women, Minorities and Children attachment is not provided and if the study is exempt from federal regulations (1.2 is yes) and E4 is not the only exemption number selected. | Inclusion of Women, Minorities and Children attachment is required for study tilted <Study Title> | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Study Population Characteristics**  2.5 Recruitment and Retention Plan | 034.6.6 | N | N | NIH,  AHRQ | 1.0 |  | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial Study Record if Recruitment and Retention Plan attachment is not provided when response to question 1.2 is “Yes” and E4 is not the only exemption number selected and answer to question 1.4a is "Yes". | Recruitment and Retention Plan attachment is required for study titled < Study Title>. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Study Population Characteristics**  2.6 Recruitment Status | 034.6.7 | N | N | NIH,  AHRQ | 1.0 |  | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial Study Record if Recruitment Status is not provided when response to question 1.2 is “Yes” and E4 is not the only exemption number selected and answer to question 1.4a is "Yes". | Recruitment Status is required for study titled <Study Title>. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 - Study Population Characteristics**  2.7 Study Timeline | 034.6.8 | N | N | NIH,  AHRQ | 1.0 |  | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial Study Record if Study Timeline attachment is not provided when response to question 1.2 is “Yes” and E4 is not the only exemption number selected and answer to question 1.4a is "Yes". | Study Timeline attachment is required for study titled < Study Title>. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 - Study Population Characteristics**  2.8 Enrollment of First Subject | 034.6.9 | N | N | NIH,  AHRQ | 1.0 |  | Excl: D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Human Subject and Clinical Trial Study Record if Enrollment of First Subject is not provided when response to question 1.2 is “Yes” and E4 is not the only exemption number selected and answer to question 1.4a is "Yes". | Enrollment of First Subject date is required for study titled <Study Title>, and you must select either Anticipated or Actual for enrollment of the first subject | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| S PHS Human Subject and Clinical TrialInformation | **Section 2 - Study Population Characteristics**  Add New Inclusion Report | 034.6.10 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is not = “I” | Excl:D43, K12  Excl : 333,666 | Both | Both |  | Provide error if Inclusion Enrollment Report is not provided and the study is exempt from federal regulations (1.2 is yes) and E4 is not the only exemption number selected. | An Inclusion Enrollment Report is required for study tilted <Study Title>. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Inclusion Enrollment Report**  Ethnic Category; Racial Category: Total Count (Cumulative) | 034.6.13 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is not = “I” | Excl: D43, K12  Excl : 333,666 | Both | Both |  | If "Using an Existing Dataset or Resource" is "Yes", "Cumulative Counts" must be greater than zero OR "Comment" must be provided. | For study titled <study title>, IER <number>, if using an existing dataset or resource, cumulative counts for racial and ethnic categories must be greater than zero. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Inclusion Enrollment Report**  Ethnic Category; Racial Category: Total Count (Cumulative) | 034.6.15 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is not = “I” | Excl: D43, K12  Excl : 333,666 | Both | Both |  | Provide warning if response to using an existing data set or resource is "Yes" and ONLY "Unknown/Not Reported" greater than zero cumulative counts are provided. | For study titled <study title>, IER <number> you have only included “unknown/not reported” counts for racial and ethnic categories. Since you have selected “yes” to existing dataset or resource, you must indicate male and/or female counts for these categories. | W | Rule should not fire | Rule should not fire | W | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 2 – Inclusion Enrollment Report**  Ethnic Category; Racial Category: Total Count (Planned) | 034.6.14 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE is not = “I” | Excl: D43, K12  Excl : 333,666 | Both | Both |  | If  "Using an Existing Dataset or Resource" is "No", "Planned Counts" must be greater than zero  OR "Comment" must be provided | For study titled <study title>, IER <number>, if not using an existing dataset or resource, planned counts for racial and ethnic categories must be greater than zero | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 3 – Protection and Monitoring Plans**  3.1 Protection of Human Subjects | 034.7.1 | N | N | NIH,  AHRQ | 1.0 |  | Excl: D43 , K12  Excl : 333,666 | Both | Both |  | Provide error if Protection of Human Subjects is not provided for a Study Record | Protection of Human Subjects attachment is required for Study Record titled <study title> | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 3 – Protection and Monitoring Plans**  3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site? | 034.7.2 | N | N | NIH,  AHRQ | 1.0 |  | Excl: D43, K12, Excl : 333,666 | Both | Both |  | Provide error if a response to the question “Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?” is not provided. | A response to the question regarding multi-site studies is required for Study Record titled <Study Title>. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 3 – Protection and Monitoring Plans**  3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site? | 034.7.3 | N | N | NIH,  AHRQ | 1.0 |  | Excl: D43, K12  Excl F’s  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Excl:K’s:  K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00, K76, K43  Excl : 333,666 | Both | Both |  | Provide error if N/A is selected in response to the Multi Site Study Protocol question for any activity code other than K’s and F’s AND when response to question 1.2a is “No” (Is this study exempt from Federal Regulations?).  **Note**: N/A is only a valid selection for, Career Development, and Fellowship applications | A response of N/A to the Multi Site Study Protocol question on study titled <study title> is valid only when the application is for a Career Dev or Fellowship Funding Opportunity Announcement, OR the study is exempt from Federal Regulations (Question 1.2a = yes). | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 3 – Protection and Monitoring Plans**  3.2 If yes, describe the single IRB plan | 034.7.4 | N | N | NIH,  AHRQ | 1.0 |  | Excl:  D43, K12  Excl : 333,666 | Both | Both |  | Provide error if a response to the question “If yes, describe the single IRB plan” is not provided when the answer to the question “Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?” is “Yes” | Since you answered Yes to the question regarding multi-site studies, a single IRB plan attachment is required for study titled <Study Title> | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 3 – Protection and Monitoring Plans**  3.3 Data and Safety Monitoring Plan | 034.7.5 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O" or "I") AND (Answers to questions 1.4a through 1.4d is ALL "Yes") | Excl: D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Clinical Trial Study if Data and Safety Monitoring Plan is not provided | For Study titled < Study Title>, a Data and Safety Monitoring Plan attachment is required since you answered Yes to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 3 – Protection and Monitoring Plans**  3.4 Will a Data and Safety Monitoring Board be appointed for this study? | 034.7.6 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d is ALL "Yes") | Excl: D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Clinical Trial Study Record if response to the question “Will a Data and Safety Monitoring Board be appointed for this study?” is not provided. | For study titled <Study Title>, a response to the question, “Will a Data and Safety Monitoring Board be appointed for this study?” is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | E | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.1 Brief Summary | 034.8.1 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study Record if summary of the protocol is not provided. | For study titled <Study Title>, a brief summary of the protocol must be provided since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.1 Brief Summary | 034.8.30 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Brief Summary of Protocol is provided. | For study titled <study title>, a brief summary of the protocol cannot be provided since you did not answer “Yes”to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.1 Brief Summary | 034.8.29 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl: D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if Brief Summary is provided | For study titled <study title>, brief summary of the protocol cannot be provided since this Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4- Protocol Synopsis**  4.2.a Narrative Study Description | 034.8.2 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if a Narrative Study Description is not provided. | For study titled <Study Title>, a Narrative Study Description must be provided since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4- Protocol Synopsis**  4.2.a Narrative Study Description | 034.8.31 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Narrative Study Description is provided | For study titled <study title> a, Narrative Study Description cannot be provided since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4- Protocol Synopsis**  4.2.a Narrative Study Description | 034.8.32 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s:  K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if Narrative Study Description is provided | For study titled <study title>, a Narrative Study Description cannot be provided since this Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.b Primary Purpose | 034.8.3 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study Record if Primary Purpose is not provided | For study titled <Study Title>, a Primary Purpose must be provided since you answered Yes to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.b Primary Purpose – Other | 034.8.4 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if an explanation for“Other” Primary Purpose is not provided | For study titled <Study Title>, an explanation is required if “Other” was selected for Primary Purpose and you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.b Primary Purpose | 034.8.33 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl:D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Primary Purpose or explanation for Primary Purpose is provided. | For study titled <study title>, a Primary Purpose or explanation for Primary Purpose cannot be provided since you did not answer Yes to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | 4.2.b Primary Purpose | 034.8.35 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s:  K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,  K38  Excl : 333,666,777 | Single |  |  | Provide error if Primary Purpose or explanation for Primary Purpose is provided. | For study titled <study title>, a Primary Purpose or explanation for Primary Purpose cannot be provided since this Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.c Interventions | 034.8.5 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if an intervention is not provided. | For study titled<Study Title>, at least one Intervention must be provided since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.c Interventions | 034.8.57 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Intervention is provided | For study titled<Study Title>, an Intervention cannot be provided since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.c Interventions | 034.8.58 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s:  K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if Intervention is provided | For study titled<Study Title>, an Intervention cannot be provided since this Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.c Intervention– Type, Description | 034.8.6 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if any Intervention Sub-element (Type , Description) is not provided. | For study titled <Study Title>, Intervention <Type, Description> must be provided for Intervention Name<Intervention Name> since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I)  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.c Intervention Name | 034.8.8 | N | N | NIH AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if an Intervention Name is not provided | For study titled<Study Title>, Intervention Name must be provided since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.d Study Phase | 034.8.10 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if Study Phase is not provided | For study titled <study title> a Study Phase is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.d Study Phase – Other | 034.8.11 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error if “Other” Study Phase is selected but description for “Other” Study phase is not provided | For study titled <study title> a Description is required if “Other” is selected as the Study Phase and you answered Yes to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.d Study Phase | 034.8.39 | N | N | NIH, AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Study Phase or description for study phase is provided. | For study titled <study title>, a study phase or a description for study phase cannot be provided since you did not answer “Yes” to questions 1.4a through 1.4d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.d Study Phase | 034.8.56 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,  K38  Excl : 333,666,777 | Single |  |  | Provide error if Study Phase or description for Study Phase is provided | For study titled <study title>, a Study Phase or description for Study Phase cannot be provided since this Funding Opportunity Announcement does not allow independent clinical Trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.d Is this an NIH-defined Phase III clinical trial? | 034.8.12 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666 | Both | Both |  | Provide error for a Clinical Trial study if response to the question “Is this an NIH-defined Phase III Clinical Trial” is not provided | For study titled <study title> a response to the question “Is this an NIH-defined Phase III Clinical Trial?” is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.d Is this an NIH-defined Phase III clinical trial? | 034.8.42 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if response to the question, “Is this an NIH-defined Phase III clinical trial?”, is “Yes” | For study titled <study title>, a response to the question “Is this an NIH-defined Phase III Clinical Trial?” cannot be “Yes”, since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.d Is this an NIH-defined Phase III clinical trial? | 034.8.70 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl  K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if response to the question “Is this an NIH-defined Phase III Clinical Trial” is ”Yes” | For study titled <study title> a response to the question “Is this an NIH-defined Phase III Clinical Trial?” cannot be “Yes”, since this Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.d Is this an NIH-defined Phase III clinical trial? | 034.8.13 | N | N | NIH,  AHRQ | 1.0 | CLINICALTRIALCODE = “N | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Study Record when the response to the question “Is this an NIH-Defined Phase III Clinical Trial” is “Yes” and the FOA does not support Clinical Trials. | For study titled <study title>, response to the question "Is this an NIH-defined Phase III clinical Trial cannot be "Yes" since the FOA does not support Clinical Trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.e Intervention Model | 034.8.14 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if Intervention model is not provided. | For study titled <Study Title>, an Intervention Model must be provided since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.e Intervention Model – **Other** | 034.8.15 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if “Other” is selected as the Intervention Model and a description for Other is not provided. | For study titled <study title>, a description is required when “other” is selected as the Intervention Model and you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.e Intervention Model | 034.8.43 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Intervention Model or description of Intervention Model is provided. | For study titled <study title>, an Intervention Model or description of Intervention Model cannot be provided since you did not answer “Yes” to questions 1.4a through 1.4d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.e Intervention Model | 034.8.74 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s:  K01,  K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00, K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if Intervention Model or description for Intervention Model is provided | For study titled <study title>, an Intervention Model or description for Intervention Model cannot be provided since the Funding Opportunity Announcement does not allow independent clinical trials | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.f Masking | 034.8.16 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a study record if response to masking is not provided. | For study titled <study title> a response to the masking question is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.f Masking | 034.8.46 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Study record if response to masking is “Yes” | For study titled <study title> a response to the masking question cannot be “Yes”, since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.f Masking | 034.8.37 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl: D43, K12  Incl F’s:    F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl  K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00, K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if response to masking is “Yes” | For study titled, <study title> a response to the masking question cannot be “Yes”, since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.f Masking  Participant, Care Provider, Investigator, Outcomes Assessor | 034.8.17 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Study record if response to masking is “Yes”, but Participant, Care Provider, Investigator, Outcomes Assessor is not selected. | For study titled <study title>, a selection of either Participant, Care Provider, Investigator and/or Outcomes Assessor is required if response to masking is “Yes” and you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.f Masking  Participant, Care Provider, Investigator, Outcomes Assessor | 034.8.47 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Study Record if response to masking is “Yes”, but Participant, Care Provider, Investigator, Outcomes Assessor is selected. | For study titled <study title>, Participant, Care Provider, Investigator, and/or Outcomes Assessor cannot be selected since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.f Masking  Participant, Care Provider, Investigator, Outcomes Assessor | 034.8.38 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s: F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00, K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error for a Study Record if response to masking is “Yes”, but Participant, Care Provider, Investigator, Outcomes Assessor is selected. | For study titled <study title>, Participant, Care Provider, Investigator, and/or Outcomes Assessor cannot be selected since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.g Allocation | 034.8.18 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl:D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Study Record if allocation is not provided. | For study titled <study title> Allocation is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.g Allocation | 034.8.48 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Study Record if Allocation is provided | For study titled <study title> Allocation cannot be provided since and you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.2.g Allocation | 034.8.49 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl  F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s:  K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if Allocation is provided | For study titled <study title> Allocation cannot be provided since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.3 Outcome Measures | 034.8.19 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Study Record if at least one Outcome Measure is not provided in the study. | For study titled <study title> at least one Outcome Measure is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.3 Outcome Measures | 034.8.50 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if an Outcome Measure is provided | For study titled <study title>, an Outcome Measure cannot be provided since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.3 Outcome Measures | 034.8.51 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s:  K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error for a Study Record if an Outcome Measure is provided | For study titled <study title>, an Outcome Measure cannot be provided since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Protocol Synopsis**  4.3 Outcome Measures – Type, Timeframe, Description | 034.8.20 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error fora Clinical Trial Study if an Outcome Measures subelement (type, timeframe, description) is not provided. | For study titled <Study Title>, Outcome Measure <Type, Timeframe , Description> must be provided since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.3 Outcome Measures Name | 034.8.21 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide an error for a Clinical Trial Study if an Outcome Measure Name is not provided | For study titled <study title>, an Outcome Measure Name is required for Outcome Measures since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.4 Statistical Design and Power | 034.8.24 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if Statistical Design and Power Attachment is not attached to the Study | For study titled <study title>, a Statistical Design and Power Attachment is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.4 Statistical Design and Power | 034.8.60 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Statistical Design and Power attachment is provided. | For study titled <study title> a Statistical Design and Power attachment cannot be provided since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.4 Statistical Design and Power | 034.8.61 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s: F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if Statistical Design and Power attachment is provided | For study titled <study title> a Statistical Design and Power attachment cannot be provided since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.5 Subject Participation Duration | 034.8.25 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if ‘Subject Participation Duration’ is not provided for the study | For study titled <study title> a Subject Participation Duration is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.5 Subject Participation Duration | 034.8.62 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Subject Participation Duration is provided | For study titled <study title> a Subject Participation Duration cannot be provided since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.5 Subject Participation Duration | 034.8.63 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s: F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error for a Human Subject Study if Subject Participation Duration is provided | For study titled <study title>, a Subject Participation Duration attachment cannot be provided since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.6 Will the study use an FDA – regulated intervention? | 034.8.26 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial Study if response to the question, “Will the study use an FDA – regulated intervention? is not provided. | For study titled <study title>, a response to the question “Will the study use an FDA – regulated intervention?” is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.6 Will the study use an FDA – regulated intervention? | 034.8.64 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if response to question, “Will the study use an FDA – regulated intervention?” is “Yes” | For study titled <study title> a response to question, “Will the study use an FDA – regulated intervention?” cannot be “Yes”, since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.6 Will the study use an FDA – regulated intervention? | 034.8.65 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s: F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl:ude K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error if response to question, “Will the study use an FDA – regulated intervention?” is “Yes” | For study titled <study title> a response to the question “Will the study use an FDA – regulated intervention?” cannot be “Yes”, since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rue should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.6a If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status? | 034.8.27 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error if “If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status” is not provided when the response to the question “Will the study use an FDA-regulated intervention?” is “Yes” | For study titled <study title>, the Availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status attachment must be provided since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.6a If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status? | 034.8.66 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error“If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status” is provided. | For study titled <study title>, the Availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status attachment cannot be provided since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.6a If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status? | 034.8.67 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl:D43, K12  Incl F’s: F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s: K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error “If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status” is provided. | For study titled <study title> the Availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status attachment cannot be provided since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs.  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.7 Dissemination Plan | 034.8.28 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Clinical Trial study if “Dissemination Plan” attachment is not attached | For study titled <study title> a Dissemination Plan is required since you answered “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 4 – Protocol Synopsis**  4.7 Dissemination Plan | 034.8.68 | N | N | NIH,  AHRQ | 1.0 | Answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error for a Human Subject Study if Dissemination Plan attachment is provided | For study titled <study title> a Dissemination Plan cannot be provided since you did not answer “Yes” to questions 1.4.a-1.4.d in the Clinical Trial Questionnaire. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials.  New Rule  October 2017 Release |
|  | **Section 4 – Protocol Synopsis**  4.7 Dissemination Plan | 034.8.69 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N”) AND ( Answers to questions 1.4a through 1.4d are ALL “Yes”) | Excl: D43, K12  Incl F’s:  F05, F30, F31, F32, F33, F37, F38, FI2, F99/K00  Incl K’s:,K01,K02, K05, K07, K08, K18, K22, K23, K24,K25, K26, K99/R00,K76, K43,K38  Excl : 333,666,777 | Single |  |  | Provide error for a Human Subject Study if Dissemination Plan attachment is provided for a F or K FOA | For study titled <study title> a Dissemination Plan cannot be provided since the Funding Opportunity Announcement does not allow independent clinical trials. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for F and K applications to Clinical Trial Not Allowed FOAs  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 5 – Other Clinical Trial Related Attachments** | 034.9.1 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “N” or “O” ) AND answers to questions 1.4a through 1.4d are NOT all “Yes” | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error if the study is NOT Clinical Trial and Other Clinical Trial-related attachments are provided. | Study titled <study titled> is not a Clinical Trial and cannot have clinical trial-related attachments. | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are blocked for studies which do not involve clinical trials  New Rule  October 2017 Release |
| PHS Human Subject and Clinical TrialInformation | **Section 5 – Other Clinical Trial Related Attachments** | 034.9.2 | N | N | NIH,  AHRQ | 1.0 | (CLINICALTRIALCODE = “R" or "O") AND (Answers to questions 1.4a through 1.4d are ALL "Yes") | Excl: D43, K12  Excl : 333,666,777 | Both | Both |  | Provide error if more than ten Clinical Trial-related attachments are provided for the study | No more than 10 Clinical Trial-related attachment are allowed for Study titled <study title> | E | Rule should not fire | Rule should not fire | Rule should not fire | Study Record fields in Sections IV and V are required for studies involving independent clinical trials (unless CLINICALTRIALCODE = I).  New Rule  October 2017 Release |