IRB Continuing Review Worksheet

Key:

*Italics: explanatory text*

Yellow highlight: information everyone needs to complete

Gray highlight: instructions about when additional questions need to be completed

Teal highlight: information you may need to complete, depending on previous answers

*Instructions: Please read carefully before completing this form:*

* *Research that requires Convened/Full Annual Continuing Review is due 6 weeks prior to expiration.*
* *Research that qualifies for Expedited Annual Continuing Review is due at least 2 weeks prior to expiration.*
* *Incomplete submissions will be returned for edits regardless of expiration date.*

***If IRB Approval Expired or Will Expire:*** *No research related activities may occur after the protocol expiration date. If the study has expired or will expire while waiting for IRB review, the following information will be required:*

* *A description of any study activities that have occurred during the lapse in approval*
* *An explanation for what led to the delayed submission of the Continuing Review Application*
* *A corrective action plan to avoid expiration in the future*
* *If this is not the first time that the study has expired, an explanation of whether the existing corrective action plan needs to be corrected, and if not, why not.*
* *If your research is greater than minimal risk and activities need to occur during the lapse for the benefit or safety of participants, an explanation of this exigency.*

# Section 1

Submitter: [the system will enter this]

Protocol Number: [the system will enter this]

Protocol Title: [the system will enter this]

Principal Investigator: [the system will enter this]

Display Faculty Assurance: *NOTE: If blank, there is no Faculty Assurance for this project.* [the system will enter this]

Expiration Date: [the system will enter this]

Date Comparison: *The system compares the expiration date from the last item with the current date and returns “True” if the expiration date is later, and “False” if the current date is later.* [the system will enter this]

Current Review Level: [the system will enter this]

If Date Comparison is “False”:

Please describe any study activities that have occurred during the lapse in approval (if not applicable, enter N/A): [enter description of activities]

Provide an explanation for what led to the delayed submission of the CR: [enter explanation]

Provide a corrective action plan to avoid expiration in the future: [enter plan]

If this is not the first time that the study has expired, comment on whether the existing corrective action plan needs to be corrected (if not applicable, enter N/A): [enter comment]

Additional Documentation: [upload documents to answer any of the above questions; indicate in the textbox the filename of the attachment that corresponds to that question]

Does this study use drugs, devices, biologics, foods, food additives, cosmetics, investigational in vitro diagnostics or lab developed test, vitamins, supplements, etc.? [yes/no]

# Section 2: Progress Report

Current Enrollment Status: [pick one of the following]

Study has not begun (no participants consented)
Open to participant enrollment
Closed to participant enrollment

Estimated remaining duration of the study, including analysis of identifiable private information. [enter duration]

Please enter a narrative summary of the study activities that occurred during the approval year including:
 a. notable comments
 b. notable participants experiences
 c. any delays in study activities, and
 d. expected activities for the coming year
*If you prefer to upload a document, leave this question blank and proceed to the next question.* [enter summary]

Narrative Summary Attachment: [upload narrative summary]
*If you entered the narrative summary in the previous question, you do not need to attach it here*.

Will the research remain active only for long-term follow-up? *E.g., no further participants will be enrolled, or primary data collection is complete.* [yes/no]

If you answered “yes”:

 Please describe any long-term follow-up activities: [enter description]

Do you anticipate submitting a modification form also? [yes/no]

 If you answered “yes”:

Please describe any planned or outstanding modifications that will be submitted to the IRB for review including the planned timeline for submission and the impact the modifications will have for enrolled participants, as applicable. [enter description]

*If you have not already started a modification request to the IRB, you will be given a link to start the request in the form.*

# Section 3: Participant Enrollment

Approved Number of Subjects (as of latest review): [the system will enter this]

What is the target enrollment over the next twelve months? If this has not changed, enter the number above: [enter number]

Number of Subjects Consented Since Last Approval: [enter number]

What is the number of participants actively participating in study procedures? [enter number]

What is the number of participants participating in only follow-up procedures (e.g., completing of required follow-up procedures or interventions, remaining active only for long-term follow-up)? [enter number]

What is the number of participants who completed all required procedures since enrollment began (i.e., no further study contact is required)? [enter number]

Are there any participants who provided consent that are no longer participating (no further study-related contact required) for reasons other than completion? [yes/no]

If you answered “yes”:

Provide a summarized list below of participants that did not complete the study but have ended participation since enrollment began. Include the reasons other than completion and the number of inactive participants in each category. (Categories to consider: determined ineligible after consent, lost to follow up, voluntary withdrawal, withdrawal by the PI, disease progression, adverse event). [enter summary]

Is this a multi-site study? [yes/no]

If you answered “yes”:

What is the total target enrollment for the other sites combined? [enter number]

What is the current enrollment for the other sites combined? [enter number]

Does the study track demographic information about the subjects (gender, ethnicity/race, etc.)? [yes/no]

If you answered “yes”:

3a: Equitable Participant Selection

*This section should include all participants since enrollment began.*

Is information from or about participant gender and/or sex being collected? [yes/no]

If you answered “yes”:

Please provide the information you have collected about gender/sex demographics since enrollment began. For example, number of male/female/intersex/other identity/unknown subjects. [enter information]

Is information from/about participants’ race and/or ethnicity collected? [yes/no]

*Race refers to categories of people based on shared physical and social qualities while ethnicity refers to populations or subgroups of people who share a common cultural background and/or descent. The categories included within this form are not exhaustive and are based on US Census data.*

If you answered “yes”:

Please provide the race/ethnicity demographic information you have collected for all participants since enrollment began. *For example, ethnicity typically captures Hispanic or Latino/x and Not Hispanic or Latino/x*. *Race typically captures American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Pacific Islander, White, Other, Multi-racial, Unknown/Not reported.* [enter information]

Please comment on the strategies or methods being used to recruit a diverse sample of participants that includes and/or reflects the larger targeted population: [enter comment]

Based on the demographic information above, are there under- and/or over-represented categories? [yes/no]

If you answered “yes”:

Please explain how any under- and/or over-representation of demographic categories is justified by the research design. [enter explanation]

3b: Recruitment

Has participant recruitment been successful? *For example, did you meet the target number of participants?* [yes/no]

Please discuss your participant recruitment procedures in terms of what has been successful versus not. Please discuss your plans for the upcoming year, including any changes to the recruitment plan to improve recruitment and increase enrollment. [enter discussion]

Has your study enrolled any participants from protected or vulnerable populations that require special considerations? [yes/no]

If you answered “yes”:

Please describe any relevant details about recruitment of protected or vulnerable populations. *For example, if part of your population is subject to undue influence (e.g., K12 students), explain how you minimized that risk.* [enter description/explanation]

# Section 4: Research Involving Products/Agents

If you answered “yes” to “Does this study use drugs, devices, biologics, foods, food additives, cosmetics, investigational in vitro diagnostics or lab developed test, vitamins, supplements, etc.?” at the end of Section 1. *If you answered “no” this section will not be available.*

Have there been any updates related to the products administered on this trial in the past year? *This may include but is not limited to: revised package inserts, revised investigator brochures, product recalls or bans, new product manufacturer, etc.* [yes/no]

If you answered “yes”:

Please confirm that all updates have been submitted to the IRB appropriately, or indicate that an amendment is forthcoming. [enter confirmation]

# Section 5: Adverse Events

Have there been any unanticipated problems or adverse events associated with this research? *For example, an unanticipated problem is something that could not have reasonably been foreseen at the beginning of the research, but has the potential of harm for participants, such as identifying a potential allergic reaction to a study product. An adverse event is an unanticipated problem that in fact caused harm for participants, such as a study participant suffering an allergic reaction to a study product.* [yes/no]

If you answered “yes”:

Please describe the unanticipated problem or adverse event. [enter description]

Have you already reported the unanticipated problem or adverse event to the IRB? [yes/no]

If you answered “no”:

Click here to complete the IRB Unanticipated Problem/Adverse Event Reporting Form. *This is required because you have indicated that you have not yet reported this problem or event to the IRB*. [link will be shown in form]

# Section 6: Risk-Benefit Assessment

Is there any new information to report that would alter the IRB’s previous determination that risks to participants are minimized AND risks to participants are reasonable in relation to anticipated benefits, if any? [yes/no]

If you answered “yes”:

Please describe the new information the IRB should consider that may alter the previous determinations for these two IRB approval criteria: [enter description]

By submitting this application, I attest that the application is complete and accurate to the best of my knowledge: [check “I Attest” box, then click “Next”, then click “Submit”]