**CONTINUING REVIEW - PRIMARY REVIEWER PRESENTATION TEMPLATE**

This form is to be used by the primary reviewers when making the presentation to the board for continuing approval of a study. The form will serve to ensure that the regulatory criteria for approval are presented and considered in the review process and also to bring consistency to the review process between IRB reviewers and across panels. **This form is for the oral summary presentation; specific concerns are to be noted in the IRIS system and addressed AFTER the presentation is completed**.

| **IRB Number**:  |
| --- |

|  |  |
| --- | --- |
| **PART I – STUDY INTRODUCTION:** | **REVIEWER’S SUMMARY**  |
| In the introduction:* announce the study title, PI and the sponsor,
* provide a brief overview of study
 |  |
| **PART II – STUDY PROGRESS** | **REVIEWER’S SUMMARY** |
| Provide an overview of the study progress to date, commenting on* Subject enrollment, including withdrawals, screen failures etc.
* Issues of non-compliance, or unanticipated problems
* Meetings of monitoring boards and recommendations
* Adverse Event profile and whether it is as expected
* New information in literature
* Any change to risk to participants
* Substantive modifications approved over the past year
* Any other unique situation
 |  |
| **PART III – PROPOSED MODIFICATIONS (If Applicable)** | **REVIEWER’S SUMMARY** |
| If the request for continuation also incorporates a request for addendum / modification, provide a brief description of the request.  |  |
| **PART IV – PROVIDE A COMMENT ON CRITERIA FOR APPROVAL** | **REVIEWER’S SUMMARY** |
| Provide a brief statement as to whether regulatory criteria for approval+ continue to be met; noting specifically if criteria for waivers and vulnerable populations continue to be met. Also include here, as applicable, HIPAA considerations, Dept. of Defense considerations (Appendix F), National Institute of Justice considerations (appendix H, consent elements, privacy certificate). **+**Minimization of risks, Reasonableness of risk in relation to potential benefits, Equitable subject selection, Process and documentation of consent / waivers or alterations of consent, Data Monitoring, Protection for Privacy, Protections for Confidentiality, Protections for vulnerable groups. HIPAA has been appropriate addressed.  |  |
| **PART V – ADDITIONAL CONSIDERATIONS AS APPLICABLE** | **REVIEWER’S SUMMARY** |
| **Conflicts of Interests** (summarize whether there are any conflicts. If so, summarize the management plan): |  |
| **Other Comments:**  |  |
| **PART VI - OVERVIEW OF THE CONCERNS OF THE REVIEWER** | **REVIEWER CONCERNS TO BE NOTED IN IRIS** |
| Note – Part VI will be addressed by review of the comments made on forms and documents in the IRIS system and on the reviewer form in IRIS which is presented on screen during a meeting  |  |

Note: The help button on the reviewer form in IRIS contains additional points to consider.