**ADDENDUM / MODIFICATION - PRIMARY REVIEWER PRESENTATION TEMPLATE**

This form is to be used by the primary reviewers when making the presentation to the board for approval of an addendum/modification to study. The form will serve to ensure that the regulatory criteria for approval are 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 – ADDENDUM / MODIFICATION** | **REVIEWER’S SUMMARY** |
| Provide a brief description of the requested addendum / modification and its impact on the study. Include comments on:   * Current local enrollment in the study * Whether the request requires subjects be re-consented * Whether the request changes overall risks of the study * Whether the scientific integrity will be maintained. |  |
| **PART III – PROVIDE A COMMENT ON CRITERIA FOR APPROVAL** | **REVIEWER’S SUMMARY** |
| Provide a brief statement as to whether regulatory criteria for approval+ will continue to be met if the proposed addendum/modification were approved.  **+**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. Also include here HIPAA considerations, Dept. of Defense considerations (Appendix F), National Institute of Justice considerations (appendix H, consent elements, privacy certificate). |  |
| **PART IV – 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 V- OVERVIEW OF THE CONCERNS OF THE REVIEWER** | **REVIEWER CONCERNS TO BE NOTED IN IRIS** |
| To 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.