Modifications

1. Is this modification request in response to an audit? [YES/NO]
2. Is the sole purpose of this modification to complete data migration for an ARIA/CRIMSON study? [Yes/No]

If Yes, GET MESSAGE THAT SAYS:

Please complete the information for this study beginning on the next page. Click on a section name in the right hand column to go directly to that section of the form.

[SKIP REST OF MODIFICATION SECTION; GO TO FIRST PAGE OF FORM]

1. Are you only converting an approved CRIMSON study budget into CLARA?[YES/NO]
2. Does this modification request involve a change in:
   1. Study budget [YES/NO]
   2. Study contract [YES/NO]
   3. Principal Investigator [YES/NO]

[FOR INDUSTRY COOP STUDIES ONLY] IF THE ANSWER TO B OR C IS YES, THE SYSTEM WILL NOTIFY THE CONTRACT MANAGER (DIANA) AUTOMATICALLY, WHEN THE PI SUBMITS THE MODIFICATION FORM. DIANA WILL COLLECT THE DOCUMENT FROM PI AND CREATE A CONTRACT AMENDMENT IF NEEDED. THE CONTRACT MODIFICATION WILL BE CARRIED IN THE CONTRACT MODULE.

[FOR INVESTIGATOR INITIATED STUDIES ONLY] IF THE ANSWER TO B OR C IS YES, THE SYSTEM WILL PRE-SELECT THE CONTRACT MANAGER IN GATEKEEPER’S FINAL REVIEW PAGE, AND CONTRACT MANAGER WILL BE NOTIFIED WHEN GATEKEEPER APPROVES THE STUDY. DIANA WILL COLLECT THE DOCUMENT FROM PI AND CREATE A CONTRACT AMENDMENT IF NEEDED. THE CONTRACT MODIFICATION WILL BE CARRIED IN THE CONTRACT MODULE.

1. Does this modification request involve a change to:
   1. Procedures, tests or services provided by the UAMS hospital or clinics [YES/NO]
   2. Physician or pharmacy services [YES/NO]
   3. Number of study subjects [YES/NO]

1. Does this modification request involve amendment to the injury or cost statement in the study consent documents? [YES/NO]
2. Was this study previously submitted to Medicare for an Approval Letter? [YES/NO]

[FOR INDUSTRY/COOP STUDIES ONLY] IF THE ANSWER TO ANY OF THE ABOVE QUESTIONS IS YES, GOES TO BUDGET MANAGER FOR REVIEW

1. Is this study being conducted under a UAMS-held IND or IDE? [YES/NO]

[FOR INVESTIGATOR INITIATED STUDIES ONLY] IF THE ANSWER TO ANY OF THE ABOVE QUESTIONS IS YES, GOES TO GATEKEEPER FOR REVIEW

1. Please describe the requested change. [TEXTBOX, REQUIRED]
2. What is the reason for the requested change? [TEXTBOX, REQUIRED]
3. In the opinion of the Principal Investigator, does the requested change affect the risk/benefit ratio of the study? [YES/NO]

If Yes,

* 1. Describe the changes to the risk/benefit ratio resulting from the modification: [TEXTBOX]

GET MESSAGE THAT SAYS:

Make your requested modifications beginning on the next page. Click on a section name in the right hand column to go directly to that section of the form.

Please be sure that any changes made in this form are also made in the protocol and the informed consent documents for the study, as applicable. Inconsistent information across the submission form, the protocol, and the informed consent documents will delay approval.

Upload any new study documents (or new versions of study documents) in the Documents section of this form. Please be sure to upload your audit response document, if this modification request is in response to an audit.