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| **GENERAL INFORMATION**  This document is intended to give investigators an overview and guidance on ALL the Sections/questions in the Modification Submission.  **Policy**   * Federal regulations and IRB Guidelines require that ***any revision to previously approved research*** involving human subjects be submitted for IRB approval. * All modifications must be approved prior to implementation. * A modification is defined by the IRB as a change that does not alter the overall character of the original project. Significant changes may require a new Initial Submission. * A modification submission should also be used to provide the IRB post-approval documents, such as letters of support and/or external IRB approval letters.   **Process**   * A Modification Submission creates a copy of the last approved submission. * Investigators should make the requested changes directly in the item/answer in each Section (as appropriate). Similarly, new versions of attachments should **replace** previous attachments. * The Compare function allows both investigators and reviewers to see the changes side by side. * The investigator is asked to provide a description of and rationale for the proposed modification and to address the effects of the modification on risks, benefits, management of risks, and informed consent process. You may wish to create this list of changes using the Compare function. * See the [Cayuse Guide for Researchers](https://docs.google.com/document/d/12K_aNq5XZfFUZ6w24a03Nl4isD__46Cu/edit?usp=sharing&ouid=113315935649170498154&rtpof=true&sd=true) |

| SECTION - MODIFICATION | **Notes** |
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| Purpose | |
| * I am requesting the following changes to the project. * I am providing post-approval documents that could not be available until RMU approved the project. | *If you do not choose at least one of the two choices above, DO NOT make any changes to the application. Back out and delete the modification submission.*  *Important note: Any changes to the study protocol must be included in a Modification submission. Consider whether the changes will require revisions of recruitment or consent materials.* |

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| *I am requesting the following changes to the project.* | |
| Summary and rationale   * *To guide the reviewer, please list each change using the bullet or number formatting and provide the rationale for each change.* * *It may be that one general statement can provide rationale for all the changes.* | *For example,*   1. *Study Personnel - Remove X and Add Y because X has changed positions* 2. *Subjects - Change inclusion/exclusion criteria to remove X because of screen failures.* 3. *Subject Numbers - Increase number from # to # because a higher than anticipated number of potential participants have not passed the eligibility screening.* 4. *XXX - to match RMU submission to local IRB submission.* |
| Have you made the change(s) listed above in each appropriate Section, changing radio buttons, checkboxes, and text boxes/areas as needed?   * Yes | *Each change listed in the summary should also be made in the corresponding Application Section.*  *The reviewer will use a compare function to easily see the changes* |

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| I am providing post-approval documents that could not be available until RMU approved the project. | |
| Have you changed the appropriate Section, changing radio buttons, checkboxes, and text boxes/areas as needed?   * Yes | *Each "Letter of Support forthcoming; will be signed upon RMU approval OR Local IRB approval pending" should be changed in the corresponding Application Section.*  *The reviewer will use a compare function to easily see the changes.* |