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**CITI Program CRC Regulatory Binder Tabs**

**Instructions**

This set of regulatory binder tabs is intended to help principal investigators (PIs) and research teams organize the information that is required to be retained in the course of their clinical research study. While you may use electronic systems or a mix of paper and electronic systems, it is very beneficial to have a central “repository” that details where and how everything can be found.

There are thirty pre-defined tabs and five additional tabs that can be customized for your own use. Required tabs (required in most studies…there are exceptions) are indicated with an asterisk (\*).

Some best practices with regards to regulatory binder management include:

* Store regulatory binders in a safe and secure space (locked cabinet/office).
* Limit the number of people who access the regulatory binders so as to minimize the number of mis-placed/mis-filed/missing documents. Consistency in filing is key.
* Keep the contents current. As changes are made and/or reports are received, file as soon as possible. Ensure documents with a pre-determined approval period (for example: licensure, CVs, and financial disclosures) are updated according to the frequency required by your organization.
* If you will not be using a particular tab, either remove it from the binder set or insert a paper indicating “Not Applicable” behind it. This will reflect that the item was intentionally omitted (and not accidentally missed).
* Maintain version numbers on all documents to simplify identifying currency. Binder-clip or otherwise separate archived documents so as to indicate their archived nature.
* Utilize blue or black ink for documentation.
* Never use white-out or obliteration. Never remove/destroy items from the regulatory binder, even if no longer used (archived).
* Keep participant-specific materials out of regulatory binders.
* Indicate any corrections with a single-line through, initials and date and, if the correction is not immediately apparent (such as a math error), explain the purpose for the correction.