DMC REQUIRED DOCUMENTATION PRIOR TO A REVIEW

To our Sponsors and Clinical Trial Study Teams: please see the next page for study documentation requirements to be received for DMC review at least **five business days** prior to a call [as well as data formats].

Please send all documentation directly to CFF DSMB Portal Administrator/Project Manager, Ms. Leslie Hargrove, lkhargrove@email.arizona.edu.

Please also *pay special attention to* our CFF DSMB Charter Guidelines and Template = separate document. To include, according to your study design the following:

Definition of adverse event (AE) of special interest or treatment emergent AEs:

An adverse event of special interest (serious or non-serious) is one of scientific and medical concern *specific to the sponsor's product or program*, for which ongoing monitoring and rapid communication by the investigator to the sponsor may be appropriate. Such an event might warrant further investigation in order to characterize and understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties (e.g., regulators) may also be warranted (Based on CIOMS VI).

Specific to Cystic Fibrosis:

- FEV1 drop of 10% of predicted or more;
- etc

Please contact your study-specific CFF DMC Study Coordinator at any time with questions.

Thank you!

DMC REQUIRED DOCUMENTATION PRIOR TO A REVIEW

DMC and Study Team Initial, Organizational (new) study review:

	The role of your CRO is to: • Generate statistical analysis plan mock-ups (see below) • Prepare Open and Closed (unblinded) reports for interim analyses • Attend the closed portion of interim analysis calls to assist the DMC with any questions or discussion items.
	Statistical analysis plan in mock-up form: Tables, charts, graphs, box-plots, summaries, spaghetti plots, open reports, closed reports, SAE summaries, etc, *applicable to your study design.* Closed reports should either identify treatment groups, or a separate document identifying treatment groups should be sent. Reports should be transmitted to the DMC Database Administrator in PDF format, and should be condensed. The DMC should receive only one PDF file for tables, one for listings, and one for figures.
	Protocol
	Draft DMC Charter
	Investigator's Brochure
	Informed Consent models
	Sponsor's Power-point presentation study summary

DMC and Study Team **Interim Analyses** Requirements:

	Sponsor Power-point slide presentation including recruitment and summary of the open report (see examples on next page)
	Summary of Open Report by blinded statistician
	Open Report Data Sets *(One PDF file each for: tables, listings, figures. May send additional files as needed.)*
	Closed session summary report
	Closed Report Files *(One PDF file each for: tables, listings, figures. Identify treatment groups, or put them in a separate file. May send additional reports as needed.)*
	Unblinded Study Team Statistician presentation and Q&A

Examples:

- Enrollment updates;
- Demographics;
- Participant dispositions – withdrawal, drop-out rate;
- Protocol violations or deviations;