Data and Safety Monitoring Board (DSMB)

The funding research service may require that a VA Data and Safety Monitoring Board (DSMB) oversee intervention clinical trials. The assignment to DSMB (HSR) will be indicated in JIT to inform the local station research office of the assignment.

Generally, studies that meet one of the following criteria are referred to the DSMB:

- Multi-site clinical trial
- Clinical studies *likely* considered greater than minimal risk
    - Definition of **Minimal Risk - T**he probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45.CFR.46.102(j))(Common Rule)

For HSR projects, the assignment of the DSMB JIT area requires the submission of a Data Analysis Plan (DAP) **45 days** from the date on which the project was released to the station in JIT. The DAP details (1) the study design and analysis plan with respect to the research questions and (2) the plan to monitor and track serious adverse events.

The DAP must be 3-7 pages, using appendices if necessary. It must include a table of contents and footer on each page that includes page number, PI name, Study ID and date.

The DAP should include the following elements, as applicable:

1) sample size rationale;
2) specific description of data collection process(es);
3) randomization approach (e.g., stratification or blocking);
4) plans and justification of any interim analyses (e.g., stopping rules for superiority, futility, or sample size re-estimation);
5) methods for prevention and handling of handling missing data (including loss to follow-up);
6) list and definitions of covariates to be included in models (including potential confounders);
7) methods for dealing with data transformations;
8) definitions of the analytical cohorts (i.e. intent-to-treat, per protocol, etc.);
9) list and definition of adverse and serious adverse events to be monitored and plans for prospectively tracking.

Include a statement of assurance with DAP document indicating agreement to refrain from recruitment activity (as distinct from initiating the study itself) until DSMB DAP approval has been received.

For questions regarding DSMB, please contact vhahsrddsmb@va.gov.