



## MTN-045 Operational Guidance #1: Couples Observation Inter-Observer Reliability Measures

The purpose of this Operational Guidance document is to clarify procedures around inter-observer reliability for the Couple's Observations.

The following provides instructions on implementation of these procedures:

- Joint observations:
  - A range of 10-20% of couples' joint product activities will be observed jointly by two observers.
  - A primary Observer should be designated and responsible for explaining the activity; however, both Observers will complete the CO tool with both versions entered into REDCap within the timeframe designated in the site Data Management SOP.
  - Sites should ensure an adequate mixture of observation partners during these exercises (i.e. not always pairing the same two Observers).
  - Immediately following each joint observation (and after study visit procedures with the couple have been completed), the two Observers will compare their CO tools and discuss any discrepancies by talking about their reason for selecting each response. This review and discussion should focus on questions in which the two Observers selected different responses. During this discussion, no changes will be made to the CO tools; however, a third document will be used to indicate which items were discussed along with comments about the disagreement and any resolution. This tool will be completed in Word and uploaded to the sftp to RTI. An example of the template is available below. A modifiable version will be available for download on the MTN website.
  - Joint observations will occur more frequently at the beginning of the study and then will reduce as an acceptable level of reliability between Observers is reached. The team should begin the study by having at least two joint couple activities per Observer jointly observed. A reliability score will be generated by RTI following entry of the forms in REDCap, which will be used to determine the continued frequency of the joint observations. This will also be used to identify questions or observation topics that may be more difficult to align across Observers and warrant further discussion within the team.
  - Joint observations should be tracked by the site in a tracking log to capture the Observers (primary and secondary) involved, the date of observation, and the reliability score provided by RTI.
- Team meetings:
  - At the start of the study, sites should hold weekly meetings with the Observers and key site leadership to discuss their experience with conducting the observations, including joint observations, any difficult cases, their scoring, and rationale for scoring. The frequency of these meetings can be adjusted, as appropriate, to meet implementation needs.
  - RTI and each site will hold weekly meetings with the Observers and key team leadership at the beginning of the study to discuss the joint observations, as well as any difficult cases.
  - Once both sites have initiated study activities and enrolled participants for at least one month, RTI will begin to convene periodic cross-site meetings to build cross-site reliability (e.g. monthly). Planned activities for these meetings will be shared at a later date.

All Operational Guidance documents must be printed and filed with regulatory documentation.

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Date

