Talking Points: Control Sites

1. Our center has committed to participate in a clinical trial funded by the NIH.
2. I will serve as the Site PI.
3. Our Site Research Coordinator(s) will be _____.
4. The trial is designed to find out whether or not a recently validated screening tool can improve the accuracy of our decisions to launch or forgo child abuse evaluations in our young, acutely head-injured patients admitted for intensive care.
5. At the four sites randomly assigned to serve as control sites, PICU and child abuse providers will practice "screening as usual" for abusive head trauma.
6. Our site has been randomly assigned to the *control* arm of the trial.
7. The study protocol does *not* require that you ask any questions, order any tests, request any consultations, capture any additional patient-related data, or make any reports of suspected child abuse that—in your own clinical judgment—fall outside the scope of your standard patient care.
8. For both you and your eligible, acutely head-injured patients, this will be a strictly observational study.
9. Our involvement in this study should last 24 months, but could be extended to 30 months.
10. We plan to launch the clinical trial on July 1st.
11. The Research Coordinator and I will work diligently to minimize the impact of study participation on your direct patient care activities.
12. The only significant risk associated with your participation in this study is the inadvertent disclosure of your specific clinical practices related to screening for abusive head trauma in your acutely head-injured patients admitted for intensive care.
13. By the way, victims of motor vehicle accidents—and patients three years of age or older—are excluded.
14. Finally, let's each take a few minutes to review the data forms that will be used throughout the trial. These are labeled data forms two, four and five.