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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Hand shakes

When we moved to Baltimore, behind us were the Lees (Pete and Robin). They had just moved from Franklin, Indiana. A town a little bigger than Sleepy Eye about 20 miles south of Indianapolis in the heart of farming country.

Franklin, like Sleepy Eye, had a canning factory but the difference was that when they were canning wells went dry. That did not happen in Sleepy Eye.

The Lees had to sell their house in Franklin when they moved to Baltimore. Pete asked around for a real-estate agent. Various people suggested Rudy (last name forgotten).

Pete: *Where can I find Rudy?*

Neighbor: *He doesn't have an office but you can usually find him in front of the bank.*

Sure enough. There he was on a bench in front of the bank the next day when Pete drove up.

A couple weeks later Rudy called. *I think we have a buyer for your house. Harry Jones, a farmer north of town, is fixing to move to town. Can you meet us in front of the bank tomorrow at nine to talk?*

So they talked. After they finished Harry shook Rudy's and Pete's hand and walked off.

Rudy: *Well. It looks like we got your house sold.*

Pete: *Don't we need some papers?*

Rudy: *What the hell do you want papers for? The man shook your hand didn't he?*

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We live in a world of hand shakes. The world runs on trust.

The handshakes in trials are that everyone will follow the straight and narrow in doing and reporting trials.

In trials everyone is joined at the hip. If something bad happens anywhere in the trial it impacts everyone. Just ask the chair and director of the coordinating center for the National Surgical Adjuvant Breast and Bowel Project (NSABP) where an investigator falsified records so as to enroll a person into the trial. The ensuing events nearly destroyed the NSABP.

The hand shakes in trials are that you and your fellow investigators will:

- Adhere to the principles of respect for persons, beneficence, and justice set forth in the Belmont Report;
- Respect and adhere to IRB requirements and procedures;
- Ensure that consents are informed and that persons enrolling understand they can withdraw any time without consequence;
- Ensure the trial is registered on CT.gov prior to start of enrollment and that registrations are updated as necessary over the course of the trial;
- Follow the protocol as written;
- Require, if the trial has a DSMB, equity representation of the leadership of the trial relative to that provided for the sponsor;
- Be honest and forthright; do not cheat, fabricate, falsify, makeup, or fudge study data;
- Report suspicious or wrongful acts to proper authorities;
- Ensure that tabular results are posted to CT.gov within one year of completion of the trial;
- Ensure that the cutoff dates for all outcomes are the same and are set by study investigators;
- Prepare a data sharing plan and post to CT.gov;
- Make a concerted effort to publish principal results when the trial is finished in a peer-reviewed indexed journal and that analyses are by intention to treat.