



## Memorandum

To: Trialists  
Fr: Curtis Meinert  
Re: Coordinating center takeovers

A takeover is the act of assuming control, management of, or responsibility for. In regard to trials and followup studies, broadly, takeovers are of the relay or revival type. Relay takeovers involve handoff of an activity to another group while the activity is ongoing, e.g., transfer of coordinating center responsibilities during enrollment. Revival takeovers involve resurrection of a suspended or ended trial or followup study. Revival takeovers are akin to undertaking a new study except with persons previously studied. Takeovers in the center here are as below.

### **Infant Health and Development Program (IHDP)**

Year: 1988  
Type: Relay  
Activity: Coordinating center  
Transition: Transfer of coordinating center operations from Stanford

### **Sleep Heart Health Study (SHHS)**

Year: 1999  
Type: Relay  
Activity: Coordinating center  
Transition: Transfer of coordinating center operations from University of Washington

### **Biomarkers of Cognitive Decline among Normal Individuals: The BIOCARD Cohort**

Year: 2009  
Type: Revival  
Activity: Data center  
History: Study suspended in 2006 because of conviction of study PI of a misdemeanor (accepting consulting fees from a drug maker). Study revived under PI-ship of JHU School of Medicine investigator via an NIH request for proposal issued in 2008.

### **Alzheimer's Disease Anti-inflammatory Prevention Trial - Followup Study (ADAPT-FS)**

Year: 2010  
Type: Revival  
Activity: Coordinating center  
History: ADAPT ceased followup in 2007; two year funding for followup of people enrolled in ADAPT provided in 2010

So, if you are in the data collection and processing business and approached for a takeover as a coordinating center or data center, what do you do? The reminders below are things to keep in mind when coming to a decision.

**Reminder 1:** Be careful!

*Comment:* Once you takeover the operation it is yours. You had better understand why you are being approached. If for a relay takeover, is it because the current coordinating center wants out or is it because investigators want a new coordinating center? If people in the coordinating center want out is it because they think the study is worthless or unethical? If it is because of toxic relationships with the sponsor or study leaders you had better understand their origins and if they are likely to arise anew with the transition. If so you are well-advised to "walk".

**Reminder 2:** Pay attention to how the request for takeover arises

*Comment:* It will be by direct contact from somebody in the study to explore interest, or by issue of a request for application (RFA), or request for proposal (RFP) by a funding agency to which one responds if interested. There will be more information available as to what is expected if the transition is via RFAs or RFPs, but the effort in responding may be for naught if your application is not successful. The prospect of funding without the usual hassle of applying for funding can cause one to leap with regrets down the road.

**Reminder 3:** What you don't know can hurt you

*Comment:* Every study has skeletons. If you have been in from the outset you know where they are buried. If you are a Johnny-come-lately you have to unearth them. That takes time so do not be hasty. You need to talk to people in the transiting coordinating center. If they are not forthcoming, you are well-advised to "walk".

**Reminder 4:** Stay away if funding is uncertain

*Comment:* There is no point to the agony of a takeover if funding is uncertain or iffy.

**Reminder 5:** Stay out if funding is inadequate or if the timetable for takeover is unrealistically ambitious

**Reminder 6:** Stay away if your view of the role and responsibility of a coordinating center or data center is not in sync with study leaders or sponsors

*Comment:* Life is short. It gets shorter when there is a philosophical mismatch with study leaders as to what the role and duties should be. If your desire is for a partnership role, stay out if the study leaders or sponsor want a service organization.

**Reminder 7:** Do not start work on transition without a funding agreement

**Reminder 8:** Do not undertake transfer of study data if transfer is at odds with existing consents

**Reminder 9:** Do not agree to takeover if the sponsor is not willing to provide support of the existing coordinating center or data center for orderly transition

**Reminder 10:** Do not agree to takeover if the current coordinating center is not willing to participate in the takeover

**Reminder 11:** The role of the coordinating center/data center will be influenced by how the center is funded

*Comment:* Its role and function likely will be different if funded directly by the sponsor versus funding via the study chair or a study center.

**Reminder 12:** If a revival involves transfer of previously collected data to link with new data to be collected (likely), then make certain that the transfer is consistent with original consents and that the transfer is cleared through IRBs

**Reminder 13:** In revivals, the greater the period of dormancy, the more difficult it will be to restart

*Comment:* The longer the period the more difficult it will be to track people for restarts. The longer the period, the greater the difficulty in linking old data to new data.

**Reminder 14:** Have your own IRB approval

*Comment:* Avoid riding piggyback on some other IRB approval (eg, as with one held by the study head) so that the coordinating center/data center can function independently of other study centers.

