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Memorandum

To: Center faculty and staff

Fr: Curt Meinert

Re: On posting study protocols and consent forms to study websites

The table below lists studies here with websites and whether they have public portions. The last two columns indicate whether study protocols and prototype consent forms are posted to the public portion of websites (listing as of 6 July).

Acronym	Study name	Public portion	Protocol posted	Consent posted
ADAPT	1. Alzheimer's Disease Anti-inflammatory Prevention Trial	Yes	Yes	Yes
ADAPT-FS	2. ADAPT-Followup Study	Yes	Yes	No
ALA-ARC	3. Am Lung Association - Asthma Clinical Research Centers	Yes	No	No
BIOCARD	4. Biomarkers of Cognitive Decline: The BIOCARD cohort	No	-	-
CAMPCS/3	5. Childhood Asthma Man Prog Continuation Study/Phase 3	Yes	Yes	Yes
CitAD	6. The Citalopram for Agitation in Alzheimer's Disease Trial	No	-	-
DIADS-2	7. Depression in Alzheimer's Disease Study-2	No	-	-
GpCRC	8. Gastroparesis Clinical Research Consortium	Yes	No	No
LOTT	9. Long-term Oxygen Treatment Trial	Yes	No	No
MUST	10. Multicenter Uveitis Steroid Treatment Trials	Yes	No	No
NASH CRN	11. Nonalcoholic Steatohepatitis Clinical Research Network	Yes	No	No
NETT	12. National Emphysema Treatment Trial	Yes	No	No
SHHS	13. Sleep Heart Health Study	Yes	Yes	Yes
SOCA	14. Studies of the Ocular Complications of AIDS	Yes	Yes	Yes
TRTT	15. Tinnitus Retraining Therapy Trial	No	-	-

Note: All of the websites are available via www.jhucct.com except for BIOCARD, CiTAD, and TRTT those websites are www.biocard-se.org, www.citadtrial.org, and www.trtt.org, respectively

Of the 15 sites, 11 had public portions. Of those, five had postings of study protocols and four had consent form postings.

There are reasons to argue that protocols and consent forms underlying randomized trials should be available to anyone, whether or not associated with the trial. The principal reason has to do with the need for openness. One can argue that we should not be experimenting on human beings if we are not willing for members of the public to know what we are doing. The

ability to research on human beings depends on public trust. That trust is eroded if basics with regard to the extent and nature of the research being done is not openly available to the public.

The obvious and most direct way to communicate openness is by posting protocols and consent forms to public websites. Posting implies a study policy embracing unrestricted access to those documents. Most assuredly, absence of posting or absence of a public website does not mean that those documents would not be provided if requested, but it does leave open the question as to whether investigators have addressed the issue of access and how the documents can be obtained if desired.

There are instances in which proprietary sponsors are reluctant to provide access to protocols because of concerns of giving away trade secrets. However, that concern, if ever valid, has lost its cogency with the FDA requirement for registration of trials.