

The Teveten® Times

The Official Newsletter for the Study of Teveten® in African-Americans

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Hypertension In Blacks

A Study in Attitudes Towards Research

Many African Americans view signing the informed consent form as signing away rights rather than protecting them, according to a recent study on research participation among African Americans in an urban hospital. The Study, co-authored by Giselle Corbie-Smith, MD, will be published later this year in the *Journal of General Internal Medicine*.

The Study also revealed African Americans' continuing fear of being treated like guinea pigs because of the Tuskegee Syphilis Study. For 40 years, from 1932-72, government researchers denied treatment to 399 men with syphilis.

The research indicates that we need to do a better job of acknowledging that these fears are real, said Stephen B. Thomas, Ph.D., a member of the research team. Dr. Thomas is director of the Institute for Minority Health Research and associate professor of community health at the Rollins School of Public Health, Emory University. He said we also need to do a better job of talking with young African Americans about the purpose of research.

African American research participants generally give African American healthcare providers the benefit of the doubt when it comes to trust. "It's not automatic, but it's an advantage of establishing rapport early on," Dr. Thomas said.

But Dr. Thomas points out that White providers can connect with Black patients and vice versa. Providers and patients of the same race or ethnicity do not always communicate successfully. "You still have a social class gap that can be a barrier to communication." Dr. Thomas said he saw the gap first hand about ten years ago when he sent a black graduate student into a public housing complex in Washington, DC. The African American student felt uncomfortable with the poverty she saw, and it was a white student who ultimately connected with the community.

Stressing cultural competence and better preparation for students of all races will become increasingly important, Dr. Thomas said. "We can't throw professionals into situations we haven't prepared them for, regardless of their race."

Dr. Thomas lectured on "Assessing the Legacy of Tuskegee on Participation of African Americans in Medical and Public Health Research" at an anniversary meeting of the 1997 presidential apology for the Tuskegee Syphilis Study.

Important Telephone Numbers

Medical Monitor - Dr. Jeffrey Dubb - Serious Adverse Events
800.877.7074 x 6584 or 800.366.8900 (24 hours)

Regional Assistant Directors - Protocol Questions

Bruce Beck.....	Pacific Region	714.671.2862
Tim Brewer	Rocky Mountain Region .	713.864.6137
Laurie Nishimura	Mid-Atlantic Region	610.640.0735
Marie Rafalowski	Southeast Region	770.719.1031
Alan Roman	Midwest Region	708.352.9043
Arthur Solomonides ..	Northeast Region	603.382.4228

Regulatory, Drug and/or Supply Questions

Judy McQuade 610.917.6184

SB Investigational Drug Ordering System (SBIDOS) and Patient Registration 610.270.4944

Remote Data Entry Help Desk

Kelley Grabill 888.823.5277

Laboratory Supplies and Lab Reports - SmithKline Beecham

Clinical Labs 800.877.7004 Press 2. Hours 5 a.m.-5 p.m.PST

Center 027 - Cleveland, OH

Through the reporting of August 4, 1999, Dr. Jackson Wright, Investigator, Center 027, Cleveland has screened 32 patients with 33 cleared through the randomization phase. Dr. Wright contributes the success of his site to "an excellent well trained staff" who have the clinical trial skills and experience necessary to maintain the trial and a rapport with patients.

Dr. Wright indicated that most of the credit due for the success of his site is attributable to his Staff Nurse Coordinators, Luzmaria Jaen, RN and Rene Hernton, MA. Luzmaria and Rene are champions at the center who have diligently worked to insure the success of the clinical trial process.

Dr. Wright has been with Case Western since 1990, which enjoys a favorable reputation in the Cleveland area. Dr. Wright and his staff utilized direct advertising, newspaper advertising and past patient contacts to form his study patient group. Along with chart reviews and personal consultations with potential patients, Dr. Wright and his staff have developed quite a successful trial.

"Patient questions should be handled directly with direct answers and assurances of the use of the best safest methods" states Dr. Wright. Dr. Wright believes that it is also important for him to speak with patients during the informed consent process to provide those assurance and to address patient concerns.

Dr. Wright acknowledged that recruiting patients who will meet requirements of the study has been the most challenging. Dr. Wright continues to stress the importance of his staff and commends them for a job well done.

ISHIB2000 JULY 15-18, 2000

Join ISHIB in Los Croabas, Puerto Rico as they address, "Improving Outcomes Through Comprehensive Care of Patients with Hypertension and Related Risk Factors." The scientific objectives of ISHIB2000 are intended to answer questions, raise issues and create a momentum to aggressively pursue research to provide long over-due solutions to the disproportionate rates of disease among ethnic minority populations. For more information contact the ISHIB2000 Conference Center at 404.875.6263 or view the ISHIB web site at www.ishib.org.

Notice: Serious Adverse Event

Please call Medical Monitor - Dr. Jeffrey Dubb for all serious adverse experiences within 24 hours at 800.877.7074 ext. 6584 or 800.366.8900 (24 hrs).

Centers may fax SAE information (within 24 hrs) to Attn.: John Spann at 610.917.4814. If faxing SAE information, please utilize the fax forms provided in your Teveten® 155 Study Reference Manual.

Letter from the Medical Monitor

Below is helpful information to clinical investigators from Dr. Jeffrey Dubb - Medical Monitor for Teveten® Study 155.

Managing Adverse Experiences

One of the primary responsibilities of the investigator is the management of adverse experiences. In addition to treating the adverse experience as effectively as possible, the investigator must evaluate the effect the event will have on the study participation:

- Can the subject safely continue receiving the test article?
- Will treatment of the event require drugs that are barred by protocol as concomitant medications?
- If this is a controlled study, will effective treatment require breaking the code? Is withdrawal from the study indicated?
- Is special reporting required?

Mandatory Reporting of Adverse Experiences

In any study involving a regulated product, the investigator is subject to FDA rules that require the prompt reporting of certain types of adverse experiences. Reports must be made both to the sponsor and to the Internal Review Board (IRB). In general, events that are serious and unexpected require expedited reporting. The classification criteria and procedural requirements for adverse event reporting are available to you if necessary. Please contact ISHIB at 404-875-6263 for a more detailed procedural explanation of your role in reporting adverse experiences.

Jeffrey W. Dubb, MD
Group Director
Cardiovascular Therapeutic Unit

Upcoming Events

September 16 - 19, 1999

American Academy of Family Physicians (Orlando, FL)

October 13 - 17, 1999

Consortium of Southeastern Hypertension Control (San Juan)

October 18 - 24, 1999

American Dietetic Association (Atlanta, GA)

November 6 - 10, 1999

American Heart Association (Atlanta, GA)

February 5 - 9, 2000

Pan-Arab Society of Hypertension (Abu-Dhabi, UAE)

March 12 - 15, 2000

American College of Cardiology (Anaheim, CA)

Teveten® Study Centers

Center No.	Investigator	Location	SB-IDOS Reg (Screened)	RDE Rep (Screened)	RDE Rep (Randomized)	
031	Bennett	NY	2	3	2	
002	Calhoun	AL	7	7	1	
004	Cheek	SC	5	9	4	
041	Conlin	MA	5	11	6	
038	Cushman	TN	2	4	2	
033	Early	GA	4	6	4	
006	Ferdinand	LA	13	12	3	
007	Flack	MI	5	8	2	
034	Flowers	GA	1	1	1	
029	Frank	OR	0	1	0	
045	Gamel	TX	10	12	7	
042	Graff	FL	8	8	8	
008	Hamilton	MD	14	15	12	
009	Harrison	NY	13	12	4	
010	Herron	IL	49	49	31	
011	Hilliard	CA	4	6	3	
012A	Hsueh	CA	5	4	2	
013	Hyman	TX	4	5	2	
001	Johnson	TN	3	6	0	
047	Marks	TX	10	17	4	
015	Marsh	OH	2	3	1	
005	Mills	TX	11	16	3	
040	Noveck	LA	27	27	16	
017	O'Connor	CA	16	21	11	
043	O'Hara	CT	5	10	1	
030	Papademetriou	DC	15	17	12	
044	Patron	FL	4	4	4	
020	Obialo	GA	2	4	0	
036	Raval	MI	32	33	17	
021	Richardson	KY	8	9	6	
022	Sica	VA	13	11	7	
019	Smith	CA	20	20	12	
035	Spigner	PA	29	36	0	
046	Sugimoto	IL	14	14	2	
023	Taylor	MS	10	10	7	
012B	Trom	CA	0	5	2	
024	Victor	TX	7	7	3	
025	Ward	CA	13	27	13	
032	Watson	CA	25	24	10	
026	Weir	MD	27	30	21	
027	Wright	OH	32	33	23	
028	Zusman	MA	12	12	9	
<i>(Revised 08/06/99)</i>			Totals:	488	569	278

ISHIB

Teveten® Study

2045 Manchester Street, NE

Atlanta, GA 30324-4110