TOHP

Trials of Hypertension Prevention
(TOHP) supported by the National Heart, Lung, and Blood Institute, National Institutes of Health

Visit ___ ___ ___
ID number ___ ___ ___ ___ ___ ___ ___ ___
Initials ___ ___ ___ ___ ___
Visit date ___ ___/___ ___/___ ___

SUPPLEMENTS FORM

1. Since your last follow-up visit, approximately what PERCENTAGE of your assigned pills have you taken? (100% is equivalent to having taken ALL PILLS; 000% is equivalent to having taken NO PILLS AT ALL). ___ ___ ___ %
(percentage of pills taken)

For Staff Use Only ___ ___

IF MISSED PILLS: What was the *primary* reason for missing? _____

2. Since your last visit have you experienced:	1 = Yes 2 = No (a)	NEW: 1 = Yes 2 = No (b)	FREQUENCY: 1 = less than weekly 2 = weekly 3 = 2–6 /wk. 4 = daily 5 = constantly (c)	DEGREE: 1 = moderate 2 = extreme 3 = very extreme (d)
A. Increased physical energy	___	___	___	___
B. Change in appetite	___	___	___	___
C. Improved mood	___	___	___	___
D. Improved vision	___	___	___	___
E. Bad taste in mouth	___	___	___	___
F. Stomach upset or nausea	___	___	___	___
G. Belching	___	___	___	___
H. Stomach pain or burning	___	___	___	___
I. Diarrhea	___	___	___	___
J. Loose, frequent stool	___	___	___	___
K. Constipation	___	___	___	___
L. Frequent urination	___	___	___	___
M. Excessive gas	___	___	___	___
N. Easy bruising	___	___	___	___
O. Nosebleeds	___	___	___	___
P. Excessive bleeding from cuts/scratches	___	___	___	___
Q. Change in sexual drive	___	___	___	___
R. Excessive thirst	___	___	___	___
S. Skin rash	___	___	___	___
T. Red blood in stools or blackened stools	___	___	___	___
U. Other / _____ (specify)	___	___	___	___

On the sheet provided, please provide further details on any events experienced at a greater than weekly frequency (frequency code = 3, 4, or 5) or a degree level which is extreme or very extreme (degree code = 2 or 3).

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Visit ___ ___ ___
ID number ___ ___ ___ ___ ___ ___ ___ ___
Initials ___ ___ ___ ___ ___
Visit date ___ ___/___ ___/___ ___

SUPPLEMENTS FORM—STAFF REVIEW

1. Has a new set of calendar packs been dispensed to the participant? ..... ☐ YES ☐ NO

   Reason if NO: _____

2. Calculating Pill Compliance:

   A. What is the date of the previous follow-up *visit at which pill compliance was calculated?* ___ ___/___ ___/___ ___

   B. What was yesterday's date? ___ ___/___ ___/___ ___

   Arrange the calendar packs in order. Beginning with the date on the packs which corresponds to the last follow-up visit (item A.) and continuing through and including yesterday's doses (item B.), COUNT THE NUMBER OF UNBROKEN DOSE BUBBLES AND RECORD THIS NUMBER IN THE SPACE PROVIDED:

   Number of UNBROKEN DOSE BUBBLES ___ ___ ___

   Check this box if it is not possible to calculate exact pill count because participant has lost calendar packs or is unable to bring in a complete set. ..... ☐

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3. Review the participant's responses to item #2 on the Supplements form and circle BELOW any item which requires a review by a staff physician. For each circled item, the staff physician should indicate by circling a 1, 2, 3, 4, or 5 if the experience is likely related to the TOHP pills.

	In opinion of MD: Due to TOHP pills? YES		UNCERTAIN		NO
E. Bad taste in mouth	1	2	3	4	5
F. Stomach upset or nausea	1	2	3	4	5
G. Belching	1	2	3	4	5
H. Stomach pain or burning	1	2	3	4	5
I. Diarrhea	1	2	3	4	5
J. Loose, frequent stool	1	2	3	4	5
K. Constipation	1	2	3	4	5
L. Frequent urination	1	2	3	4	5
M. Excessive gas	1	2	3	4	5
N. Easy bruising	1	2	3	4	5
O. Nosebleeds	1	2	3	4	5
P. Excessive bleeding from cuts/scratches	1	2	3	4	5
Q. Change in sexual drive	1	2	3	4	5
R. Excessive thirst	1	2	3	4	5
S. Skin rash	1	2	3	4	5
T. Red blood in stools or blackened stools	1	2	3	4	5
U. Other _____ (specify)	1	2	3	4	5

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4. TOHP ID# of person administering form ..... ___ ___ ___ ___

5. TOHP ID# of person editing form ..... ___ ___ ___ ___

Attach to self-administered form (#SUP) and return to CC.

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