This Workflow Document spells out the steps related to the intake, evaluation, treatment, and follow-up of a participant in NBIRR-01. All of the forms discussed in this WORKFLOW -- including this workflow -- can be found on the website, www.nbirr.org, under **Documents/Document Exchange/Platform Instructions/NBIRR Forms.**

1. FIND OUT ABOUT and CONTACT NBIRR:
   a. participant candidate sees ad or somehow learns about NBIRR
      marketing by site
      word of mouth
      hear Radio Spot
      web blogs, etc.
      www.clinicaltrials.gov
   b. candidate or representative initiates communication
      uses 'contact us' page to provide contact information & brief summary
      contacts Call Center **(800) 288-9328**
   NOTE: filter and redirect inquiries by third parties on candidate's behalf:
      -inquiries should be made only by candidate, if not, the inquiry should be deflected back to the individual who will be provided links to info and asked to have the candidate make the inquiry (the candidate has to consent so this step is vital and legally necessary)

2. SCREENING by CALL CENTER in not currently being performed. Call Center will refer directly to nearest clinic. It is the responsibility of each clinic to do its own screening.

3. IN-OFFICE SCREENING BY NBIRR SITE STAFF
(Patient NEVER uses online computer forms and never comes into contact with computer EXCEPT for doing cognitive tests ANAM & CNSVS. Patients never have access to the CareVector Platform [CVP])
-site contacts and schedules candidate for initial interview by phone or in person based on site preferences
   -interviewer reviews Inclusion - Exclusion Criteria, as appropriate
   -interviewer / site coordinator:
Complete WIRB-Approved: Research Subject Information and Consent Form [NOTE: Each site must adapt the Template to their site and submit the competed form to the WIRB for approval. Read top-corner-right instructions from WIRB: " Approvable Template must be approved for sites before use AS MODIFIED May 26, 2009, WIRB(r) "

   provide copy of Research Subject Information and Consent Form to patient
      -review general protocol
      -confirm funding mechanism for treatments
      -confirm they want to proceed with consent and protocol
   Registers Patient on CareVector Platform (CVP). This is done while creating a New Patient on the CVP. Complete online CareVector Patient Personal Info & Patient Demographics sections. These forms are contained on the "Patient" tab on the CVP: Patient Personal Info & Demographics fields. To get to the forms, first click on the pencil

icon to the left of the patient ID number. A new menu will open. Click on the 'pencil' icon at the right of the Patient Personal Info and then the Demographics field and the forms will open in a pop-up - MAKE SURE TO ALLOW POPUPS on your browser settings.

Complete Patient History Forms:

1. Brief Patient Health Questionnaire
2. Personal Health Questionnaire 9 (PHQ-9)
3. Personal Health Questionnaire: Physical Symptoms (PHQ-15)
4. Perceived Quality of Life (PQoL)

NOTE: For these and other forms, print out the forms, complete by hand, and enter data later into CareVector Platform. All the forms are available on the nbirr.org site at: Documents/Document Exchange/Platform Instructions/NBIRR Forms. Also note: there are over 2 dozen forms in this folder. Use the scroll bar or the up/down arrows on the right-hand side of the list to scroll through the list.

4. SITE PI SCREENS ABOVE INFORMATION COLLECTED AND MAKES FINAL DETERMINATION ON PARTICIPANT ACCEPTABILITY FOR NBIRR AT THAT SITE
   -if acceptable, schedule visit for initial medical evaluation & hyperbaric exam with Site PI

5. SITE PI WORKFLOW:
   ASCERTAIN BASELINE

   -confirm with patient that they have consented and want to proceed
   -**urine drug test, pregnancy test**
   Labcorp Account # 19531200
   (in name of CareVector, LLC - on behalf of IHMF)
   Test Code: 794370 9-Drug Panel
   Test Code: 004036 Pregnancy Urine
   (these are charged to the study, NOT the site, and will be paid for by IHMF from the per treatment fee of $25 - per the agreement - that the site pays to IHMF for protocol development and administration.

(NOTE: THE SITE IS NOT OBLIGATED TO SEND THE $25 FEE WHEN A PARTICIPANT IS TREATED PRO BONO/FOR FREE.)

Baseline Questionnaires are Administered:

If MILITARY etiology:
- PTSD checklist - PCL-Military
- 3Q DVBIC Screening Tool (if military injury)
- Combat Experience Scale (if military injury)

If CIVILIAN etiology:
- PTSD Checklist (PCL-Civilian)

All:
- Disability Rating Scale
- MAST & DAST

Document Baseline Cognitive Status

Conduct Monitoring Test Battery ('MTB' - see list of tests at bottom)

History & Physical by Site PI:

-establish nature of injury (head injury, blast injury and type)
-record diagnoses according to military or civilian MD or PhD Psychologists
-Administer Questionnaires:
Patient History 1: General
Patient History 2: Demographic
Physician Obtained Symptom List
NEURO EXAM: 1
NEURO EXAM: 2
-Try to collect before proceeding with protocol (if available):
-pre- or post-deployment ANAMs (if military and available)
-imaging
-eeg
-professionally administered neuropsych tests

NOTE: TRY TO COLLECTANY/ALL BACKGROUND DATA BEFORE PROCEEDING WITH HBOT. IN CASE OF VETERANS, PLEASE ATTEMPT TO GET AS MUCH INFORMATION AS POSSIBLE ABOUT THE NATURE OF THEIR INJURY, e.g.: # OF EXPOSURES TO BLASTS; TIME OF EXPOSURE; LOSS OF CONSCIOUSNESS?; ANYTHING BLASE RELATED, WHETHER FROM IEDs, OTHER EXPLOSIONS, OR FRIENDLY FIRE. IMPORTANT: FIND OUT IF THERE IS/WAS A HISTORY OF BRAIN TRAUMA/CONCUSSIONS BEFORE ENTRY INTO SERVICE.

Site PI decides if participant is cleared for treatment

6. TREATMENT PHASE (complete the "HBOT Session" form for every treatment):

Cycle I:

HBOT 1.5, 1 hour, 20 sessions
at conclusion of cycle, do MTB (all) & pregnancy test (for women)

Cycle II:

HBOT 1.5, 1 hour, 20 sessions
MTB; if PBNRS < 90%, continue to Cycle III
pregnancy test
PI Neuro Exam (per form)

Pause: 30-day interim between first 40 treatments and second 40 treatments.

Cycle III:

HBOT 1.5, 1 hour, 20 sessions

MTB; if PBNRS < 90%, continue to Cycle IV
pregnancy test

Cycle IV (final):
HBOT 1.5, 1 hour, 20 sessions
pregnancy test
MTB
PI Neuro Exam (per form)

7. FOLLOW-UP PHASE:

Follow Up - 6 months
PI or staff interview by phone or internet
MTB

Follow Up - 12 months
PI or staff interview by phone or internet
MTB

Follow Up - 18 months
PI or staff interview by phone or internet
MTB

Follow Up - 24 months
PI or staff interview by phone or internet
MTB

NOTES:

MTB = "MONITORING TEST BATTERY"
(These tests / forms are done at start and after every block of 20 treatments, and at 6, 12, 18, 24 months after treatment ends.)

ANAM4 (computer workstation, locally installed)
CNSVS (computer workstation, internet accessible)
Rivermead Post Concussion Symptoms
Percent Back to Normal (PBNRS)
Patient Health Questionnaire (PHQ) 15,9,7 (PHQ-7 = GAD-7 Anxiety)
Perceived Quality of Life Scale (PQoL) [both pages 1 & 2]
Return to School or Work
NEURO EXAM: 1
NEURO EXAM: 2 Use these forms after 40 treatments and at completion of HBOT treatments, or as required at discretion of Site PI.