Herbal Medicine – Adverse Event Reporting Form

1. Today's Date:

2. Herbal Medicine Adverse Event related to:
   - Allergic reaction to Herbs
   - Drug-Herbs interaction
   - Supplement-Herbs interaction
   - Food-Herbs interaction
   - Unintended Herbal side effect
   - Inadequate Herbal dose effect

3. Patient INITIALS:

4. Patient age (not date of birth):

5. Patient gender:
   - Female
   - Male
   - Intersex
   - Transgender
   - Prefer not to disclose

6. Patient weight (in pounds):

7. Race:
   - Hispanic/Latino
   - Asian
   - American Indian or Alaskan Native
   - Black or African American
   - White
   - Native Hawaiian or Other Pacific Islander
   - Multiracial
   - Unknown

8. Date of Adverse Event:

9. Adverse Event reported:
    - Shortness of breath (SOB)
    - Rash
    - Itching
    - Fever
    - Diarrhea
    - Other

10. Symptoms associated with Adverse Event:

11. Laboratory test changes (name and reference range):

12. Preexisting medical conditions:

13. Medications taken concurrently:

14. Supplements taken concurrently:

15. Known allergies:

16. Herbal Medicine product:
    - Patent TCHM self-administered by patient
    - Patent TCHM prescribed by state-licensed acupuncturist
    - Custom RAW TCHM formula compounded & dispensed by state-licensed acupuncturist in-house
    - Custom RAW TCHM formula compounded & dispensed by supportive personnel in-house
    - Custom RAW TCHM formula compounded & dispensed by 3rd party company
    - Custom 5:1 granule TCHM formula compounded & dispensed by state-licensed acupuncturist in-house

- Custom 5:1 granule TCHM formula compounded & dispensed by supportive personnel in-house
- Custom 5:1 granule TCHM formula compounded & dispensed by 3rd party company

17. Product manufacturer name:

18. Herb Compounding company and website:

19. Suspected product name (if custom use "Classic Base Formula Name modified", e.g. Xiao Yao San modified):

20. Product Lot# if patent or RX# if custom:

21. Total daily intake (dose in grams):

22. List all TCHM formula ingredients, include each ingredient amount & lot # if compounded in your office:

23. Date range of TCHM product or custom prescribed:

24. How soon after start of TCHM intake did Adverse Event occur:

25. Patient complaint(s):

26. Western diagnosis:

27. TCM pattern(s) (please use ICD11-Chapter 26 https://icd.who.int/en):

28. TM treatment principle:

29. Describe an Adverse Event:

30. Substance suspected to cause interaction:

31. Remediation measures taken:

32. Concomitant medical therapy, including dates:

33. Comments:

34. Adverse Event reporter: First and last name, and contact email:

Serious Adverse Events must be reported to FDA on MedWatch Form 3500
https://www.fda.gov/media/76299/download

I hereby agree that this Adverse Event data is HIPAA compliant and will be securely stored. It will only be used for reference and research purposes and not for any commercial reason.

- o I agree