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### Education

- 1994  
M.S. in Mathematics,  
Fu-Jen Catholic University, Taiwan
- 2002  
M.A. in Mathematical Statistics,  
University of Maryland, College Park, U.S.A.
- 2005  
Ph.D. in Mathematical Statistics,  
University of Maryland, College Park, U.S.A.

### Professional Experiences

- 2013/4-present  
Institute of Population Health Sciences, National Health Research  
Institutes, Taiwan  
Associate Investigator
- 2014/8-present  
Graduate Institute of Biostatistics, College of Public Health, China  
Medical University, Taichung, Taiwan  
Joint Appointment Associate Investigator
- 2015/7-present  
Journal of Biopharmaceutical Statistics  
Associate Editor
- 2015/4-present  
Invited to join PLOS ONE Statistical Advisory Board
- 2015/4-present  
Taiwan Association of IRB (TAIRB), Taiwan  
Member
- 2013-present  
Central Institutional Review Board (c-IRB), Taiwan  
Member
- 2013-present  
DSMB of Taiwan Cooperative Oncology Group (TCOG), Taiwan  
Member
- 2009/1-present  
Chang Gung Medical Foundation Institutional Review Board, Taiwan  
Member
- 2008/5-2013/3  
Institute of Population Health Sciences, National Health Research  
Institutes, Taiwan  
Assistant Investigator
- 2005/9-2008/5  
Institute of Population Health Sciences, National Health Research

Institutes, Taiwan  
Postdoctoral fellow

### Research Interests

Statistical Methodologies in Clinical trials, Pharmaceutical statistics, Pharmacogenetic statistics, Epidemiology, Biostatistics.

### Research Activities & Accomplishment

Over 49 SCI papers and 7 book chapters in clinical trials, pharmaceutical statistics, pharmacogenetic statistics, epidemiology, and geriatric research. National Health Research Institutes-Institutional Repository: <http://ir.nhri.org.tw/handle/3990099045/3168>

### Selected Publications

Yang HC<sup>#</sup>, **Tsou HH<sup>#</sup>**, Pei SN, Chang CS, Chen JH, Yao M, Lin SJ, Lin J, Yuan Q, Xia N, Liu TW, Chen PJ, Cheng AL, Hsu C\* and Taiwan Cooperative Oncology Group. (2018). Quantification of HBV core antibodies may help predict HBV reactivation in lymphoma patients with resolved HBV infection. *Journal of Hepatology*. 2018. Vol. 69, 286-292. (<sup>#</sup>First authors, \* Corresponding authors)

Kuo HW, Liu SW, **Tsou HH**, Hsu YT, Wang SC, Fang CP, Liu CC, Chen ACH, Liu YL\*. Inflammatory chemokine eotaxin-1 is correlated with age in heroin dependent patients under methadone maintenance therapy. (2018) *Drug and Alcohol Dependence*. 2018 Feb 01;183:19-24.

**Tsou HH\***, Chen CT, Hsiao CF, Cheng YC. 2018. Evaluation of Biosimilarity Based on an Empirical Bayes Method. *Journal of Bioequivalence & Bioavailability*. 10(1):7-10 (2018)-7

**Tsou HH\***, Chen CT, Lan KK Gordon. 2017. Strategies in designing interim analyses under Discrete Random-Effects Model in a multiregional trial. In *JSM Proceedings, Biopharmaceutical Section*. Alexandria, VA: American Statistical Association. 2812-2816.

Liu TH, Chung RH, Wang SC, Fang CP, **Tsou HH**, Shih CL, Kuo HW, Wang Y, Liu YL. Missense mutation at CLDN8 associated with a high plasma interferon gamma-inducible protein 10 level in methadone-maintained patients with urine test positive for morphine. *PLOS ONE*. 2017 Nov 16;12(11):Article number e0187639.

Chen YR, Chou HC, Yang CH, Chen HY, Liu YW, Lin TY, Yeh CL, Chao WT, **Tsou HH**, Chuang HC, Tan TH. Deficiency in VHR/DUSP3, a suppressor of focal adhesion kinase, reveals its role in regulating cell adhesion and migration. *Oncogene*. 2017 Jul 31. doi: 10.1038/onc.2017.255. [Epub ahead of print] *Oncogene* (2017), 1–9.

Chen CT, **Tsou HH\***, Hsiao CF\*, Lai YH, Chang WJ, Liu JT. A Tolerance Interval Approach to Assessing the Biosimilarity of Follow-On Biologics. *Statistics in Biopharmaceutical Research*. 2017 Sep;9(3):286-292 (\*

Corresponding author)

Kuo HW, Shih CL, Tsung JH, Liu SW, Chu SK, Yang HC, **Tsou HH**, Wang ZH, Chen ACH, Liu YL\*. Pharmacogenomics Study on Cadherin 2 Network with Regard to HIV Infection and Methadone Treatment Outcome. (2017) PLOS ONE. 2017 Mar 30;12(3):Article number e0174647.

Chan DC, **Tsou HH**, Chang CB, Yang RS, Tsao JY, Chen CY, Hsiao CF, Hsu YT, Chen CH, Chang SF, Hsiung CA, Kuo KN. (2017). Integrated Care for Geriatric Frailty and Sarcopenia: a Randomized Control Trial. Journal of Cachexia, Sarcopenia and Muscle. Feb; 8(1):78-88.

Chen CT, Chang WJ, Hsiao CF, **Tsou HH**\*. (2016). Evaluation of biosimilarity between two biological products using alternative approaches. In JSM Proceedings, Biopharmaceutical Section. Chicago, Illinois: American Statistical Association. 3203-3208. (\* Corresponding author)

Liu JT<sup>#</sup>, Chen CT<sup>#</sup>, Lan KKG<sup>#</sup>, Tzeng CS, Hsiao CF\*, **Tsou HH**\*. (2016). Assessing Benefit and Consistency of Treatment Effect under a Discrete Random Effect Model in Multiregional Clinical Trials. In: J. Lin et al (Eds.), *Statistical Applications from Clinical Trials and Personalized Medicine to Finance and Business Analytics*, ICSA Book Series in Statistics, Springer, Springer International Publishing Switzerland 2016. DOI 10.1007/978-3-319-42568-9. ISBN 978-3-319-42567-2. ISBN 978-3-319-42568-9 (eBook). P127-136 (\* Corresponding author)

Chiang NJ\*, Hsu C\*, Chen JS\*, **Tsou HH**, Shen YY, Chao Y, Chen MH, Yeh TS, Shan YS<sup>†</sup>, Huang SF<sup>†</sup>, Chen LT<sup>†</sup>. Expression levels of ROS1/ALK/c-MET and therapeutic efficacy of cetuximab plus chemotherapy in advanced biliary tract cancer. Scientific Reports. 2016 May 3;6:Article number 25369.

Liu JT<sup>#</sup>, Chen CT<sup>#</sup>, Lan KKG<sup>#</sup>, Tzeng CS, Hsiao CF\*, **Tsou HH**\*. (2016). Assessing Benefit and Consistency of Treatment Effect under a Discrete Random Effects Model in Multiregional Clinical Trials. ICSA-Graybill Applied Statistics Symposium Proceedings. (<sup>#</sup>First authors, \* Corresponding authors)

Hsu CP, Chuang HC, Lee MC, **Tsou HH**, Lee LW, Li JP, Tan TH. (2016). GLK/MAP4K3 overexpression associates with recurrence risk for non-small cell lung cancer. Oncotarget. 2016. Jul;7(27):41748-41757.

Chan DC, **Tsou HH**, Chang CB, Yang RS, Tsao JY, Chen CY, Hsiao CF, Hsu YT, Chen CH, Chang SF, Hsiung CA, Kuo KN. (2016). Integrated Care for Geriatric Frailty and Sarcopenia: a Randomized Control Trial. Journal of Cachexia, Sarcopenia and Muscle. In press.

Wang WY, Lin TY, Twu CW, **Tsou HH**, Lin PJ, Liu YC, Huang JW, Shieh HY, Lin JC. (2016). Long-term clinical outcome in nasopharyngeal carcinoma patients with post-radiation persistently detectable plasma EBV DNA.

Oncotarget. 2016 Jul;7(27):42608-42616.

Liu JT#, **Tsou, HH\*\***, Lan KKG#, Chen CT, Lai YH, Chang WJ, Tzeng CS, Hsiao CF\*. (2016). Assessing the Consistency of Treatment Effect under the Discrete Random Effects Model in Multiregional Clinical Trials. *Statistics in Medicine*. 2016 Jun;35(14):2301-2314. (#First authors, \* Corresponding authors)

Liu SW, Liu YL\*, Hwang LL, Wang SC, Kuo HW, Wu SL, Dai YW, Liu SC, Ho IK, Chen ACH, Hsiao CF, **Tsou HH\***. Chemokine IP-10 is correlated with cardiac responses and status of infection with HIV and HCV in methadone maintenance patients. *International Journal of Cardiology*. 2015 Sep 1;194:36-38.. (\*Corresponding author)

Chen JS\*, Hsu C\*, Chiang NJ\*, Tsai CS\*, **Tsou HH**, Huang SF, Bai LY, Chang IC, Shiah HS, Ho CL, Yen CJ, Lee KD, Chiu CF, Rau KM, Yu MS, Yang Y, Hsieh RK, Chang JY, Shan YS\*\*, Chao Y\*\*, Chen LT\*\*, on behalf of the Taiwan Cooperative Oncology Group. A KRAS mutation status-stratified randomized phase II trial of gemcitabine and oxaliplatin alone or in combination with cetuximab in advanced biliary tract cancer. *Annals of Oncology*. 2015. *May*;26(5):943-949.

Yang HC, **Tsou, HH**, Chuang MH, Chen CL, Liu TW, Chen PJ, Cheng AL, Hsu C\*. (2015). Long-term outcome of chemotherapy-induced HBV reactivation in lymphoma patients with resolved HBV infection, *Journal of Hepatology*. 2015 Apr;62, Suppl. 2:S563. (\*Corresponding author)

**Tsou HH\***. Evaluation of Biosimilars-Statistical Perspectives. *Journal of the Chinese Statistical Association*. 2015, Vol. 53, No.1, 11-22. (\*Corresponding author).

Hsu C, **Tsou HH**, Lin SJ, Wang MC, Yao M, Hwang WL, Kao WY, Chiu CF, Lin SF, Lin J, Chang CS, Tien HF, Liu TW, Chen PJ, Cheng AL. Chemotherapy-induced hepatitis B reactivation in lymphoma patients with resolved HBV infection: a prospective study. *Hepatology*. 2014, Volume 59, Issue 6, 2092-2100, June 2014.

**Tsou HH**, Yang HC, Chuang MH, Wu HY, Hsu YT, Chang WJ, Hsiao CF\*, Hsu C\*. Prevention of chemotherapy-induced HBV-related hepatitis flare in lymphoma patients with resolved HBV infection: cost analysis. *Journal of Hepatology*. April 2014 Volume 60, Issue 1, Supplement, Pages S206–S207.

Wang SC, **Tsou HH**, Chung RH, Chang YS, Fang CP, Chen CH, Ho IK, Kuo HW, Liu SC, Shih YH, Wu HY, Huang BH, Lin KM, Chen ACH, Hsiao CF, Chen YT, Liu YL. The Association of Genetic Polymorphisms in the k-Opioid Receptor 1 Gene with Body Weight, Alcohol Use and Withdrawal Symptoms in Patients with Methadone Maintenance. *Journal of Clinical Psychopharmacology*. 2014, April; 34(2):205-211.

Chiang NJ, Hsu C, Chen JS, **Tsou HH**, Chao Y, Shan YS, Huang SF, Chiu CF, Lee KD, Chen LT. Impact of ROS1, ALK and/or MET expression level on the therapeutic efficacy of GEMOX with and without cetuximab in ABTC: A *post-hoc* analysis of a randomized phase II trial. *Journal of Clinical Oncology*, 2014 Jan;32(3 Suppl):Abstract number 267..

Liu JT, Tzeng CS, **Tsou HH\***. Establishing Non-inferiority of a New Treatment in a Three-Arm Trial: Apply a Step-Down Hierarchical Model in a Papulopustular Acne Study and an Oral Prophylactic Antibiotics Study. *International Journal of Statistics in Medical Research*. 2014, 3, 11-20. (\*Corresponding author).

Wang SC, **Tsou HH**, Ho IK, Lin KM, Liu YL. Pharmacogenomics study in a Taiwanese methadone maintenance cohort. *Journal of Food and Drug Analysis*. 2013, Dec;21(4 Suppl.):S62-S68.

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Chan DC, Lee YS, Wu YJ, **Tsou HH**, Chen CT, Hwang JS, Tsai KS, Yang RS. A 12-Year ecological study of hip fracture rates among older Taiwanese adults. *Calcified Tissue International*. 2013, 93(5):397-404.

Lin HL, Hsu YT, Liu CY\*, Chen CH, Hsiao MC, Liu YL, Shen WW, Hsiao CF, Liu SI, Chang LH, Tang HS, Lai HL, Lin PS, Lin KM, **Tsou HH\***. Comparison of escitalopram and paroxetine in the treatment of major depressive disorder. *International Clinical Psychopharmacology*. 2013, 28(6):339-345. (\*Corresponding author)

Wu SL, Wang SC, **Tsou HH**, Kuo HW, Ho IK, Liu SW, Hsu YT, Chang YS, Liu YL. Hepatitis C Virus infection influences the S-methadone metabolite plasma concentration. *PLOS ONE*. 2013, 8(7):e69310.

Wang SC, Ho IK, **Tsou HH**, Liu SW, Hsiao CF, Chen CH, Tan HK, Lin L, Wu CS, Su LW, Huang CL, Yang YH, Liu ML, Lin KM, Liu SC, Wu HY, Kuo HW, Chen AC, Chang YS, Liu YL. Functional genetic polymorphisms in *CYP2C19* Gene in relation to cardiac side effects and treatment dose in a methadone maintenance cohort. *OMICS: A Journal of Integrative Biology*. 2013, 17(10):519-526.

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Kuo HW, Liu SC, **Tsou HH**, Liu SW, Lin KM, Lu SC, Hsiao MC, Hsiao CF, Liu CY, Chen CH, Lu ML, Shen WW, Tang HS, Liu SI, Chang LH, Wu HY, Chang YS, Yeh TK, Chen AC, Liu YL. *CYP1A2* genetic polymorphisms are associated with early antidepressant escitalopram metabolism and

adverse reactions. *Pharmacogenomics*. 2013, 14(10):1191-1201.

Chang YS, **Tsou HH**, Wang SC, Fang CP, Liu YL, Ho IK. Comparing multiple testing correction methods between two softwares for single nucleotide polymorphisms association analyses: Using OPRD1 and diastolic blood pressure in methadone maintenance patients as an example. 2013 IEEE Symposium on Computational Intelligence in Bioinformatics and Computational Biology (CIBCB). 2013, Apr:154-159.

Chen YT, **Tsou HH**, Kuo HW, Fang CP, Wang SC, Ho IK, Chang YS, Chen CH, Hsiao CF, Wu HY, Lin KM, Chen ACH, Tsai-Wu JJ, Liu YL. OPRM1 genetic polymorphisms are associated with the plasma nicotine metabolite cotinine concentration in methadone maintenance patients: A cross sectional study. *Journal of Human Genetics*. 2013,58(2):84-90.

Wang SC, **Tsou HH**, Chen CH, Tian JN, Ho IK, Hsiao CF, Chou SY, Lin YF, Fang KC, Huang CL, Su LW, Fang YC, Liu ML, Wu HY, Lin KM, Liu SC, Kuo HW, Chen ACH, Chen YT, Liu YL. (2012). Genetic polymorphisms in the opioid receptor mu1 gene are associated with changes in libido insomnia in methadone maintenance patients. *European Neuropsychopharmacology*. Oct;22(10):695-703.

**Tsou HH**<sup>#</sup>, Tsong Y, Liu JT, Dong X, Wu YT. (2012). Weighted evidence approach of bridging study. *J. Biopharmaceutical Statistics*. 22(5):952-65. (\* Corresponding author)

**Chan DC, Tsou HH, Yang RS, Tsao JY, Chen CY, Hsiung CA, Kuo KN**. (2012). A Pilot Randomized Controlled Trial to Improve Geriatric Frailty. *BMC Geriatrics*. Sep 25; 12(1): 58. (SCI; Impact Factor=1.97, 2013)

**Tsou HH**<sup>\*</sup>, Tsong Y, Chang WJ, Dong X, Hsiao CF. (2012). Design and analysis issues of multi-regional clinical trials with different regional primary endpoints. *J. Biopharmaceutical Statistics*. 22(5),1051-9. (\*Corresponding author)

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Tuan TF, Chung CT, **Tsou HH**, Chen FW, Lin HL, Lai YK, Lee WS, Chao YS, Hwang LL, Chen CT. (2012). Putative tumor metastasis-associated genes in human gastric cancer. *International Journal of Oncology*. Sep;41(3), 1068-1084.

Tian JN, Ho IK, **Tsou HH**, Fang CP, Hsiao CF, Chen CH, Tan HKL, Lin L, Wu CS, Su LW, Huang CL, Yang YH, Liu ML, Chen YT, Liu SC, Hsu YT, Kuo HW, Liu CT, Yang YT, Chen ACH, Shih YH, Liu YL. (2012). UGT2B7 genetic polymorphisms are associated with the withdrawal symptoms in methadone maintenance patients. *Pharmacogenomics*. 13(8):879-888..

**Tsou HH**, Hung HMJ, Chen YM, Huang WS, Chang WJ, Hsiao CF. (2012). Establishing Consistency Across All Regions in A Multi-regional Clinical Trial. *Pharmaceutical Statistics*. Jul;11(4), 295-299.

Liu YL, Tian JN, Kuo HW, **Tsou HH**, Liu SW, Lu S, Lin KM, Chen YT. (2012). CYP1A2 genetic polymorphisms associated with antidepressant escitalopram metabolism and adverse reactions at early stage. *Clinical Pharmacology and Therapeutics*. 2012 Mar;91(Suppl. 1):S62.

Chen CH, Wang SC, **Tsou HH**, Ho IK, Tian JN, Yu CJ, Hsiao CF, Chou SY, Lin YF, Fang KC, Huang CL, Su LW, Fang YC, Liu ML, Lin KM, Hsu YT, Liu SC, Chen ACH, Liu YL. (2011). Genetic polymorphisms in CYP3A4 are associated with withdrawal symptoms and adverse reactions in methadone maintenance patients. *Pharmacogenomics*. 12(10):1397-1406.

K.Y. Chang, C.J. Yen, C.Y. Hsieh, **H.H. Tsou**, C.F. Chiu, C.C. Chen, C.J. Tsao, K.Y. Tsai, S.T. Tsai, J.Y. Chang. (2011). A Phase II Study of Neoadjuvant Bio-chemotherapy With Cetuximab, Paclitaxel, and Cisplatin (CPC) Followed by Cetuximab-based Concurrent Bio-radiotherapy in High-risk Locally Advanced Head and Neck Cancer – Representative of Head and Neck Cancer Study Group of Taiwan Cooperative Oncology Group. *European Journal of Cancer*. 2011 Sep 23;47:S547-S548.

**Tsou HH**, Chien TY, Liu JP, Hsiao CF. (2011). A Consistency Approach to Evaluation of Bridging Studies and Multiregional Trials. *Statistics in Medicine*. 30(17):2171-2186.

Wang SC, Ho IK, **Tsou HH**, Tian JN, Hsiao CF, Chen CH, Tan HKL, Lin LN, Wu CS, Su LW, Huang CL, Yang YH, Liu ML, Wu JY, Lin KM, Chen CY, Liu SC, Wu HY, Tsai MH, Lin PS, Liu YL. (2011). CYP2B6 Polymorphisms Influence the Plasma Concentration and Clearance of the Methadone S-Enantiomer. *The Journal of Clinical Psychopharmacology*. 2011 Aug;31(4):463-469.

Lin KM, Chiu YF, Tsai IJ, Chen CH, Shen WW, Liu SC, Lu SC, Liu CY, Hsiao MC, Tang HS, Liu SI, Chang LH, Wu CS, **Tsou HH**, Tsai MH, Chen CY, Wang SM, Kuo HW, Hsu YT, Liu YL. (2011) ABCB1 gene polymorphisms are associated with the severity of major depressive disorder and its response to escitalopram treatment. *Pharmacogenetics and Genomics*. 21(4):163-170, April 2011. doi: 10.1097/FPC.0b013e32833db216.

**Tsou HH**, Chow SC, Lan KKG, Liu JP, Wang M, Chen HD, Ho LT, Hsiung CA, Hsiao CF. (2010) Proposals of Statistical Consideration to Evaluation of Results for a Specific Region in Multi-regional Trials – Asian Perspective. *Pharmaceutical Statistics*. Jul;9(3):201-206.  
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Lin KM, **Tsou HH**, Tsai IJ, Hsiao MC, Hsiao CF, Liu CY, Shen WW, Tang HS,

Fang CK, Wu CS, Lu SC, Kuo HW, Liu SC, Chan HW, Hsu YT, Tian JN, Liu YL. (2010). CYP1A2 genetic polymorphisms are associated with treatment response to the antidepressant paroxetine.

*Pharmacogenomics* 2010; Nov;11(11):1535-43

Ko FS#, **Tsou HH**#, Liu JP, Hsiao CF. (2010). Sample size determination for a specific region in a multi-regional trial, *Journal of Biopharmaceutical Statistics*, 24: 870-885. (# co-first author)

Chan DC, **Tsou HH**, Chen CY, Chen CY. Validation of the Chinese-Canadian study of health and aging clinical frailty scale (CSHA-CFS) telephone version. *Archives of Gerontology and Geriatrics*, 2010; May-Jun;50(3):e74-e80.

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**Tsou HH**#, Hsiao CF#, Chow SC, Liu JP. A two-stage designs for drug screening trials based on continuous endpoints. *Drug Information Journal* 2008; 42(3):253-262. (# co-first author)

Chang ML, Lin PS, **Tsou HH**. Application of hierarchical models for detection of spatially clustered diseases in Taiwan. *Journal of the Chinese Statistical Association* 2008; 46: 22-35.

**Tsou HH**, Hsiao CF, Chow SC, Yue LQ, Xu YL, Lee SJ. Mixed non-inferiority margin and statistical tests in active controlled trials. *Journal of Biopharmaceutical Statistics* 2007; 17: 339-357.

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Lin JC, Siu LK, Fung CP, **Tsou HH**, Wang JJ, Chen CT, Wang SC, Chang FY. Impaired Phagocytosis of Capsular Serotypes K1 or K2 *Klebsiella pneumoniae* in Type 2 Diabetes Mellitus Patients with Poor Glycemic Control. *Journal of Clinical Endocrinology and Metabolism* 2006; 91(8):3084-3087.

Rothmann M, **Tsou HH**. On non-inferiority analysis based on the delta-method confidence intervals. *Journal of Biopharmaceutical Statistics* 2003; August,13(3):565-583.

Rothmann M, Li N, Chen G, Chi G, Temple R, **Tsou HH**. Design and analysis of non-inferiority mortality trials in oncology. *Statistics in Medicine* 2003; 22(2):239-264.

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	mortality trials. <i>Proceeding of the Annual Meeting of the American Statistical Association</i> 2001; August:5-9.
	<b>Patent</b>