# ARIC Manuscript Proposal #3464

**1.a. Full Title**:  Validation of Zio XT Patch accelerometer for objective assessment of physical activity in community-dwelling individuals

  **b. Abbreviated Title (Length 26 characters)**:
Zio XT in PA measurement

**2.    Writing Group**:
Writing group members: Jacek K. Urbanek, Lacey Etzkorn, Ciprian Crainiceanu, Kelley Pettee Gabriel, Lisa Pompeii, Joe Coresh, Lin Y. Chen, Jennifer Schrack, others welcome.

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. _JU____ **[please confirm with your initials electronically or in writing]**

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**3.    Timeline**: Statistical Analysis: 1 month
                   Manuscript Preparation: 4 months

### 4. Rationale:

Physical activity (PA) is an important modifiable risk factor for a wide range of diseases, chronic conditions, and functional outcomes that develop across the lifespan. Using primarily report-based measures, habitual PA, operationalized as meeting public health recommendations for aerobic physical activity, has been linked to improved cardiorespiratory fitness (1) and reduced risk of chronic conditions, including cardiovascular disease, stroke, diabetes, breast and colon cancers, osteoporosis, depression, and physical and cognitive functioning later in life (2–4). Due to technological advances, the cost and relative ease of implementing device-based measures into large population-based cohort studies have become more practical, and published studies using these measurements increased exponentially over the past decade (5). Commonly used wearable devices use microelectromechanical systems (MEMS) accelerometer sensors to detect gravitational acceleration (usually expressed in g-units) in one-to-three orthogonal planes; anterior-posterior, mediolateral, and vertical (6). Wearable devices are relatively small, wireless, and non-invasive, with long battery life, generating an objective comprehensive assessment of daily free-living PA across multiple levels of exertion (7). Moreover, the frequency of research publications with the keywords "accelerometer" and "older adults" has grown exponentially from 5 in the year 2000 to 118 in 2017 (5).

During Visit 6 ARIC study introduced a new wearable device called the Zio XT; a small chest-worn device primarily designed to collect ambulatory ECG data for 14 consecutive days. Although the Zio XT Patch was not originally developed and tested to detect and quantify PA-related movement, the Zio XT does feature a tri-axial accelerometer with a frequency of around 90 observations per minute. These data, together with high-density field-based echocardiography data create a whole new spectrum of exciting opportunities and research questions that can be addressed using a single wearable. It is, however, unknown if accelerometry data collected by Zio XT can produce meaningful summaries of PA, comparable with ones obtained with popular research-grade wearable PA monitors such as the ActiGraph wGT3x-BT; a reliable and valid accelerometer that is considered a current gold-standard of physical activity assessment. During Visit 6, a subset of ARIC participants (n =23) also wore an ActiGraph wGT3x-BT as part of the Physical Activity and Falls Ancillary Study (R56 AG049886; MPI: Pompeii and Gabriel). We propose to compare vector magnitude counts, a cumulative metric of PA, calculated using Zio XT accelerometry data with the same metrics obtained using hip-worn Actigraph wGT3x-BT data and discuss the potential of Zio XT to be used as a wearable PA monitor.

### 5. Main Hypothesis/Study Questions:

**Aim 1: To determine the convergent validity of accelerometry data collected by the Zio XT Patch compared to the ActiGraph wGT3X-BT (comparison measure).**

<u>Hypothesis 1</u>: Metrics of PA obtained with Ziopatch XT and ActiGraph wGT3X-BT accelerometry data will be highly correlated with each other.

<u>Hypothesis 2</u>: Metrics of PA obtained with Ziopatch XT can be used to assess the free-living PA of individuals.

**6. Design and analysis (study design, inclusion/exclusion, outcome and other variables of interest with specific reference to the time of their collection, summary of data analysis, and any anticipated methodologic limitations or challenges if present).**

<u>Study Population:</u> We will include all participants who attended the Visit 6 examination and wore the Ziopatch XT and Actigraph wGT3x-BT accelerometry at the same time.

<u>Exposure</u>

Vector Magnitude Counts (VMC) of Zio XT accelerometry data aggregated in 5-minute intervals

<u>Outcome</u>

Vector Magnitude Counts (VMC) of Actigraph wGT3X-BT accelerometry data aggregated in 5-minute intervals

<u>Covariates:</u>

None

<u>Statistical Analysis:</u>
The data form both devices will be time-synchronized using internal device clocks. Non-wear time of the devices will be defined as 60 minutes of consecutive VMC values lesser than 0.005g.

Exploratory analysis and visual comparison of PA metrics will be performed using average diurnal patterns and Bland-Altman plots. Mean absolute percentage error will be used to determine differences of VMC across both devices. Linear regression will be used to assess the co-linearity and the agreement of two sets of PA metrics.

**7.a. Will the data be used for non-CVD analysis in this manuscript? ____ Yes ___x_ No**

> **b. If Yes, is the author aware that the file ICTDER03 must be used to exclude persons with a value RES_OTH = "CVD Research" for non-DNA analysis, and**

**for DNA analysis RES_DNA = "CVD Research" would be used? \_\_\_\_ Yes \_\_\_\_ No**
(This file ICTDER has been distributed to ARIC PIs, and contains
the responses to consent updates related to stored sample use for research.)

**8.a. Will the DNA data be used in this manuscript?**
         \_\_\_\_ Yes    \_\_x\_\_ No

**8.b. If yes, is the author aware that either DNA data distributed by the
      Coordinating Center must be used, or the file ICTDER03 must be used to
      exclude those with value RES_DNA = "No use/storage DNA"?**
         \_\_\_\_ Yes    \_\_\_\_ No

**9.  The lead author of this manuscript proposal has reviewed the list of existing
     ARIC Study manuscript proposals and has found no overlap between this
     proposal and previously approved manuscript proposals either published or still
     in active status.**  ARIC Investigators have access to the publications lists under the
     Study Members Area of the web site at:  http://www.cscc.unc.edu/ARIC/search.php

     \_\_\_x\_\_\_ Yes    _____ No

**10. What are the most related manuscript proposals in ARIC (authors are
     encouraged to contact lead authors of these proposals for comments on the new
     proposal or collaboration)?**

**None**

**11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use
any ancillary study data? \_x\_\_\_ Yes    \_\_\_ No**

**11.b. If yes, is the proposal**
        \_\_\_     **A. primarily the result of an ancillary study (list number\***
\_\_\_2014.18_____)
        \_\_\_     **B. primarily based on ARIC data with ancillary data playing a minor
        role (usually control variables; list number(s)\* _____  _____
        _____)**

\*ancillary studies are listed by number at http://www.cscc.unc.edu/aric/forms/

**12a. Manuscript preparation is expected to be completed in one to three years.  If a
manuscript is not submitted for ARIC review at the end of the 3-years from the date
of the approval, the manuscript proposal will expire.**

**12b. The NIH instituted a Public Access Policy in April, 2008** which ensures that the
public has access to the published results of NIH funded research.  It is **your
responsibility to upload manuscripts to PUBMED Central** whenever the journal does

not and be in compliance with this policy.  Four files about the public access policy  from http://publicaccess.nih.gov/ are posted in http://www.cscc.unc.edu/aric/index.php, under  Publications, Policies & Forms. http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to Pubmed central.

**13. Per Data Use Agreement Addendum for the Use of Linked ARIC CMS Data, approved manuscripts using linked ARIC CMS data shall be submitted by the Coordinating Center to CMS for informational purposes prior to publication**. Approved manuscripts should be sent to Pingping Wu at CC, at pingping_wu@unc.edu. I will be using CMS data in my manuscript ____ Yes __x__ No.

References:

1. Talbot LA, Metter EJ, Fleg JL. Leisure-time physical activities and their relationship to cardiorespiratory fitness in healthy men and women 18-95 years old. Med Sci Sports Exerc. 2000 Feb;32(2):417–25.

2. Guidelines Index - 2008 Physical Activity Guidelines - health.gov [Internet]. [cited 2018 Jun 10]. Available from: https://health.gov/paguidelines/guidelines/

3. Warburton DER, Nicol CW, Bredin SSD. Health benefits of physical activity: the evidence. CMAJ Can Med Assoc J J Assoc Medicale Can. 2006 Mar 14;174(6):801–9.

4. Cooper R, Mishra GD, Kuh D. Physical activity across adulthood and physical performance in midlife: findings from a British birth cohort. Am J Prev Med. 2011 Oct;41(4):376–84.

5. Shiroma EJ, Schrack JA, Harris TB. Accelerating Accelerometer Research in Aging. J Gerontol A Biol Sci Med Sci. 2018 Apr;73(5):619–21.

6. Karas M, Bai J, Strączkiewicz M, Harezlak J, Glynn NW, Harris T, et al. Accelerometry data in health research: challenges and opportunities. Review and examples. bioRxiv. 2018;276154.

7. Schrack JA, Cooper R, Koster A, Shiroma EJ, Murabito JM, Rejeski WJ, et al. Assessing Daily Physical Activity in Older Adults: Unraveling the Complexity of Monitors, Measures, and Methods. J Gerontol A Biol Sci Med Sci. 2016 Aug;71(8):1039–48.