**Title:** BiAffect: a ResearchKit study to unobtrusively understand mood and cognition in bipolar disorder

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**Institution:** University of Illinois Chicago

Consent Form

*How can we better understand the mood fluctuations and subtle cognitive changes in people with bipolar disorder together?*People with bipolar disorder can have very different and more or less severe mood symptoms day to day. This affects quality of life and makes managing treatment difficult. Moreover, recent scientific studies have shown that people with bipolar disorder often have subtle but distinct difficulties with cognition, such as inability to focus, during both depression and mania. Some people notice that these difficulties do not completely go away even after they fully recovered from their mood symptoms. It has been hypothesized that these cognitive difficulties in bipolar disorder strongly predict level of functioning in the future. In this Researchkit study, we would like to investigate the feasibility of BiAffect, a mobile application or ‘app’ on iPhone that aims to understand the relationship between mood and neurocognitive functioning in bipolar disorder using keystroke dynamics (such as typing speed and typing errors) and other passive sensor information (such as accelerometer). Note that these research activities are limited to beta/feasibility testing, and thus are not intended as a means to diagnose or treat bipolar disorder in study participants.

Currently, diagnosis and treatment of bipolar disorder rely on careful history taking and mental status examination by an experienced clinician, at times aided by self-report or caretaker-informed questionnaires. In general, these reports have to be interpreted by providers in order to extract patterns that could indicate an imminent change in mood. Moreover, they do not necessarily represent objective psycho-physiological markers.

On the other hand, the pervasive use of mobile wireless devices has significantly shaped interpersonal communications in modern life. Indeed, as personal smartphone technology advances, people are increasingly interacting with one another via typed (rather than oral) communications. For this reason, we want to investigate if keyboard dynamics and sensor data from iPhone serve as more objective biomarkers or “virtual mental-health footprints” of bipolar disorder.

If you decide to join the study you will need to download the study application on your mobile device. This application will install a custom-built keyboard that replaces the standard default iPhone keyboard in order for the researchers to better understand keyboard dynamics metadata (but not to track the actual words). Then periodically we will ask you to answer questions and perform some activities via your mobile phone. These survey questions may be about your health, exercise, diet, sleep, medicines, etc. or about how you are feeling in general. In addition to surveys, the activities will be some brief tasks that you perform while holding your phone for a short period of time. Your study data will include your responses to surveys and the measurements from the phone itself when you perform an activity.

**Data Gathering**

*How is your data collected and maintained?*Your data, without your name, will be added to the data of other study participants and analyzed by the study team. You will have a unique account that you can use to review your own data.We will electronically process your data and separate your account information (email) from your study data (your responses to surveys and the measurements from the phone itself when you perform activities). We will combine your coded study data (without your name or other identifying information) with those of other study participants. The combined data will be encrypted and transferred electronically to secure servers at Sage Bionetworks (sagebase.org) for storage, and will be accessible by researchers at the University of Illinois at Chicago (www.uic.edu).

**Privacy**

*How will the information I provide be kept confidential?*We are committed to protect your information and keep your identity as confidential as possible, however total confidentiality cannot be guaranteed. Except as required by law, you will not be identified by name or by any other direct personal identifier. The data collected through the app will be encrypted on the smartphone, transferred electronically and stored securely on the data repository and analysis platform using cloud services at Sage Bionetworks. Your contact information, including your name and e-mail address will be stored separately from the study data. We will use a random code number instead of your name on all your study data. This code cannot be used to directly identify you. Information about the code will be kept in a secure system.We will not access your personal contacts, other applications, text or email message content, or websites visited. We will never sell, rent or lease your contact information.

**Data Use**

*How will the data collected be utilized?*The research team will analyze the combined data and report findings back to the community through blogs or scientific publications. Your data, without your name, will be added to the data of other study participants and may be analyzed by the study team. You will have a unique account that you can use to review your own data.

**Time Commitment**

*How much time will study activities require?*This study should take you about 10 minutes each week. We will send notices on your phone asking you to complete these activities and surveys. You may choose to act at your convenience, (either then or later) and you may choose to participate in all or only in some parts of the study. You can adjust the app settings to turn on and off sending data at any time.

**Study Survey**

*What kinds of questions will the surveys ask?*We may periodically ask you to answer questions about yourself (e.g., your sleep, appetite, and your energy and activity level), your medical history (e.g., if you or any of your blood relatives have been given a diagnosis of bipolar disorder), and your current health and symptoms (e.g., if you have been feeling down, depressed, hopeless, or trouble with your concentration) to track changes. You may skip any questions that you do not wish to answer.

**Study Tasks**

*What kinds of tasks need to be performed?*We will ask you to perform specific tasks weekly while holding or using your mobile phone and record sensor data directly from your phone.

**Withdrawing**

*How can I withdraw from this study?*Your participation in this study is voluntary. If you are eligible and decide to participate, we will ask you to provide an e-signature, by signing with your finger on the screen at the end of the enrollment process. We will also send a copy of this consent form, along with your e-signature, to your email address.

You do not have to sign this consent form. But if you do not, you will not be able to participate in this research study. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.Although you can withdraw from the study at any time, you cannot withdraw the coded study data that have already been distributed. If you withdraw from the study, we will stop collecting new data but the coded data that you have already provided will not be able to be destroyed or deleted.The Study Principal Investigator or the sponsor may also withdraw you from the study without your consent at any time for any reason, including if it is in your best interest, you do not consent to continue in the study after being told of changes in the research that may affect you, or if the study is cancelled.

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If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the University of Illinois at Chicago (UIC) office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.