

**Research Subject Consent for Research Participation**

**JuLi Registry™**

**TITLE:** Juva Life JuLi Registry (The JuLi Registry)

**PROTOCOL NO.:** JULI1000  
WIRB® Protocol #20202388

**SPONSOR:** Juva Life  
812 Hamilton St  
Redwood City, CA 94063

**INVESTIGATOR:** Peter D. Beitsch, MD  
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Dallas, Tx 75206  
United States

**STUDY-RELATED**  
**PHONE NUMBER(S):** 214-420-8499 (24 hours)

Please read this informed consent form carefully. It tells you important information about a research study.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you are eligible for now or in the future.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep. As a participant in this research study, you will be referred to as a research Subject.

**Financial Conflict of Interest disclosure**

**What is this Research Study?**

This research study involves the creation of a Registry and using data collected in the Registry for research purposes. The Registry is sponsored by Juva Life, a Lifesciences Company focused on the development of cannabis-based medications and managed by a group of research physicians called Targeted Medical Education Research.

1 A Registry is a databank of information about people who have something in common.  
2 This Registry includes information about women and men who are utilizing cannabis or  
3 hemp-derived CBD formulations/products to manage symptoms associated with personal  
4 health conditions. (Most CBD products, which are legal in all 50 states, are derived from  
5 the hemp plant.)  
6

7 This Registry is anticipated to enroll between 200 and 2000 people. The Registry will  
8 gather data on your medical history, any associated symptoms, use of hemp-derived CBD  
9 or cannabis formulations and how your symptoms respond to different formulations,  
10 doses and timing of the use of these formulations.  
11

### 12 **Who is operating the Registry?**

13  
14 The Registry is being sponsored by Juva LIFE (Redwood City, CA) and managed by Targeted  
15 Medical Education Research (Cupertino, CA). Targeted Medical Education is an  
16 independent group of medical doctors who conduct research. The Registry data is being  
17 collected and hosted by an independent medical database company using specialized  
18 software designed for the study. The Registry is being done under the oversight of an IRB  
19 (Institutional Review Board) who is responsible for making sure the research is conducted  
20 properly.  
21

### 22 **What is being asked of you?**

23  
24 Your participation in this research is completely voluntary. You are being asked to  
25 participate in this research, which involves you sharing certain information about you,  
26 your medical history and the type of hemp-derived CBD or cannabis formulation/products  
27 you are using. You will be provided and select from curated product recommendations  
28 with dosing schedules that you may follow and alter based on your personal experience.  
29 The research also includes surveys that ask questions about your experience, personal  
30 satisfaction with and changes in the use of the products you are taking to alleviate  
31 symptoms.  
32

33 If you agree to participate in the Registry, we will collect certain health information about  
34 you as described below. We will only collect information that is needed to meet the  
35 research aims of and successfully execute this Registry. You may, at some point in the  
36 future, be invited to contribute blood (no more than 10cc; which is about 2 teaspoons),  
37 urine or other body fluids to support specific research objectives. You may also be asked  
38 to participate in future surveys.  
39

401. You will record information about you, your health history and symptoms, any hemp-  
41 derived CBD or cannabis product recommendations and the results of using those  
42 products.  
43

44 This information includes:

- 1
- 2
  - Some of your personal characteristics (for example, your age, gender, etc.)
  - 3
  - Your medical history and the current symptoms you are seeking to relieve by using
  - 4 a cannabis- or hemp-derived CBD product
  - 5
  - Cannabis and/or hemp-derived CBD product selection, use and outcomes (how
  - 6 you responded to the recommendations)
  - 7
  - Information about your satisfaction with your products, including symptom relief,
  - 8 that you directly report through surveys that will be sent directly and privately to
  - 9 you.
- 10
- 11 2. You will be asked to register in the Registry software application (the app). This
- 12 software will allow you to record (journal) your cannabis usage and satisfaction
- 13 with the results. The software will prompt you to record usage and satisfaction.
- 14
- 15 a.) As part of registration, you will be asked to provide your email and cell phone.
- 16 Your email or cell phone number will only be used to send you surveys at various
- 17 intervals. Your email address and cell phone will be secured by the Registry
- 18 database. The surveys will be delivered confidentially via the Registry. The surveys
- 19 will include targeted questions about your experience and satisfaction with the
- 20 use of cannabis to relieve your selected symptom/s.
- 21
- 22 3. The information collected about you in the Registry does not include identifiers
- 23 such as your name, street address, or date of birth.
- 24

25 You can choose not to take part. There will be no penalty or loss of benefits to which you

26 are otherwise entitled. You can agree to take part and later change your mind. There will

27 be no penalty or loss of benefits to which you are otherwise entitled.

28

### 29 **How long will I be in this Registry?**

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31 You are being asked to actively participate in the Registry for approximately three months,

32 as long as you are using cannabis/hemp-derived CBD formulations. You will provide basic

33 information once you enroll in the Registry, and then follow up information at 1, 2, 3, 4

34 week, 2 month and 3 month intervals. You may be asked at some point in the future to

35 answer additional surveys. Your data will remain in the Registry for the duration of the

36 Registry.

37

38 You may withdraw participation at any time. If you withdraw, no new data will be

39 collected from you in this Registry. However, your withdrawal will not impact any actions

40 that have already taken based on your informed consent, such as analysis conducted on

41 your data. Research or analysis already performed using your data will not be destroyed

42 even if you cancel your informed consent. In addition, the Targeted Medical Education

43 Research researchers will keep and use your data as necessary to comply with applicable

44 laws or maintain the completeness of any studies performed with your data.

To withdraw, please contact JUVA Support at 1-669-696-5882 and they will direct you to the Research Team. Or talk to your healthcare provider who is participating in the study.

**Are there alternatives?**

This Registry simply contains data about your use of hemp-derived CBD or cannabis-products to manage certain symptoms. Your alternative is to not take part in this research Registry. If you have a provider overseeing your symptoms and care, you may still be provided recommendations for these kinds of products and followed by your provider without being in the Registry.

**What happens to the information collected for this Registry?**

Once your information is collected in the Registry, the Targeted Medical Education Research researchers will analyze the data for publication purposes.

Those involved in creating, maintaining, and using the Registry are required by law to protect your identifiable health information. Any identifiable health information recorded in the Registry (which include medical history , age, mobile phone number and email address) will be encrypted (special coding designed to manage and protect private information). This encryption will help restrict access of your identifiable health information to approved parties only, like your provider, Targeted Medical Education Research and the people who are hired to maintain the electronic software system that hosts the Registry. The Registry will not include your name, address or date of birth.

We will use information that includes only the limited identifiers described above, or information that is de-identified, when the Targeted Medical Education Research providers conduct the research.

The results of research using your information from the Registry may be published in medical journals, for the purposes of developing treatment guidelines, other reports, hemp or cannabis- medication development, but your name or other identifiable information will not be included in these publications.

We and all involved in working on this Registry and studies conducted using this Registry data will use security safeguards to protect your identifiable health information from disclosure to others to the extent required by law.

Some of your identifiable personal and health record information may be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- Targeted Medical Education Research

- Others at a providers 's practice who are helping to conduct the study
- People who work for or with the research sponsor
- The IRB overseeing the study

#### **What are the possible risks from participating?**

There are no specific health risks to participating in this Registry or in the use of your information for future research as described in this consent form. Your confidential information will be protected as described above in the "What happens to the information collected for this Registry" section.

There is always a risk that the identifiable information collected about you for the Registry may be used or disclosed in an unauthorized manner. Multiple layers of protection are built into the database to prevent this.

#### **Are there any possible benefits from participating?**

You may not benefit from being in this Registry. However, having personal access to information about your cannabis experience over time may help you gain insights on effective personal symptom management.

In addition, having your data in the Registry may help researchers develop a better understanding of how hemp-derived CBD and other cannabis-products along with specific formulations and dosing schedules benefit patients with disease related symptoms and other health conditions. People with symptoms like pain, poor appetite, anxiety and sleeplessness in the future may benefit from the information obtained from this research.

#### **Financial considerations:**

- As this is a Registry study and not a clinical trial, you will be responsible for paying for your own products.
- There are no costs to participate in the Registry.
- The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.
- You will be provided a modest payment, in the form of a gift card, to thank you for the time it takes for you to complete surveys. Payment includes a \$15-25 gift card for each survey completed. You will receive payment only for the surveys completed. You will receive payment when you complete the initial patient survey, at week 1, 2, 3 and 4 and then at the end of months 2, and 3.

#### **Who can I talk to if I have questions?**

Your first choice should be to talk with your provider who is participating in this Registry. He or she should be able to discuss the Registry, your participation, and your rights as a Subject in this Registry. You may also access the Research Team by calling JUVA at 1-669-696-5882 and they will direct you to the Research Team.

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an institutional review board (“IRB”). An IRB is a group of people who perform independent review of research studies to make sure the rights and welfare of research Subjects are protected. You may talk to them at (800) 562-4789; you may also reach them at [help@wirb.com](mailto:help@wirb.com) if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research Subject.

#### **AGREEMENT and CONSENT**

If you agree to be in this Registry, please select this box to electronically sign this form.



- Your decision to be in this Registry is voluntary.
- You will not be penalized or lose benefits if you decide not to participate or decide to stop participating.
- You may cancel your permission to participate in this research at any time, subject to the limitations in the “How long will I be in this Registry” section.
- You may take a copy of this home with you or receive it electronically.

	Investigator or designee	Participant
	I have discussed this with this person	Having read the above, I agree to participate
Signature		
Printed Name		

Date/Time		
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