Privacy & Confidentiality Agreement

Policy Description

It is JointCraft Inc.'s policy to ensure compliance with applicable privacy legislation related to research studies conducted in Canada. This includes research studies led by JointCraft Inc.as well as done in partnership with others (e.g., pharmaceutical partner, other licence holders, research institutions).

Introduction and Scope

This policy outlines the procedures for ensuring compliance with applicable privacy legislation and procedures for addressing non-compliance. It applies to the collection, storage, use, and disclosure of information obtained from research study participants for JointCraft Inc. studies.

Definitions

Agent: In relation to a health information custodian, means a person that, with the authorization of the custodian, acts for or on behalf of the custodian in respect of personal health information for the purposes of the custodian, and not the agent's own purposes, whether or not the agent has the authority to bind the custodian, whether or not the agent is employed by the custodian and whether or not the agent is being remunerated.

Centre Code: A two letter code is given to each participating centre by JointCraft *Inc. If the participating centre is* JointCraft *Inc., the two-letter code is JC. Central Office:* JointCraft *Inc. Central Office is located at 1-3280 Langstaff Road, Vaughan, ON L4K5B5.*

De-Identified: Refers to records (including those containing personal health information (PHI)) that cannot be directly linked to the participant and are linked to participants via coded identifiers only.

Health Information Custodian: A person or organization who has custody or control of PHI as a result of or in connection with performing the person's or organization's powers, duties or work.

Health Information: Any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearing house; and (2) relates to the past, present, or future physical or mental

health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Human subject: Refers to a living individual about whom an investigator (whether professional or student) conducting research obtains:

- *Data through intervention or interaction with the individual, or*
- *Identifiable private information.*

Identifying Information: Information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual.

- *Individually Identifiable Health Information: Information that is a subset of health information, including demographic information collected from an individual, and:*
- *Is created or received by a health care provider, health plan, employer, or health care clearing house; and*
- *Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and*
- *That identifies the individual; or*
- *With respect to which there is a reasonable basis to believe the information can be used to identify the individual.*

Limited Data Set: Refers to protected health information that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.

JointCraft *Inc. Participant Serial Number: A coded identifier generated by* JointCraft *that consists of the participant's centre and enrolment number. For example, JC001 would be the* JointCraft *Inc. Participant serial number for the first participant enrolled in a given study.*

Non-Compliance - Privacy Breach: A privacy breach occurs when personal information is collected, retained, used, or disclosed in a manner that is not in accordance with the acts and regulations. Privacy breaches generally include the unauthorized disclosure of personal information for example by a file being lost, misplaced, or stolen, or by inadvertently disclosing through human error (e.g. mail/email sent to wrong individual).

Personal Health Information (PHI): With respect to an individual, whether living or deceased, means:

- *Information concerning the physical or mental health of the individual.*
- *Information concerning any health service provided to the individual.*

- *Information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual;*
- *Information that is collected in the course of providing health services to the individual; or*
- *Information that is collected incidentally to the provision of health services to the individual.*

Personal Information (PI): Recorded information about an identifiable individual, including,

- *Information relating to the race, national or ethnic origin, colour, religion, age, sex, sexual orientation or marital or family status of the individual,*
- *Information relating to the education or the medical, psychiatric, psychological, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved,*
- *Any identifying number, symbol or other particular assigned to the individual,*
- *The address, telephone number, fingerprints or blood type of the individual,*
- *The personal opinions or views of the individual except where they relate to another individual,*
- *Correspondence sent to an institution by the individual that is implicitly or explicitly of a private or confidential nature, and replies to that correspondence that would reveal the contents of the original correspondence,*
- *The views or opinions of another individual about the individual, and*
- *The individual's name where it appears with other personal information relating to the individual or where the disclosure of the name would reveal other personal information about the individual.*

Protected Health Information: Protected health information is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research.

Collection of Personal Information/Personal Health Information

JointCraft Inc. collects the information from the research studies to help us understand what influences, acceptance, and choices, including sensory and non-sensory factors relating to cannabis products.

JointCraft Inc. collects both personal information (PI) and personal health information (PHI), as defined above, from participants who have provided written consent to participate in a research study. Information is collected for study purposes only, or as required by the regulations. The PI/PHI collected is detailed prospectively via the research study protocol, any applicable case report forms/electronic data capture forms and via the informed consent form.

This information may be communicated to JointCraft Inc. via paper-based or electronic data. PI/PHI communicated in paper format may additionally be retained electronically.

Examples of PI/PHI that may be collected as needed on a specific basis are presented in Table 1.

Table 1. Personal Information/Personal Health Information Collection and Rationale

Information Collected	PI / PHI	Rationale For Collection
Race/ethnicity	PI	Collected to facilitate assessment of demographic information relevant to the study question and eligibility criteria as applicable.
Gender/Sex	PI	For the purposes of stratification, statistics, and confirmation of eligibility, as applicable.
Date of birth (DOB) (Either year/month/date or year/month are acceptable)	PI	Required for eligibility purposes, statistical information, and to assess safety reports. If not permitted, partial DOB,(year/month only) is acceptable.
Testdates/results, adverse events, medical history, concomitant medications and other supporting documents as applicable to the study	PI / PHI	For the purposes of the research as outlined in the protocol and informed consent form.
Participant initials	NA	Requested to confirm information received is for the correct participant., the code can be participant initials, scrambled initials, or other local coding process as long as the identifier is unique to the participant JointCraft Inc. will accept any two (or three) letter code (See Table 2).
Other	PI / PHI	If other PI/PHI is planned for collection in the study this should be prospectively indicated in the protocol, consent, and case report forms/electronic data capture for review.

Identification of documents sent to JointCraft Inc.

JointCraft Inc. requires that copies of protocol-mandated supporting documents that are sent to central office be identified, as shown in Table 2, with the participant's trial code, JointCraft Inc. participant serial number, and participant initials or a two/three letter code assigned by the centre only. These are required for quality assurance purposes only, to ensure that the documents received are associated with the correct participant for review. The initials or two/three letter code provided is required to remain the same throughout the course of the trial.

Table 2: Identifier Requirement Example

Identifier Name	Example
Study Code	JC-01
Participant Code	001-AB
Study Session Code (DD-MMM-YYYY-##)	01-JAN-2023-01

JointCraft Inc.is required to locally obscure all directly identifying information or participant identifiers such as, name, address, telephone number from copies of any supporting documents. The centre is responsible for ensuring that the information sent to JointCraft Inc.is in compliance with local regulations and policies.

Access and Provision of PI/PHI Retained by JointCraft Inc.

Access can only be granted if authorized by the responsible person, Personnel are subject to written obligations of confidentiality to secure and protect the information obtained in the research study, both inside and outside JointCraft Inc. and in the management and communication of data.

JointCraft Inc. uses operational, procedural, and technological safeguards to protect participants' information.

Notwithstanding the foregoing, personal information may be disclosed without the consent of the participant in some exceptional circumstances such as when disclosure is required or permitted by law. In addition, the terms herein set out other parameters when personal information may be shared with third parties.

Access to the Information Collected

JointCraft Inc. may allow access to the information collected as follows:

- The principal research department and Responsible Person in charge of controlling access to the information collected.
- Those authorized to access such information under the supervision and responsibility of the Responsible Person (including internal employees)
- JointCraft Personnel involved in coordinating research studies will have access to any participant's medical, familial, and research files to the extent necessary to fulfill their jobs, but such access will be used for the sole and exclusive purposes of undertaking, completing, processing, monitoring, reviewing, auditing and/or analyzing the results of the research study.
- As required for generating adverse reaction and serious adverse reaction reports, notifying participants about product-related matters, including product recalls (if applicable), or preparation of other applicable reporting to Health Canada and other regulators.
- Access by JointCraft Personnel in the event of a participant experiencing any adverse or serious adverse reactions.
- Participants will have access to their own personal information subject to certain limitations at law; and
- Access may be allowed to regulators for purposes of monitoring, auditing, review or regulatory inspections.

Disclosure to Third Parties

JointCraft Inc. may disclose the information collected to external and third parties in accordance with the following:

- Except as provided for herein or as required or permitted by law, the principal research department and Responsible Person will not disclose personal information about a participant to a third party unless the participants whose information may be shared consents in writing to such disclosure or such sharing is otherwise permitted or required.by law.
- Except as provided for herein or as required or permitted by law, no personal information will be transmitted to insurers, educational institutions, or other public institutions, without the written consent of the participant whose information may be shared.

- Aggregated and anonymized information (information which cannot identify or be linked back to an individual) may be shared with third parties who are interested in the results of the research studies.

Because JointCraft Inc. has qualified for and obtained a license to conduct research studies, in some instances JointCraft Inc. may be contracted by third parties to conduct research on their behalf. In those circumstances, JointCraft Inc. would perform the research study and collect, use, and disclose the information in accordance with the terms of Privacy and Confidentiality Statement, however, the third parties for whom JointCraft Inc. may undertake research studies will be able to monitor and audit the research which would mean that certain people at the third parties will have access to personal information about the participants to perform their monitoring and audit functions, but for no other purpose.

JointCraft Inc. Personnel will disclose medical and other personal information to health care providers in case of a serious adverse or adverse reaction to assist with the management of such reactions and care of the affected participant or to Health Canada or other applicable regulators in the preparation of serious adverse or adverse reaction or other required reports.

Obtaining informed consent

JointCraft Inc. requires that informed consent be appropriately obtained from each participant in a research study in accordance with Participant Informed Consent.

Withdrawal of consent

Personal information/personal health information obtained prior to the withdrawal of consent will be collected/retained. Date of death may be obtained from public sources (e.g., newspaper obituaries or public registries) following withdrawal of consent. No further information is to be collected following the withdrawal of consent.

Data storage, destruction/archiving, and retention storage

All paper records at JointCraft Inc. Are stored behind locked doors with controlled access according to SOP-QUA-025-Record Retention.

Electronic records within the JointCraft Inc. Computing system are protected by security measures, as described in SOP-QUA-025-Record Retention

Destruction/Archiving

Destruction of paper documents occurs in accordance with SOP-QUA-027 Record Retention, which protects the confidential nature of the document. Any material considered to be in the public domain can be recycled or disposed of through general garbage disposal; examples include:

Electronic and/or paper records containing personal information/personal health information will be archived in a secure manner in accordance with SOP-QUA-027 Record Retention. Audit trails for data changes will be maintained.

Retention

Records will be maintained according to SOP-QUA-027 Record Retention.

Requests from Participants to Access Information about them Retained by JointCraft Inc.

Requests from participants to access information about them held by JointCraft Inc. must be directed to the Responsible Person for further assessment.

Non-Compliance

Issues of non-compliance with privacy requirements resulting in privacy breaches may be identified. Issues should be directed to the Responsible Person, in consultation with other groups internally, will assess to determine an appropriate course of action. The assessment and corrective action plan will be documented and will include but is not limited to identification of the scope of the potential breach and steps to contain the breach.

Roles and Responsibilities

This policy applies to all JointCraft Inc. Staff involved in study conducted at JointCraft Inc. This includes the following responsibilities:

Position	Responsibilities
All JointCraft Inc. Staff	Ensure compliance with privacy and confidentiality requirements. Notify the Responsible Person of issues of non-compliance as outlined in this policy