Holon Inclusive Health
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Informed Consents Technology Services

Overview

Advances in technology and analytical tools enable discoveries that are essential to our understanding of health and disease, and ultimately to the improvement of human health, healthcare delivery, and healthcare technology itself. Because of these advances, the health information and data of research participants are increasingly being collected, stored, and shared using more powerful and prolific technologies. The increased power and ease of these tools, as well as the increased demand for privacy, raise issues of vital concern to patients as well as prospective research participants.

Patients and/or research participants contribute their time, data, and health information, and it is fundamental that their rights, welfare, and interests are respected throughout the healthcare process and research process, starting with the process of obtaining informed consent.

Clinicians and investigators must enable prospective subjects to sufficiently understand and make informed decisions concerning the collection and use of their personal data, and the risks and benefits of participation. As part of a research study, a research participant's personal data may:

• Be stored and used indefinitely.
• Be subjected to risks that are uncertain or unclear.
• Be reinterpreted and change in relevance over time.
• Raise privacy concerns, in part because of the risk of re-identification, as well as the possibility of breach of confidentiality.

Clinicians and investigators must not only consider and address these factors when designing a research study, but also find meaningful and effective ways to describe these and other technology-specific factors within the informed consent process and consent form.

Purpose

This document contains informed consent language for technology services at Holon Inclusive Health Services and advanced information to help describe technologies used in practice and in the research setting within the informed consent form. Given the complexity of the scientific and

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ethical issues that arise when conducting medical care as well as human research, this consent form provides as best as possible, language that clearly conveys this complex but important information.

Submit suggestions, ask questions, and share this material by contacting us at admin@hihealhsystem.com

Chat Technology

Chat technology is a real-time, instant messaging electronic communication between two users, connected by a network. Once a chat has been established, users enter messages that appear on the other user's screen. Many networks and online services offer a chat feature.

Chat technology includes a number of free or paid solutions.

Examples of free solutions include SnapChat, Gmail Chat, Skype, and Yahoo! Messenger.

Examples of paid solutions include: Klara, Velaro, Olark, LiveChat, and SnapEngage.

Depending on the technology selected, it can either run as a standalone program, web service, or web application.

When communicating via online chat that is not part of a videoconference, or by text in general, individuals should consider the inability to observe visual and auditory cues, which could lead to possible problems in interpretation of both questions and responses. Voice intonation and facial expressions are often used to convey and/or emphasize meaning.

Thus, you and your provider may need to ask explicit clarifying questions in order to accurately interpret responses, and provide additional information in order to ensure that potential participants understand questions and information being communicated via a chat session. Another consideration is that a separate language or shorthand has developed around chat technology. If your or your clinician or investigator are not familiar with this lingo, chat sessions may generate more confusion than clarity. (See netlingo.com/acronyms.php for a list of acronyms and text shorthand)

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Chat technologies are frequently not encrypted. Holon Inclusive Health, – Jessica Whelan LLC, and all All Affiliates do utilize an encrypted text system through Klara and Call My Doc Services. Any services outide of these two services may be considered unencrypted. Unencrypted means that chat sessions are not encrypted or secured during their transmission, and could be intercepted or received from their browser cache.

Statement of informed consent Chat Messaging:

Chat Messaging - Confidentiality

You understand that your confidentiality will be kept to the degree permitted by the technology being used. Chat messages are not secure when sent in an unencrypted format. First, they can be intercepted (read by others or altered by others), and second, the reader cannot be certain that the sender is who they claim to be.

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Chat Messaging - Encryption

The most effective way of ensuring that what we write will only be read by each other is to use encryption. Some encryption programs are packaged as portable software, which means you can run them from a USB flash drive on any computer. If we communicate without encryption, it is possible that third parties could intercept and read our conversation without our consent. However as long as your information cannot be easily re-identified, any risk to you will be reduced.[1] Your healthcare team and/or research team recommends using encryption software, including Klara and Call My Doc. If you are confused about these ask the staff and/or the research staff about encryption software. If you reply or send messaging via a non-encrypted format with a clinician or researcher, or reach out to them in a non-encrypted formatted you accept liability and responsibility that your data may not be protected. Initial that you understand the preceding regarding Chat messenger.

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Chat Messaging – Use of Different Email Account

For purposes of working with Holon Inclusive Health System (HIHS) – Jessica Whelan LLC (JWLLC), and all Affiliates, and/or research studies, you may want to set up a new instant messaging account not associated with your full name. Using an instant messaging account that is not linked to your full name (e.g. someguy@hotmail.com) will also provide a degree of confidentiality. By initialing you understand that setting up a new account without identifiable data will better protect your information.

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Chat Message - Storage
Initial that you understand that text messages are stored by the telecommunications provider and therefore may not be secure especially depending on the service.

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Data Collection and Privacy Considerations

In healthcare and in research, a formal data collection process is necessary to ensure integrity of data and to protect against the risks of unauthorized use of patient information and/or research data. The primary rationale for preserving data integrity is to support the detection of errors, whether made intentionally (deliberate falsifications) or not (systemic or random errors). Equally important is the process to address the privacy and security of a patient's and/or research participant's identity throughout the data's lifecycle from collection and transmission, to sharing, storage, and destruction.

Risks of unauthorized use of research data are already associated with traditional data collection means and methods (i.e. via paper or local computers). However, in today's interconnected world, data is not just locked in a cabinet. Data is held by and analyzed with various methods, and transmitted across institutions over wired or wireless networks (e.g. Cellular, Bluetooth, and telephone networks) that present the risk of intercepted transmissions. These networks are

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susceptible to eavesdropping and wireless carrier security holes, allowing unauthorized users access to the accounts and usage data.

Hackers can use hardware and technologies to intercept and decrypt calls.[2] Use of the Internet adds another complexity to security risks as investigators use cloud services and other offerings that are dependent on a multitude of third-party services such as apps or cloud providers. Such services may enhance or decrease risk, depending on several factors including the nature of the research and the method in which the data will be processed.

Clinicians and research teams must are aware of these risks and, then assess and attempt to mitigate them in collaboration with their HIHS, JWLLC, and affiliates, and IRBs. All clinicians, staff, investigators, and research staff work to decrease risk as best as they can. To learn more about online privacy, see Glenn Greenwald's TED Talk on why privacy matters.

Patient Information and Research Data Collection – No Guarantees Information Will Remain Confidential

I understand that there is no guarantee my information will remain confidential during collection. HIHS and JWLLC and affiliates utilize Athena health records, Klara, Call My Doc, MedTrainer, Neuroflow, Dulcian Health, Nucleus MD, Phreesia, FlexScanMD, GSuite, DropBox, Google Drive, Survey Monkey, and Wix. My confidentiality can be protected by the protections in place on the technology being used, as well as through additional precautions suggested by my clinicians, the staff, research team recommended in this document, and other steps you can take personally. While efforts are made to protect your data, confidentiality of your data cannot be guaranteed.

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Research Data Collection – Risks to Loss of Privacy

You understand that we collect information, including personal information that you voluntarily provide to us when you choose to participate in HIHS and JWLLC and affiliates questionnaires and surveys or research tools. When you use interactive tools accessed through the Internet, there may be some risk(s) to your privacy. For example, we may have outside companies perform services relating to the development, operation and maintenance of this research website or relating to other services. These third-party service

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providers may have access to your personal information, as is reasonably necessary, for their services. We take great care to protect your information; however, there is a slight risk of loss of privacy. This is a low risk because we code your data by separating your personal information (information that can directly identify you (such as your name or phone number) from the questionnaire or survey data. We limit the number of members of the staff / team that are allowed to see your identifiable information. All others will only be able to see your coded information. Any time data is collected for research purposes we take great care to keep the information coded and de-identified so anyone outside the system will not have access to this information. Further, you understand that the information that is obtained in connection with the questionnaires and surveys and that can be identified with you will remain confidential and will be disclosed only with your permissions or as required by law. You understand that the information collected about you will be coded using a fake name (pseudonym) or number system for initials and numbers, for example ABC–123, etc., and the information which has you're identifiable information will be kept separately from the rest of your data.[4] However, even with removal of this information, experts in re-identification may be able to reverse our processes and /or attempt to re-identify an individual given enough cross-reference information about him or her. You also understand that accidental public disclosure may occur such as unintended data breaches by hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes.

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Research Data Collection – Protections Utilized by Study Team

You understand that the following procedures will be used to collect and protect the confidentiality of your study records, mobile apps, tablets, electronic kiosks, email, cloud based services, electronic health records, telemedicine, mobile health, wearable devices, photography, and voice recording services. We utilize electronic systems such as Phreesia, Klara, NucleusMD, Dulcian Health, Neuroflow, Call My Doc, Athena Health Records, FlexScanMD, MedTrainer, Doxy.me, VSee, GSuite, and other services.

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You understand that all electronic files [include all the types of electronic files that are used, such as databases, spreadsheets, containing identifiable information will be password

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protected. Such files will also have password protection to prevent access by unauthorized users. Only the members of the staff will have access to the passwords. Back-up data may be kept on server logs even after this research has been completed. At the end of the client practitioner relationship or at the end of a study, when investigators publish their findings, the information will be presented in summary format: you will not be identified in any publications or presentations.

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You understand that data will be kept for the length of the client practitioner relationship and / or the study. You understand that after that time all identifiable data about you will be destroyed or de-identified in accordance with the law, meaning we may retain and share certain elements of the study records for future research, but we will replace your identifying information with a code that does not directly identify you.

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Transmission of Research Data

Transmission refers to data in motion from one machine or device to another. Client data and / or research data may be transmitted in a variety of forms, over wired or wireless networks, using various transmission technologies or other file sharing applications, phones, and routers.

Personal identifiable data of the patient and / or research participant should not be transmitted (disclosed) for research purposes outside of a Covered Entity's network prior to review and approval by the necessary reviewers within the health system, IRB, IT, and / or others, such as patient or research compliance officers.

In patient health care and / or research, transmissions of research data must be reasonably secure both within an institution (internal) and between institutions (external). A secure transmission process should be used, even if the data is anonymous, coded, or includes non-sensitive information. For example, data should be encrypted whenever "in transit" over any public networks, such as the Internet. Unencrypted email notifications are generally not secure, except in very limited circumstances, and should not be used to share or transmit research data externally.

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However, many organizations may offer email encryption services that can help mitigate the risks of emailing data over the Internet.

Prominent examples of unsecure transmissions include messaging via Facebook or other social media and text messages, which are stored by the telecommunications provider and therefore are not secure when transmitted. Terms such as Secure Sockets Layer (SSL and HTTPS) or Secure File Transfer Protocol (SFTP) are indications that the data is being encrypted during transmission.

Informed Consent Transmission of Health Records & Research Data

You understand that by initialing and signing this informed consent, you give permission for the transfer of a copy of this data to HIHS, JWLLC, and affiliates, and research entities affiliated with these organizations or other contractors affiliated with these organizations. Data will be secured in the electronic health records system on the Athena Health cloud system. Other services utilized include Klara, Phreesia, Doxy.me, Doximity, AdobeSuite, Fax lines through Charter, CallMyDoc, FlexScanMD, Dulcian Health, Neuroflow, Nucleus MD, HealthGrades, Epocrates, Genomind, and Medtrainer. Paper records may be stored in a virtual and physical location. When in a physical location all information will be stored in a locked room in a locked cabinet. Holon Inclusive Health and affiliated agents will be the only entities able to access the records unless specified by yourself. IF part of a research study, the research sponsor (ie Allergan, Otsuka, Genomind, Sunovion, or other research sponsors) will also have access to the records. You understand that you may request for specific information as to where your records are kept physically locked, virtually locked, what sponsor may have access including their agency and company and affiliation as well as the PI at the receiving agency, their company and their affiliate who is also responsible for maintaining security and confidentiality of the transferred data. You may inquire regarding this information at admin@hihealthsystem.com

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You understand that all original research records, both hard copy and electronic, will be maintained at the Holon Inclusive Health and Affiliates in accordance with current records retention requirements. Any information shared with any other affiliate or agency may no longer be protected under the same laws as Holon Inclusive Health.

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Transmission of Healthcare and/or Research Data

We are careful to ensure that the information you voluntarily provide to us is as secure as possible; however, you must be aware that transmissions over the Internet cannot be guaranteed to be completely secure.

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Online Tracking and Cookies

The web includes elements that may not be evident to the average user, such as tracking cookies or web beacons. Connections between a site visited and third-party services are not always obvious (e.g., as a user moves from one site to another, third parties may "watch" the activity to collect marketing research important to their clients' business). In fact, some people may be unaware that many third-party sites sometimes have the ability to monitor and track our activity on the sites we visit. This is rarely transparent to users, despite the fact that it may carry privacy risks to them. The challenge is how to communicate this to participants, many of whom will lack understanding of how relationships among various online sites work. It is important to explain those risks as clearly as possible to research participants. (To learn more, watch former Mozilla CEO Gary Kovacs's TED talk about exposing online tracking).

When browsing the web, the browser retains certain pieces of information, such as a history of the sites visited (also known as 'tracking'). Tracking is often accomplished with "cookies," small files that are stored on the user's computer and hold a modest amount of data specific to a particular website and the device used to access it. These files can be accessed either by that online service or that device itself.

Cookies allow the online service to deliver an experience to a particular user (e.g., remembering the kinds of books or music a user enjoys), or enable a site to sustain information from one visit or site to the next (e.g., maintaining a 'shopping cart' for items previously put in that cart, but not yet purchased).[6] Some cookies are temporary only, and are deleted when the browser is closed. These "session cookies" are commonly used to keep a user logged in to their online account as s/he navigates within the site. Other cookies persist indefinitely and may track the user's

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browsing behavior across sites or provide customization, such as remembering preferred page layout on a particular site. Familiar experiences based on persistent cookies include websites welcoming users back by name or sites displaying advertisements drawn from other sites visited.[7]

Patients should consider privacy risks created by tracking technologies and recommend suitable privacy safeguards before using online research data collection sites. Such safeguards may include browser privacy settings or comprehensive anonymization mechanisms.[8]
https://www.privacylaws.com/Publications/enews/International-E-news/Dates/2012/6/No-need-ofinformed-consent-for-authentication-and-session-ID-cookies/

Most web browsers offer privacy settings designed to enable "Do Not Track" and/or "Private Browsing". Such settings will not make you entirely anonymous, however, as their Internet service provider (ISP), employer network, or the individual websites themselves can still track what pages that they visit. Below is a model statement investigators may adapt to describe online tracking and cookies for web interactions.

Online Tracking

You understand that although every reasonable effort has been taken, privacy and anonymity during Internet interactions cannot be guaranteed. It is possible that additional information beyond that collected for research elements that are not always evident, including online tracking mechanisms. As you move from one site to another, third parties not involved in your care and/or research, may "watch" your online activity, including your visit to our website, research site, or other online or electronic sites. That third party may employ security and privacy policies different than ours, over which we have no control.

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<<We can provide some recommended tools and practices to prevent online tracking mechanisms and improve your online privacy. For practices, first check your web browser's privacy settings to enable "Do Not Track" and/or "Private Browsing." Please note such settings will not make you entirely anonymous however as your Internet Service Provider (ISP) or employer network can still track what pages you visit. For recommendations on how to improve online privacy go to: privacyrights.org/online-privacy-using-internet-safely).

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Storage and Archiving including Cloud, Back-ups, and Access

As part of the informed consent process, we try to inform patients and research participants (1) how research data about participants will be stored--- Generally on the Athena Health Electronic Health Record System, (2) the duration of data storage – applicable to Federal and state laws, and (3) what happens to any identifying information – after term may be destroyed within the realm of Federal and state laws .

You understand that Data will be stored on Athena and only shared with those affiliated with Holon Inclusive Health whom have a release of information, are part of your care, or in cases of research are receiving de-identified data. Athena utilizes a cloud for the storage of health records. If you choose to share information in alternate formats than through Athena Health and affiliated partners the same protections and HIPAA protections may not be in place.[9] Popular services that you may be choosing to use include Dropbox and Amazon Cloud, among many others. Holon Inclusive Health and affiliates to not assume responsibility for the safety of data on these alternate sites.

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The cloud can be used for data sharing and research and provide closed or open access to data. Most cloud services and apps were not designed with research regulatory compliance or human subject protection ethics or considerations in mind. In many cases, free services offered by cloud providers are not compliant with regulatory requirements such as HIPAA. However, these same providers may have a more secure fee-for-service model that provides adequate coverage. For example, Dropbox can be made HIPAA-compliant within their paid service model and with appropriate changes. It is important for patients to be familiar with the differences in service tiers for the technology they choose to employ. Check with these services or apps to inquire about specific pre-approved solutions, or whether there is a process to obtain approval and secure compliance if you would like your provider to utilize these alternate forms of communication. Some of these also may require a cost. If a client wishes the provider to utilize other services or apps that are not already paid for, this may be acceptable if the client chooses to assume the cost of the service or app that they would feel more comfortable using.

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Informed Consent Cloud Repository

You understand that clinicians and / or investigators will store your data in a controlled-access repository in the cloud. The repository is controlled-access, meaning only certain research team members have authorized accounts to access the data. "In the cloud" refers to servers in a data center that are managed by a third party and accessible through the Internet. Any computing device with access to the Internet could connect to this closed-access repository. We use Athena Health Records methods to protect data and methods to ensure data will be used for the approved purpose.

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Informed Consent Cloud Storage

You understand that your health data and / or study data will be stored in the cloud. "In the cloud" refers to servers in a data center that are managed by a third party and accessible through the Internet. When storing your study data, we will replace your name with a random code on all your study data. The coded data will be encrypted and stored on a secure cloud server under the control of Athena and Holon Inclusive Health to prevent improper access.

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Informed Consent Archiving Computer Data

You understand that archiving means saving for use at a later date. Computer data, such as instant messaging files, captured web site records, and copies of electronic mail will be archived. This data will be stored in password-protected files on a cloud system with Athena Health, Klara, Call My Doc, FlexScanMD, JWLLC and affiliates, Phreesia, Dulcian Health, NucleusMD, Neuroflow, and other apps that I choose to engage in using. Archived computer data will be also stored at Holon Inclusive Health with Affiliates in locked and secure areas and with access limited to authorized individuals from Holon Inclusive Health and Affiliates unless proper ROI documentation is obtained or emergent needs arise regarding the ability for other clinicians to care for your health, or that relate to the controlled substance contract.

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Research Data Destruction

Research data destruction isn't simply deleting the data. Devices are becoming harder to destroy and data are routinely recovered from devices that have been burned, crushed, submerged in water, or dropped from great heights. Additional steps must be taken to sufficiently destroy data so the data cannot be recreated, reconstructed, or extracted. This can be done through techniques and technologies specifically designed to make the data destruction irreversible. Common methods for data destruction include overwriting (requires overwriting software), degaussing (requires a device called a Degausser, that removes the magnetic field of the storage device), and physical destruction (e.g., disk shredding). The choice of destruction methodology should be based on the risk posed by the sensitivity of the data being destroyed and the potential impact of unauthorized disclosure. Reference data retention policies for the minimum period of time the research funder and your institution requires you to maintain data. Review other relevant institutional and publication requirements, as well as guidelines for data retention and destruction. Data collected in a federal- or state-funded project may require public access to data, which may result in specific requirements for how, when, and what data is destroyed. For example, if data contains PII about research subjects and a separate de-identified data set has been created, there may be an obligation to destroy the data containing the identifiers. For data obtained through an agreement with an outside provider or institution, you may be required to return the data at the end of the project, or to destroy the data and document that you have done so.

As data becomes more available and linked across many devices, both mobile and fixed, the challenge of a complete destruction of all possible copies and backup of the data is exponentially increased. The research team should be aware of every location for the study-associated data and its back-up location. Documentation of research data should be kept up to date to attest the full data set is accounted for and destroyed from all locations. When documenting research data, include: source of data, size of data set, number of records, variables, format of data, and final disposition of data.

Research Data Destruction

You understand that data will be kept for the length of your treatment and for the duration that federal and state laws require. All original health records, research records, both hard copy and electronic, will be maintained at Holon Inclusive Health or with its affiliate providers in

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accordance with current records retention requirements. We will destroy research data kept on backups, but we may not able to destroy data that was saved on the institution's server logs even after this patient information and / or research has been completed. Any information shared with outside institutions, applications, electronic systems or affiliates may no longer be protected under federal law. We will destroy your research data at the end of the study, meaning we will not retain your information in coded or other form. However, we may not be able to destroy patient records or research records that were transmitted or copied by outside organizations or applications that you personally chose to employee using. The outside organizations will be responsible for maintaining the security and confidentiality of the transferred data. If you have any questions regarding affiliates we have utilized you may contact us at admin@hihealthsystem.com . If you utilized any electronic systems outside of those Holon Inclusive Health has contracted with, those systems would be your responsibility.

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Electronic Informed Consent

Electronic Informed Consent (e-Consent) is an evolving platform for consenting research participants, either on-site or remotely, using a computer-based consent process. As with traditional paper-based informed consent, e-Consent is not only a form, it's also a process. Any e-Consent process conducted on-site or remotely should include an opportunity for subjects to ask questions and receive answers prior to providing their consent to participate in the study. The consent process can be implemented on a number of electronic systems such as computers, tablets, and phones. These platforms may also use multiple media types (e.g., text, graphics, audio, video, podcasts, and interactive web sites, biological recognition devices, and card readers, etc.) to convey information related to the study and to obtain documented informed consent.[11] Additional considerations should include the process to validate identity and how the consent form will be signed electronically (e.g., Adobe e-sign). You may want to consider the following if using an electronic consent:

Reading the Informed Consent

On the screens, you will view the informed consent document. Please read all sections of the informed consent document. After each section, you may be asked to answer some questions before continuing onto the next section. After you have read all sections, you will be given the

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opportunity to go back and review all sections. Swipe the screen from bottom to top with your finger to scroll through each section of the informed consent document. When you reach the end of a section, you will be able to touch the Continue button.

If there is a word or group of words that you do not understand, touch and hold your finger on the word until a small box appears, then tap the "unfamiliar term" selection. This will highlight the word and allow your physician to explain the meaning to you during your discussion. Please touch the "Continue" button below to read the informed consent document.

Email

Email is a communication tool; there are many email service companies such as Gmail, Microsoft Outlook, Yahoo!, and many others.

Patients should determine whether the email service is suitable for use in research in reference to regulations such as HIPAA and other data privacy laws. While employers provide email for employees at a health system, patients should determine if the office email is an appropriate tool for communication with research participants or patients. For example, email encryption may be essential to protect a research participant's protected health information.[1] If a non-employee email service, such as a thirdparty email service is used, keep in mind that each email service company has its own terms of use agreement and privacy policies. Users must follow rules dictated by the terms of use, some of which are common sense while others are based on the company's specific policies.

Patients should take into account that communicating with a research participant via email could lead to possible problems in interpretation of both questions and responses. The patient and / or research participant will be unable to read visual and auditory cues, such as facial expressions and voice intonation, which are often used to convey and/or emphasize meaning. Thus, patients, clinicians, and research investigators may need to ask explicit clarifying questions to accurately interpret responses and provide additional information to ensure potential participants understand the questions and information being communicated.

Informed consent: Email

You understand that there is no guarantee your email information will remain confidential. If you wish to write your clinician in a HIPAA compliant format, utilizing Athena is recommended first line to contact your clinician or researcher through your INDIVIDUAL

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HEALTH PORTAL --- please if you have difficulties contact staff at admin@hihealthsystem.com to ensure your proper set up on the Athena Health Portal. Your confidentiality can be protected by the protections in place on the technology being used and additional precautions suggested by the research team. While efforts are made to protect your data, confidentiality of your data cannot be guaranteed especially on other platforms outside of the Athena Health system.

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You understand that if you insist on using technology outside of the Athena health system and the patient portal in addition to (Klara, Phreesia, CallMyDoc, FlexScanMD, NucleusMD, Neuroflow, Dulcian Health, Doximity, and any other Athena partner) the technology you use to write and send your email(s) can increase decrease the protection of your information. To increase protection though, for example, you can use a strong password, anti-virus and anti-malware protections, and a secure wireless network.

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Holon Inclusive Health and Affilicates can work with you on how to increase your security when using email, however we recommend that you utilize your ATHENA HEALTH PORTAL. You should avoid emails from unknown users, or emails asking for more information than Holon Inclusive Health or your research team explained you would be asked to share. If you receive a suspicious email, contact the research team immediately.

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You understand that when sending emails, make sure to limit the personal information you include, such as your full name, address, social security number, and other personal information. An email account can be hacked by an unauthorized user. There is a risk your emails could be read or altered by unintended recipients. Holon Inclusive Health and Affiliates will be making all attempts to communicate first and foremost to you through your ATHENA HEALTH PORTAL. This is the most encrypted and best way to access your personal health information. It will also help your providers and / or research coordinators monitor your care the best as well as track any pertinent health data. Applications affiliated with Athena generally are included within the same protections and also flow into the health record.

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You understand that although it is unlikely that someone will try to gain access to your email, since email is sent over a wireless network, there's a risk it may be intercepted. To decrease this risk, always choose to send emails over a secure wireless network. If you have concerns about using an established email, you can establish a new email account (making sure to not include your name). It is easy to start a free webmail account [include link to suggested webmail signup, such as Gmail] completely for this purpose.[13]

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Email - encryption

Email notifications are generally not secure, except in very limited circumstances, and should not be used to share or transmit research data. The ATHENA HEALTH PORTAL should be utilized for this purpose. For this healthcare and or a study, data will be encrypted when "in transit," or while being moved in the network to the secure storage location.

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Mobile Health: Devices and Apps

Mobile Health (mHealth) is the method of delivering healthcare through mobile technology. mHealth can include mobile devices and apps (e.g. laptop, tablet, iPhone, Android) and wearable technology (e.g. Fitbit). The use of mobile technologies allows investigators to collect data from the you the patient and/or research participant when you are not physically present at the doctor's office. This allows for a dramatic increase in data collection to aid researchers in understanding the illness or disease being studied.

A mobile device is a computing device that can easily be carried or moved, such as a smartphone, tablet computer, portable hard drive (e.g., flash drives, USB memory sticks, or similar storage devices). These devices are particularly susceptible to loss or theft. If mobile devices are used for initial collection of subject identifiers, investigators must encrypt subject data files. Patients should consider using a device that can be wiped remotely in the event of loss or theft.[14]

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A mobile app is a software program that can be downloaded to a device. The data the app collects can be stored locally to the device or sent to remote storage locations. Mobile apps can collect data through two different mechanisms: passive and active data collection. In passive data collection, the participant has little awareness of the data collection effort, which requires no explicit actions on the participant's part. Active data collection involves explicitly asking participants for information, preferences, and opinions.

Data may be secured by a number of means such as app password protection, or encrypted data transmission and storage. Each mechanism must comply with institutional policies and protect you while using the app.

You agree that by using any mobile device or application you are consenting to Holon Inclusive Health and its Affiliates to be able to collect the data from these apps or devices or applications for health and or research purposes.

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Informed Consent Downloading Apps

If you decide to participate in care and or particular research studies you will need to download the applications on your mobile phone. Currently JWLLC utilizes Athena, Klara, CallMyDoc, NucleusMD, Neuroflow, Dulcian Health, Doximity, Healthgrades, Wix (Holon Health System). We will periodically ask you to answer questions and perform some tasks via your mobile phone. These tasks may include answering questions about your health, exercise, medicines, and additional surveys, as well as performing some brief activities while holding your phone. This will help your clinician and or research to better understand how you are doing and monitory your health. Your data will include your responses to surveys and the measurements from the phone itself when you perform a task. Tasks can include mediation, behavioral surveys, health surveys, mood charts, questionnaires, or other health tools. Your data, will go to your individual health record, and if you are part of a research study will be de-identified and added to the data of other study participants and made available to groups of certified investigators for analysis. You may ask us questions regarding any of this process at admin@hihealthsystem.com or ask your clinician. If you have problems signing up or registering, please contact the staff so they can ensure proper implementation. If you utilize the apps or devices, you understand

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that it constitutes as consent for tracking your health data by your clinician and / or researcher.

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PROCEDURES: What will you be asked to do?

Download a mobile app (free) and register an account: You need to have the health and/or study app on your phone in order to participate in this method of health monitoring and /or study. Everyone who enrolls will first complete an electronic registration process. The registration process can be done through the study app or the study web portal. Registration will include entering your name, email address, and other general information about yourself. As part of this process you are also confirming your agreement to participate in the study.

Tasks: We will ask you to perform specific tasks while holding or using your mobile phone.

Examples of such tasks are:

- Log in and check activities due
- Participate in activities such as reading patient education
- Participate in activities that are individual care coordination activities like mindful meditations, journaling, or symptom monitoring
- Participate in surveys or behavioral health or medical screening tools

mHealth Activities Informed consent

You understand that your clinician may utilize mHealth tools to better monitor their patient's health and outcomes. You understand that these tasks that you may be doing utilizing mHealth may take you about 60 minutes each week but may be more or less dependent on your individual care plan and abilities to utilize the technology. These will be developed in conjuction with you and your health provider on and individual basis, but will be expected to be completed based on the plan that you both agree upon. If you are part of a research study the protocol may be set based on the study needs. We will send notifications on your phone asking you to complete these tasks 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 have the right to refuse to answer particular

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questions or participate in particular aspects of the study. Engaging in the activities constitutes as consent to be engaged in the activities.

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mHealth General Risks:

The use of technology as part of this research project can present risk(s). Generally, it is possible that private data from a mobile device may be intercepted during transmission. However, all of the mHealth partners being utilized are encrypted and partnered with Athena Health. Any data that is taken for research purposes from the mHealth by researchers will have personal identifiers removed in order to evaluate general population data. However, It is also possible that your data could be accessed by others should you lose your mobile device or lend the device to other people. Some additional risks are related to a loss of confidentiality, especially when using electronic devices to transmit, store, and access data. There are some possibilities that others may see your open webpage or smartphone communications. You are also aware that certain apps or app protections may affect the battery life of the device.

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Informed Consent App or Device Security Protections:

You are aware that it is highly recommended that you set up a passcode on your own phone and/or electronic device to help prevent unauthorized access to your device and health and /or research data. You also understand that it's also recommended that a remote disable feature be set up on your device in case it's lost or stolen. This will allow you to remotely disable or remove any apps and/or data.

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Informed Consent Limits to Data Protections or Confidentiality

You understand that in order to get access to intended or target data, the clinician or investigator might happen to get access to or be unable to avoid seeing certain data. While the clinician and / or investigator might have gained access to your location data, or financial, or other personal information on your device, this data will not be recorded or

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retained. Instead, we will only extract data that has already been stated in previous paragraphs.

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Informed Consent Data Transmission and Storage on Electronic Devices

You understand that Health and / or research data will be sent from the electronic device [or mobile app] to the research team via Athena Health electronic health records and its partner apps. If the data will be on paper forms, these will be scanned into the Athena Health electronic record. If data will be stored electronically on a cloud server with Athena Health Electronic Records. Please note that we will keep this information confidential by limiting individual access to health and / or research data and keeping it on the Athena Health System. The data will be stored with traditional Athena secure storage/maintenance of the data, password-protected computers, data encryption methods etc. For any questions you may contact admin@hihealthsystem.com
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Informed Consent: Risks, Discomforts and Inconveniences Using Mobile Apps

You understand that other people may glimpse the study notifications and/or reminders on your phone and realize you are enrolled in this study. This can make some people feel self-conscious. You can avoid that by putting a passcode on your phone to block unauthorized users from accessing your phone content.

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You understand to be safe – just as you would not text while driving, do not fulfill health related and / or study tasks while driving. Wait until you are in a safe place to perform tasks!

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You may have concerns about data security, privacy, and confidentiality. We take great care to protect your information, however there is a slight risk of loss of confidentiality. This is a low risk because we work to protect your privacy by separating your personal information (information that can directly identify you, such as your name or phone number) from the research data. However, even with removal of this information, it is sometimes possible to re-identify an individual given enough cross-referenced information about him or her. This risk, while very low, should still be contemplated prior to enrolling. Data collected in at Holon Inclusive Health for health related and / or study related purposes can and will count against your existing mobile data plan if you are subject to such plans. You may configure the applications to only use wi-fi connections to limit the impact this data collection has on your data plan. If for some reason the app cannot be configured it is your responsibility to unenroll and notify the staff at admin@hihealthsystem.com You can respond to the surveys via the web portal instead of via your mobile phone, but all the tasks must be completed using your mobile phone.

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Informed Consent Costs

There is no cost to you to participate in this study other than costs related to your mobile data plan, if applicable.

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Informed Consent mHealth Confidentiality

Your confidentiality will be kept to the degree permitted by the technology being used. No guarantees can be made regarding the interception of data sent via the Internet by any third parties.

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mHealth Information Stored in Medical Record

The information about you gathered from the mobile device or app will be stored in your medical record history. Your primary care physician and other medical professionals to will be able to view the information you shared and that was collected about you during your participation in using these devices for health purposes and or research purposes.

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Secondary Use of Data

The mobile application company chosen for this research study may have access to your information and use it in other ways. There is also the chance that depending on the agreement the research team and the mobile application company established, the mobile application company may own some or all of your information. Generally the applications chosen such as Klara, CallMyDoc, NucleusMD, FlexScanMD, Neuroflow, Dulcian Health, Neuroflow, and other apps chosen are partners with Athena Health. If you have questions, contact staff at admin@hihealthsystem.com

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Mobile Health: Wearables

Mobile Health (mHealth) is the method of delivering healthcare through mobile technology. mHealth can include mobile devices and apps (e.g. laptop, tablet, iPhone, Android) and wearable technology (e.g. Fitbit). The use of mobile technologies allows clinicians and / or investigators to collect data from the patients and or research participant when s/he is not physically present at the doctor's office. This allows for a dramatic increase in data collection to aid researchers in understanding the illness or disease being studied.

Wearables are worn technologies that have sensors built in. These sensors can connect to the web (e.g., wi-fi) or be plugged into a computer to track information. A majority of wearables have smart technology capabilities. Smart technology is a device or system that has advanced

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technology allowing it to be connected to the Internet and used interactively. Examples of common wearables include fitness trackers, smart watches, smart clothing, sport watches, etc.

Wearables can track movement, distance, and speed using GPS, accelerometers, and gyroscopes. Additionally, once in contact with skin, wearables can record body functions such as heart rate, perspiration, temperature, and muscle activity. While wearables are not generally used to diagnose medical conditions or illnesses, they are often used to track the activity of a research participant. This technology is seen to decrease the burden on a research participant who would typically track their activities in a journal or diary. It can also allow for the collection of additional research data such as heart rate, temperature, body fat composition etc., without the use of separate medical equipment. Additionally, the activity recorded by the wearable can often be seen by the investigator in real time, through an online system.

Health data and /or Research using wearables is subject to the same regulations and ethical norms as a traditional paper-based data collection. That said, wearables raise unique concerns regarding the ease and real time nature of the data collection, as well as concerns regarding third party access to the data.

Patients must take care to be clearly informed about these concerns and any relevant risks.

Informed Consent Activity Monitor

You understand that the use of a device does not pose any medical risk and does not diagnose any medical conditions or illnesses. Wearing an activity monitor may cause minimal discomfort. The devices are small, weighing only a few ounces, and can be easily worn on the torso by attaching it to a belt or waistband, pants, shirt, or undergarment.

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Informed Consent Physical Activity Monitor

You understand that you may be given a physical activity monitor [for the specific name you may ask your clinician and or research staff] and they will also be able to give you instructions on how to use the device. The device will be worn as shown to you by your clinician or research staff. It may be a belt, wristband, or some other sort of wearable

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device and it will record certain activities that your clinician or research staff will go over with you and it will record, e.g., your levels of physical activity during the day and will record the number of hours you sleep each night. You understand that you may be asked to use this device for and extended period of time and will be taught how to follow your physical activity levels on a website or in the Athena portal. The website may also also help you keep track of your dietary intake (types and amounts of food you eat) types of physical activity (exercise) that you do and heart health factors such as weight, heart rate, blood pressure, and blood sugar.

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Many times the device/ mobile activity monitor is an item you can buy in a store, and it is generally not painful to wear. Generally it is a plastic monitor around the wrist. Problems that may arise while wearing the device, e.g., you may feel a little skin irritation or itching if the monitor is worn too tightly around the wrist or you may hear a ticking noise while wearing the device. If there are issues you may notify your clinician and /or research staff and admin@hihealthsystem.com

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Informed Consent Wearable Device Risks

By accepting a wearable device you understand that you are consenting to having your health data monitored and / or having or data enrolled into monitoring for research purposes.

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There is also the possibility of minor skin irritation associated with wearable devices. We recommend taking it off occasionally, not wearing it too tightly, and keeping it clean and dry. You should regularly clean your wearable device—especially after working out or sweating. Rinse the wearable device with water or wipe it with a small amount of rubbing alcohol. Do NOT use hand soap, body soap, dish soap, or household cleaners which could get trapped beneath the band and irritate skin. Always dry the wearable device well before

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putting it back on. If you start to experience skin irritation on your wrist, we suggest you remove the device and contact a member of the study team to discuss the issue and determine whether you would like to continue participating in the study.

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Informed Consent Wearable Confidentiality

To ensure your confidentiality while wearing the device to the extent permitted by law, the following measures will be taken:

• You will be assigned a unique identifier code and all the information you provide will be listed under your code.

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• There will be only one hard copy with your name/identity and all information [questionnaires, surveys, etc.] will be stored in a secure filing [room, cabinet, etc.]. This [room, cabinet, etc.] can only be accessed by the [PI, co-investigators, research coordinators, or your health clinician etc.].

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• There will only be one file maintained on a password-protected server. This file can only be accessed by the [PI, co-investigators, research coordinators, or your health clinician etc.].

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• The de-identified data will be kept [as with applicable for state and federal laws for maintaining health data], which could mean till the end of the study and even post leaving the clinic, even after you have completed your part or terminated your care with the clinician. If the results of the study are published, your identity will remain confidential.

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You will not have any rights to publications, trademarks, or products developed from the research.

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• The company that manufactures the wearable will have access to your data, but they will not have access to your identity because coded identification (ID) numbers will be used rather than names. Your data would be anonymous to the manufacturing company [if available, list out manufacturing company name]. [If applicable: Please talk with the research staff about how your information may be shared with the company]

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Informed consent: Privacy and Confidentiality for Wearable that Uploads Data to a Website

Patient and / or study participants' data collected from the device website will be downloaded weekly by the research study database manager. This data will be entered into the study database under the participants' study identification number. Depending on the language in the Business Associates Agreement, device may have access to your data.

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The staff at the clinic and / or the research study staff have developed an agreement to uphold the privacy standards set by the Health Insurance Portability and Accountability Act (HIPAA), protecting information that is directly linked to you (e.g., name, address, social security number, etc.).

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Online Survey Tools

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Clinicians and / or investigators may utilize online surveys or questionnaires to gather data from many participants in a short amount of time. There are a wide variety of online tools available for online surveys.

Use of thirdparty survey software companies such as SurveyMonkey, Psychsurveys.org, Mechanical Turk, Zoomerang, Lime, and others may be permitted for most minimal risk studies that employ online survey procedures. However, it is important to note that third party survey software companies differ from survey tools made available through academic institutions (e.g., Qualtrics or REDCap). For example, when using a third party to administer surveys, the website might store collected data on their own company backups or server logs which may be kept beyond the timeframe of the research project. You should be aware of the conditions and terms of the survey company's storage and retention policy.

Informed Consent Participating in an Online Survey

If you agree to be part of Holon Inclusive Health and all Affiliates for healthcare you will may be asked to complete a computer survey that asks you information about your health. We expect this survey to take a variable number of minutes to complete dependent on your own abilities, technology access etc. If you are having difficulties you may always contact the staff or research staff to assist you. By participating in the survey you are accepting and consenting to participation.

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Generally, clinicians or investigators will not be able to link your survey/interview responses to you as they are left intentially de-identified, but they will know that you participated in the research if you provide your contact information. We may plan to publish the results of any surveys in a study, but will not include any information that would identify you. By participating in a survey you acknowledge this understanding.

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You may choose to not answer an individual question, or you may skip any section of the survey by skipping the question or clicking "Next" at the bottom of each survey page to move to the next question.

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Informed Consent Coded Responses

Your survey responses will be coded so that the research staff will not be able to link your responses back to you. When completing the survey, your responses will only be saved to the survey software and accessible for the research staff to view after you hit "submit." Only authorized research staff will be given access to the survey data, but since the survey software is located on the Internet there is a risk it could be hacked into by unauthorized users. To further protect your survey information, make sure to use a strong password into the survey software system and to not share that password with anyone. <<If applicable, the survey includes a section at the end for you to include your personal contact information for the research staff to contact you for further information. If you are concerned about your identity being found out, please talk to the research staff and or Holon Inclusive Health staff on ways to protect your survey information.>>.[20]

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Informed Consent: Participating in a Survey – Provide Email Address

If you wish to participate in a survey or other research, you may be given one asking to please follow the link given to you and fill out a survey: The survey will take you variable amount of minutes to complete dependent on your own abilities. At the end of the survey, you will be asked to provide your email address. Your response is confidential, and your colleagues' responses are anonymous. After we finish collecting data and make sure your response is matched with your raters' responses, your email address will be deleted from the data. Completion of the the questionnaire or survey acts as consent to your participation.

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Informed consent Research Electronic Data Capture (REDCap)

This study will collect data in Research Electronic Data Capture (REDCap). REDCap was developed specifically around HIPAA-Security guidelines and is implemented and maintained according to [Institution Name] guidelines. REDCap currently supports > 500 academic/non profit consortium partners on six continents and 38,800 research end-users. REDCap servers are securely housed in an on-site limited access data center managed by [name of institution's department here (e.g. divisions of biostatics)]. All web-based information transmission is encrypted. The data is all stored on a private, firewall-protected network. All users are given individual usernames ids and passwords, and their access is restricted on a role-specific basis. 22

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Informed Consent Survey Monkey and the US Patriot Act

Please note that the online survey is hosted by Survey Monkey, which is a web survey company located in the USA. All responses to the survey will be stored and accessed in the USA. This company is subject to U.S. Laws, in particular, to the US Patriot Act/Domestic Security Enhancement Act allowing authorities to access records with your responses stored and accessed in the USA. The security and privacy policy for Survey Monkey can be viewed at: surveymonkey.com/mp/policy/privacy-policy /. 23

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Social Media

Social networking has changed the way we interact with friends and associates. Social networks such as Facebook, Twitter, YouTube, and Google+, play a significant role in our lives. Social media can be defined as any online and mobile resource that provides a forum for generating, sharing, or discussing ideas and content. Specific applications and web tools, many of which are free, are based on different, sometimes overlapping, themes and purposes, variably grouped as online communities (e.g., patient support groups, population-specific dating services); social networking (e.g., Facebook; Twitter); professional networking (e.g. LinkedIn); content production and sharing (e.g., YouTube, Tumblr, blogs); location-based services (e.g. Tinder,

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Grindr); and others. Many social media web services contain one or more platforms that allow users to view one another's networks and interact with one another in real time. These include comment spaces, chat rooms, discussion forums, and the like. [24]

In healthcare and / or research, social media is most often used for recruitment. This method of recruitment is subject to the same regulatory and ethical norms as traditional recruitment, including the requirements of prospective review and approval, compliance with applicable federal and state laws, fair and equitable subject selection, respect for the privacy and other interests of potential participants, and sensitivity to the norms and values of different communities. That said, social media recruitment raises unique issues, including the ease with which personal health information can be accessed via these sites. For these reasons, greater care may be required for you to understand the privacy risks.

Social media may also be used as a venue for patients and or research participants to communicate with healthcare staff and / or study staff and/or other participants. This carries several risks, including the risk that participants will be un blinded because of someone's description of their experience in the trial, and the risk of participants posting misleading information that undermines participant understanding of the study. Efforts should be made to inform participants of these risks and educate them on the importance of appropriate online communication while enrolled in the study.

To learn more about ways to protect yourself on social networks see: staysafeonline.org/stay safeonline/ protect-your-personal-information/social-networks.

Below are model statements investigators may adapt to describe social media recruitment.

Informed Consent Facebook, Twitter, LinkedIn, Psychology Today, Healthgrades, Doximity, Alignable App

Facebook will have access to the information collected through the app. In addition, Facebook will have access to any information that we provide to you using this app. You should also know that your individual Facebook privacy settings will determine who can see the app in your profile, your posts regarding the app, and if you invite your Facebook friends to participate. Your participation in the study may be made public. Facebook may reveal or confirm that you have participated in the study based on their policies and practices.

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Video, Audio, and Photography Recordings

Clinicians and / or investigators may choose to use video (moving picture), audio (sound), or photograph (image) to record information for research. Methods of recording research participants can include use of a camera, camcorder, smartphone, voice note, Skype, Zoom, Adobe Connect, etc. Recording the voice and/or image of an individual creates a distinct type of record that requires unique handling and storage, as well as consent. Patients need to be mindful of the fact that voice and fullface photos and comparable images are considered personal health identifiers. As such, like other research data, the informed consent should include information on:

• All the video, audio, or photographs that will be obtained, e.g., record/video for a focus group or as part of the client record, or as part of an interview session for the medical records are subject to (HIPAA)

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• Voice messages to the clinician, headshots for the patient record for identification, chat messages, interviews for research purposes, symptom documentation videos may be recorded. The patient participating in these activites acknowledges that as consent for the clinician and or researcher to have that information.

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• There may be videos/audio/photograph that will be used for educational and research purposes to create more accurate record of research proceedings. If information were ever to be used for commercial purposes a secondary consent will be obtained / waiver for release.

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• Audio or video recordings may be transcribed by Athena health partners such as Klara, CallMyDoc, Phreesia, Cambridge Brain Sciences, VSee, Doxyme, Epion, NucleusMD, Neuroflow, and Dulcian Health, and be placed into the

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patient health record. Any data used for a research study will be de-identified and coded to protect a participatnt's identity.

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• The audio, video, or images will be, stored on secure Athena Health Cloud servers.

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• Only clinicians, their staff, and research staff will have access to the audio, video, or images (study staff, contracted individuals for transcription) unless I sign other consents releasing this information.

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• How the audio, video, or images will be password protected and fall into protections under HIPAA law.

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• The images and/or recordings will be retained as compliant with state and federal law for health records and destroyed also within the same context.

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Informed Consent Video Recording of Study Activities

Interviews may be recorded using video devices. Recordings will assist clinicians with accurately documenting your responses. By actively choosing to participate in recording

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sessions you consent to the video recording. You have the right to not participate in recording and to decline to participate or choose another health system. Recordings for this purpose will only be utilized for health record or the research study purposes.

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Informed Consent Audio Recording of Study Activities

Interviews may be recorded using audio recording devices. Recordings will assist with accurately documenting your responses. You have the right to refuse the audio recording and choose another health system. Recordings in this consent line will only be utilized for health record documentation purposes.

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Informed Consent Photographing of Study Activities/Participants

Photographs of participants may be taken to preserve an image related to the research. You have the right to refuse to allow photographs to be taken. Photographs taken per this consent line are only to be for documentation related in the chart purposes.

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Telemedicine Informed Consent

Introduction

Telemedicine involves the use of electronic communications to enable health care providers at different locations to share individual patient medical information for the purpose of improving patient care. Providers may include primary care practitioners, specialists, and/or subspecialists. The information may be used for diagnosis, therapy, follow-up and/or education, and may include any of the following:

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- Patient medical records
- Medical images
- Live two-way audio and video
- Output data from medical devices and sound and video files

Electronic systems used will incorporate network and software security protocols to protect the confidentiality of patient identification and imaging data and will include measures to safeguard the data and to ensure its integrity against intentional or unintentional corruption.

Client understanding of Telebehavioral Health:

As a client or patient receiving behavioral services through telebehavioral health technologies, I understand:

Telebehavioral health is the delivery of behavioral health services using interactive technologies (use of audio, video or other electronic communications) between a practitioner and a client/patient who are not in the same physical location.

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The interactive technologies used in telebehavioral health incorporate network and software security protocols to protect the confidentiality of client/patient information transmitted via any electronic channel. These protocols include measures to safeguard the data and to aid in protecting against intentional or unintentional corruption.

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Software Security Protocols

Electronic systems used will incorporate network and software security protocols to protect the privacy and security of health information and imaging data, and will include measures to safeguard the data to ensure its integrity against intentional or unintentional corruption.

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Benefits & Limitations:

This service is provided by technology (including but not limited to video, phone, text, apps and email) and may not involve direct face to face communication. There are benefits and limitations to this service.

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Expected Benefits:

- Improved access to medical care by enabling a patient to remain in his/her ophthalmologist's office (or at a remote site) while the physician obtains test results and consults from healthcare practitioners at distant/other sites.
- More efficient medical evaluation and management.
- Obtaining expertise of a distant specialist.

Possible Risks:
As with any medical procedure, there are potential risks associated with the use of telemedicine. These risks include, but may not be limited to:

- In rare cases, information transmitted may not be sufficient (e.g. poor resolution of images) to allow for appropriate medical decision making by the physician and consultant(s);
- Delays in medical evaluation and treatment could occur due to deficiencies or failures of the equipment;
- In very rare instances, security protocols could fail, causing a breach of privacy of personal medical information;

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In rare cases, a lack of access to complete medical records may result in adverse drug interactions or allergic reactions or other judgment errors; By signing this form, I understand the following:

1. I understand that the laws that protect privacy and the confidentiality of medical information

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also apply to telemedicine, and that no information obtained in the use of telemedicine which identifies me will be disclosed to researchers or other entities without my consent.

_____ **INITIAL**

2. I understand that I have the right to withhold or withdraw my consent to the use of telemedicine in the course of my care at any time, without affecting my right to future care or treatment.

_____ **INITIAL**

3. I understand that I have the right to inspect all information obtained and recorded in the course of a telemedicine interaction, and may receive copies of this information for a reasonable fee.

_____ **INITIAL**

4. I understand that a variety of alternative methods of medical care may be available to me, and that I may choose one or more of these at any time. My practitioner has explained the alternatives to my satisfaction.

_____ **INITIAL**

5. I understand that telemedicine may involve electronic communication of my personal medical information to other medical practitioners who may be located in other areas, including out of state.

_____ **INITIAL**

6. I understand that it is my duty to inform my practitioner of electronic interactions regarding my care that I may have with other healthcare providers.

_____ **INITIAL**

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7. I understand that I may expect the anticipated benefits from the use of telemedicine in my care, but that no results can be guaranteed or assured.

_____ INITIAL

Technology Requirements:

I will need access to, and familiarity with, the appropriate technology in order to participate in the service provided.

_____ INITIAL

Exchange of Information:
The exchange of information will not be direct and any paperwork exchanged will likely be provided through electronic means or through postal delivery.

_____ INITIAL

During my telebehavioral health consultation, details of my medical history and personal health information may be discussed with myself or other behavioral health care professionals through the use of interactive video, audio or other telecommunications technology.

_____ INITIAL

Local Practitioners:

If a need for direct, in-person services arises, it is my responsibility to contact practitioners in my area such as _____, _____, or _____ or to contact my behavioral practitioner's office for an in-person appointment or my primary care physician if my behavioral practitioner is unavailable. I understand that an opening may not be immediately available in either office.

_____ INITIAL

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Self-Termination:
I may decline any telebehavioral health services at any time without jeopardizing my access to future care, services, and benefits.

_____ INITIAL

Risks of Technology:
These services rely on technology, which allows for greater convenience in service delivery. There are risks in transmitting information over technology that include, but are not limited to, breaches of confidentiality, theft of personal information, and disruption of service due to technical difficulties.

_____ INITIAL

Modification Plan:
My practitioner and I will regularly reassess the appropriateness of continuing to deliver services to me through the use of the technologies we have agreed upon today, and modify our plan as needed.

_____ INITIAL

Emergency Protocol:
In emergencies, in the event of disruption of service, or for routine or administrative reasons, it may be necessary to communicate by other means:

- ☐ In emergency situations

Disruption of Service:
Should service be disrupted

- _____

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For other communication

- _____

Practitioner Communication:

My practitioner may utilize alternative means of communication in the following circumstances:

_____

My practitioner will respond to communications and routine messages within

_____

Client Communication:
It is my responsibility to maintain privacy on the client end of communication. Insurance companies, those authorized by the client, and those permitted by law may also have access to records or communications.

I will take the following precautions to ensure that my communications are directed only to my psychologist or other designated individuals:

o _____
o _____

Storage
My communication exchanged with my practitioner will be stored in the following manner:

o _____
o _____

Laws & Standards:

The laws and professional standards that apply to in-person behavioral services also apply to telehealth services. This document does not replace other agreements, contracts, or documentation of informed consent.

_____ **INITIAL**

Patient Consent To The Use of Telemedicine

I have read and understand the information provided above regarding telemedicine, have discussed it with my physician or such assistants as may be designated, and all of my questions have been

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answered to my satisfaction. I hereby give my informed consent for the use of telemedicine in my medical care.

I hereby authorize Holon Inclusive Helath to use telemedicine in the course of my diagnosis and treatment.

Signature of Patient (or person authorized to sign for patient): _____
Date: _____

If authorized signer, relationship to patient:_____

Witness: _____

Date: _____

I have been offered a copy of this consent form (patient's initials) _____

SECONDARY CONSENTS

I agree to have my recordings archived outside of my health record for future research purposes by Holon Inclusive Health.

_____ Signature

I agree and authorize the release to have my recordings, photos, or other images used for educational (medical) purposes by Holon Inclusive Health, and affiliates for things such as testimonials.

_____ Signature

I agree and authorize the release to have my recordings, photos, or other images used for commercial purposes by Holon Inclusive Health, and affiliates for things such as testimonials.

_____ Signature

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I agree to have my recordings, photos, or other images stored so that I may be appoached to have them used in the future for purposes such as patient and or client testimonials.

_____ Signature

Informed Consent Focus Group Recording

The use of video/audio recording may be used in a focus group. Participation in a focus group acts as consent for participation in video/audio recording for that sort of study. You have the right to withdraw from a focus group if you choose to not be video/audio recorded. Please be advised that although the investigators will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the investigators from guaranteeing confidentiality. The investigators would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others outside of the group. The video/audio from the focus group may be used for future research studies, educational purposes, conference presentations, etc.

The recording(s) will be used for [include purpose of recording; e.g., sample language may include:

- analysis by the research team; possible use as a teaching tool to those who are not members of the research staff (i.e. for educational purposes); commercial purposes. If the tapes will be used for commercial purposes, the consent must specifically state whether the subject would be compensated for this use.]
- The recording(s) will include [indicate whether the subject's name or any other identifier will be recorded. If videotaping will be utilized, indicate the extent to which subject's identity would be masked (e.g., facial features partially blocked; recording will not include facial pictures; recording will include full facial pictures.
- The recording(s) will be stored [include measures taken to protect subjects privacy. For example: in a locked file cabinet with no link to subjects' identity; in a locked file cabinet and linked with a code to subjects' identity; in a locked file cabinet and labeled with subjects' name or other identifiable information] and will be [indicate the length of time the recording(s) will be retained, e.g. destroyed upon completion of the study procedures; destroyed upon publication of study results; retained indefinitely.] 28

_____ Signature

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I have read and understand the information provided above in its entirety of this agreement, have discussed it with my practitioner or such assistants as may be designated, and all of my questions have been answered to my satisfaction. I hereby give my informed consent for the use of technology services in my medical care.

Confirmation of Agreement:

Client or Guardian Printed Name

_____

Signature of Client or Guardian

Printed Name of Practitioner or Staff Witness

_____

Signature of Practitioner or Staff Witness

Glossary of Terms

Application (App): App is an abbreviated form of the word "application." An application is a software program that's designed to perform a specific function directly for the user or, in some cases, for another application.[30] For Health-related mobile apps, please see the definition below.

Archived Computer Data: A collection of computer files that have been collected for backup purposes. Computer data may be archived for storage, future use, and/or to move the data to another location. The data that is archived can be a list of file names and folders, or the files can be organized in a directory to help with ease of future use.[31]

Blog: A website used as a journal; can be personal or professional in nature.[32]

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Chat room: An online location where individuals can come together to have text-based chat discussions that occur in real time.[33]
Cloud computing: Delivery of services, such as storage and applications, over the Internet.[34]

Confidentiality: Pertains to the treatment of information that an individual has disclosed in a relationship of trust, and with the expectation that it will not be divulged without permission to others in ways that are inconsistent with the understanding of the original disclosure.[35]

Cookie: A text file placed on user's computer by a website or web server. Often used to keep track of individuals as they navigate a site, and more broadly, the web.[36]

Covered Entity: An organization or corporation that directly handles Protected Health Information (PHI) or Personal Health Records (PHR). HIPAA defines covered entity as "health plans, health care clearing houses, and health care providers who electronically transmit health information." [1] HIPAA covered entities must comply with the HIPAA Rules to protect the privacy and security of health information and must providing individuals with certain respect to their health information. [37]

Data Grab: A low-cost and anonymous system that allows for the capture of customer behavior data.[38]

End User Licensing Agreement (EULA): A legal contract between a software developer or vendor and the user of the software. It specifies in detail the rights and restrictions that apply to the software. Although there are big differences among EULAs, typical components are definitions, a grant of license, limitations on use, a copyright notice and a limited warranty. Some EULAs also provide detailed lists of what may and may not be done with the software and its components.[39]

Handheld device: A portable computing or electronic device, typically small enough to fit in the hand.[40]

Health-related mobile app: A mobile application designed to capture health-related information. The most common uses for a health-related mobile app are fitness and nutrition tracking. Often referred to as a "health app." [41]

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HIPAA: Health Insurance Portability and Accountability Act of 1996 is United States legislation that provides privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals, and other healthcare providers. 42

Interactive Multimedia: A computer-delivered electronic system that allows the user to control, combine, and manipulate different types of media, such as text, sound, video, computer graphics, and animation. Interactive multimedia integrates computer, memory storage, digital (binary) data, telephone, television, and other information technologies.43

Internet Service Provider (ISP): A company that provides you with access to the Internet (usually with a fee) through various technologies such as: dial-up, cable, Digital Subscriber Line (DSL), Integrated Services Digital Network (ISDN), etc.44
Internet: Global network of computers that connects to other devices to send and receive information by dedicated routers and servers.45

Mobile: Refers to the ability to provide untethered functionality.46

Mobile Device: Anything that can be used on the move and unwired, ranging from Wi-Fi-enabled laptops and mobile phones, to wireless devices that can communicate via Federal Communications Commission (FCC)-allocated frequency. A mobile device is a computing device that can easily be carried or moved, such as a smartphone, tablet computer, portable hard drive (e.g., flash drives, USB memory sticks, or similar storage devices).47

Mobile Medical Application (MMA): The FDA defines MMA as a "software application that can be executed (run) on a mobile platform or a web-based software application that is tailored to a mobile platform but is executed on a server," where that software already meets the general definition of a medical device as found in 210(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act. 48

Multimedia: The use of computers to present a combination of interactive content from different content forms such as: text, graphics, audio, video.49

Privacy: The right to keep personal information private, as opposed to the general public50.

Protected Health Information (PHI): Individually identifiable health information that is transmitted or maintained in electronic media or other form or medium that is created or collected by a "covered entity," and can be linked to an individual.51

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Secure File Transfer Protocol (SFTP): A network that enables file access, transfer, and management over a secured file transferring system.[52]

Secure Socket Layer (SSL): A technology that manages server and client authentication to establish encrypted transmission of communications over the Internet.[53]

Server: A computer program that provides services to other computer programs (and their users) in the same or other computers. Servers are used to manage the resources of a collection of computers or other devices.[54]

Smart Technology: An electronic device or system that can be connected to the Internet, used interactively, and can have some intelligence to monitor and analyze activity.[55]

Third-Party Services: Web-based technologies that provide services for payment. Often a third-party service agreement is negotiated and signed, defining the terms and conditions for the services. [56]For more information on third-party services, please see the Federal Trade Commission website.

Tracking Cookies: Small pieces of data sent from a website and stored in the user's web browser that help a third party identify the user or computer. Cookies are not viruses but can track your online use and share personal information for the server to use to customize web pages.[57]

Web Application: A program that is stored on a remote server and delivered over the Internet on a browser.[58].

Web Beacon: An embedded object in a web page or email, typically transparent that tracks behavior or use of the web page or email. Web beacons can be detected by looking for tags that load from a different server then the one being used. Often web beacons are embedded with cookies.[59]

Web Service: Client and server applications that allow for communication between two electronic devices over a network.[60]

Wireless: Telecommunications in which electromagnetic waves (rather than some form of wire) carry the signal over part or all of the communication path. Some monitoring devices, such as

intrusion alarms, employ acoustic waves at frequencies above the range of human hearing; these are also sometimes classified as wireless.[61]

Wireless Device: Includes anything that uses a wireless network to either send or receive data. [62]

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Twitter, Inc.: "Twitter Privacy Policy." https://twitter.com/privacy?lang=en.

University of Albany Division for Research:

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