LETTER DESCRIBING 21 CFR PART 11 SOFTWARE COMPATIBILITY

University Hospitals Health System Inc aka UHHS
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Title 21 of the Code of Federal Regulations Part 11 ("Part 11"), entitled "Electronic Records; Electronic Signatures", applies to electronic records generated as part of a clinical trial and submitted to the Food and Drug Administrations (FDA) under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. The above-referenced entity ("Licensee") is a licensee of **Allscripts TouchWorks version 19.4** (the "Software") and has represented to Allscripts that it is engaged in clinical research and expects to use the Software to capture, store or transmit clinical data that may ultimately be used to support a product marketing application with the FDA.

In furtherance of such use, the Licensee has requested confirmation that the Software is considered compatible with the requirements in Part 11 and has technical controls that will facilitate the Licensee's certification of compliance. As further specified and limited in the Licensee's product documentation and as implemented by the Licensee, Allscripts hereby confirms that the software:

(a) is a closed system as defined by Part 11 and has the ability to have access rights and administrative rights to the system limited to authorized persons designated by the Licensee;
(b) has the ability to generate accurate and complete copies of electronic records as inputted in both human readable and electronic format;
(c) is configured such that patient clinical information and system audit logs cannot be purged from the Software;
(d) automatically creates a secure, computer-generated, time-stamped audit trail that (1) records the creation, modification, or deletion of health data, (2) records the identity of the individual who made said changes and (3) retains the previously recorded information that was either modified or deleted;
(e) has the ability to create custom sequencing of key system steps and events, however enforcement of said sequence is solely the responsibility of the Licensee through written policies and training of authorized users;
(f) has the ability to create user access authentication processes and safeguards (i.e. unique combinations of user identification codes and passwords, limits on and recordings of failed login attempts, requirements for periodic password changes, protection of idle terminals, and user de-authorization capabilities);
(g) can enable user-level security for each terminal location;
(h) has system and data back-up capabilities;
(i) has a limited ability to track some system modifications, version updates, or upgrades issued by Allscripts; and
(j) has the ability to create unique, time-stamped electronic signatures that are:
    i. secured using biometrics or a combination of a user identification code and a password;

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ii. linked to respective electronic records with a notation of the signer's identification code and activity;
iii. included as part of any human readable form of the electronic record; and
iv. executed by requiring the user to re-enter either their biometric readings, their password, or their user identification code and password combination for each signing

As stated by the FDA in guidance documents, only the user may certify Part 11 compliance. The FDA does allow Allscripts to state, and Allscripts hereby confirms, that the technical controls described above are built into the Software and aid with Part 11 compliance.

This confirmation is provided to Licensee on May 5, 2022.

By accepting, referencing, and/or disclosing this letter to any third parties, the Client agrees and accepts that: (1) the sole purpose of this letter is to document the facts pertaining to FDA Part 11 compliance; (2) the information provided in this letter is subject to change due to new laws, regulations, or FDA policies issued after May 5, 2022; (3) while the information and recommendations presented in this letter are good-faith interpretations made by Allscripts based on the publicly available information, the Department of Health and Human Services and FDA are the *final* and *sole* authorities that define FDA Part 11 policies; (4) for clarification, this letter neither modifies any signed contracts or agreements the Licensee has entered into with Allscripts nor creates any Allscripts representations, warranties, guarantees or covenants for any matter other than confirmation of the Software's 21 CFR Part 11 compatibility.

Sincerely,

Tejal Vakharia

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SVP, Chief Compliance Counsel
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