

CLAIMS

What is claimed is:

1. A method comprising:

codifying, by a server, a pre-existing informed consent document into machine actionable rules using machine-learning, wherein the machine actionable rules define what a patient has consented to be done with a specimen and data derived from the specimen in a plurality of locations;

storing within non-transitory memory in the server, the machine actionable rules;

tracking, by the server, changes to the machine actionable rules; and

automatically generating, by the server, a new consent document based at least in part on global regulations data derived from proprietary and public sources, by using the machine actionable rules with any changes and a machine-learning regulatory intelligence knowledgebase (RIK), wherein the machine-learning RIK includes the global regulations data.

2. The method of claim 1, wherein the codifying is linked to and performed based upon prevailing global, country, regional, and local regulations in force at the time of generating the new consent document in at least one of the plurality of locations.

3. The method of claim 1, wherein tracking changes to the machine actionable set of rules includes dynamically tracking changes in restrictions regarding what can be done to the specimen and/or whether the patient withdraws consent.

4. The method of claim 1, wherein dynamically tracking changes in restrictions includes providing rule-based querying for specific consent profiles.

5. The method of claim 1, wherein dynamically tracking changes in restrictions includes providing a risk assessment from a consent perspective.

6. The method of claim 1, wherein automatically generating, by a server, the new consent document includes generating the new consent document based on an outline of desired consent, categories of consent needed, and regulations.

7. A system comprising:

a machine-learning regulatory intelligence knowledgebase (RIK), wherein the machine-learning RIK includes global regulations data derived from proprietary and public sources; and
a server with a processor and a memory configured to:

codify a pre-existing informed consent document into machine actionable rules using machine-learning, wherein the machine actionable rules define what a patient has consented to be done with a specimen and data derived from the specimen in a plurality of locations;

store within the non-transitory memory, the machine actionable rules;

track changes to the machine actionable rules; and

automatically generate a new consent document based at least in part on global regulations data derived from proprietary and public sources, by using the machine actionable set of rules with any changes and the machine-learning RIK, wherein the machine-learning RIK includes the global regulations data.

8. The system of claim 7, wherein the codifying is linked to and performed based upon prevailing global, country, regional, and local regulations in force at a time of generating the new consent document in at least one of the plurality of locations.

9. The system of claim 7, wherein tracking changes to the machine actionable set of rules includes dynamically tracking changes in restrictions regarding what can be done to the specimen and/or whether the patient withdraws consent.

10. The system of claim 9, wherein dynamically tracking changes in restrictions includes providing rule-based querying for specific consent profiles.

11. The system of claim 9, wherein dynamically tracking changes in restrictions includes providing a risk assessment from a consent perspective.

12. The system of claim 7, wherein automatically generating, by the server, the new consent document includes generating the new consent document based on an outline of desired consent, categories of consent needed, and regulations in at least one of the plurality of locations.

13. A computer program product, said computer program product comprising:
computer code for codifying a pre-existing informed consent document into machine actionable rules using machine-learning, wherein the machine actionable rules define what a patient has consented to be done with a specimen and data derived from the specimen in a plurality of locations;

computer code for storing within a memory, the machine actionable rules;

computer code for tracking changes to the machine actionable rules; and;

computer code for automatically generating a new consent document based at least in part on global regulations data derived from proprietary and public sources, by using the machine actionable rules with any changes and a machine-learning regulatory intelligence knowledgebase (RIK), wherein the machine-learning RIK includes the global regulations data.

14. The computer program product of claim 13, wherein the codifying is linked to and performed based upon prevailing global, country, regional, and local regulations in force at a time of generating the new consent document in at least one of the plurality of locations.

15. The computer program product of claim 13, wherein tracking changes to the machine actionable set of rules includes dynamically tracking changes in restrictions regarding what can be done to the specimen and/or whether the patient withdraws consent.

16. The computer program product of claim 15, wherein dynamically tracking changes in restrictions includes providing rule-based querying for specific consent profiles.

17. The computer program product of claim 15, wherein dynamically tracking changes in restrictions includes providing a risk assessment from a consent perspective.

18. The computer program product of claim 13, wherein automatically generating, by the server, the new consent document includes generating the new consent document based on an

outline of desired consent, categories of consent needed, and regulations in at least one of the plurality of locations.