## Clinical Research

Overall, under current disciplines, patients have no ownership rights over data collected from research. Obtaining informed consent is required.

While there may be some desire for legal and regulatory policy changes, that is out of scope for this document.

### Testing a new intervention or drug

This is what most people think of as clinical research. Obtaining the subject patients’ informed consents is essential to research.

Each patient consents to participation, which may include a new intervention or drug. It can be presumed that the consent is an umbrella that includes data collection in addition to treatment. Consents may include subsequent use of the data in meta-analysis.

Separating the consent into its components – clinical acts and data collection -- can occur before or after the act of consent.

Issues:

* Under current disciplines, following their consent, patients have no control over the use of their data from research. The data are often proprietary and subject to intellectual property protections. They are not subject to patients’ ownership rights.
* Under double-blind research protocols, patients have no access to the data. Clinicians also may not have access to individual patients’ data.
* The data may not include current clinical coding, as the objects of research may not have been included in current standardized code sets. This may make subsequent patient queries difficult, even if permitted.
* Institutional review boards (IRBs) control the policies, including conformance with legal, regulatory, and ethical requirements. The patients’ may be granted some rights by IRBs, and that language will be included in the consent documents.
* Paper documents with wet signatures are the norm. Capturing consents electronically will require a trusted intermediary transcriptionist.

### Pragmatic Trials

This research collects data regarding the efficacy of current interventions or drugs. Obtaining the subject patients’ informed consents is essential to the data-gathering, which may be a simple re-purposing of data that is normally collected during treatment.

Each patient consents to participation as part of the provider’s admission process. It can be presumed that the consent is an umbrella that includes data collection in addition to treatment.

Separating the consent into its components – clinical acts and data collection -- can occur before or after the act of consent.

Issues:

* Under current disciplines, following their consent, patients have no control over the use of their data from research. The data may be proprietary and subject to intellectual property protections. They are not subject to patients’ ownership rights.
* Patients have no access to the data concurrent with the intervention or use of drugs. They may have access after the research is complete.
* Institutional review boards (IRBs) control the policies, including conformance with legal, regulatory, and ethical requirements. The patients’ may be granted some rights by IRBs, and that language will be included in the consent documents.
* Paper documents with wet signatures are the norm. Capturing consents electronically will require a trusted intermediary transcriptionist.

### Meta-analysis

This research combines the results of more than one research study to form a larger statistical sample. The patient data may be de-identified. Obtaining the subject patients’ informed consents is presumed to have happened for each research study, and those consents will have included subsequent use in meta-analysis.

Issues:

* Under current disciplines, following their consent, patients have no control over the use of their data from research. They are not subject to patients’ ownership rights. The data may be proprietary and subject to intellectual property protections.
* Under current disciplines, patients are not informed of the use of their data in meta-analysis.
* Under current disciplines, patients have no access to the meta-analysis data.

### Biobank

This involves the collection, storage, and processing of human tissue samples for research. This includes genomic samples. Obtaining the subject patients’ informed consents is essential to research.

Each patient consents to participation. It can be presumed that the consent is an umbrella that includes data collection in addition to the tissue. Consents may include subsequent use of the data in meta-analysis.

Separating the consent into its components – clinical acts and data collection -- can occur before or after the act of consent.

Issues:

* Under current disciplines, following their consent, patients have no control over the use of their tissue and the associated research data. The data may be proprietary and subject to intellectual property protections. They are not subject to patients’ ownership rights.
* There may be multiple research studies done using the samples, sometimes over a period of several years
* Patients have no access to the research data.
* Institutional review boards (IRBs) control the policies, including conformance with legal, regulatory, and ethical requirements. The patients’ may be granted some rights by IRBs, and that language will be included in the consent documents.
* Paper documents with wet signatures are the norm. Capturing consents electronically will require a trusted intermediary transcriptionist.