Research Matters

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Outline

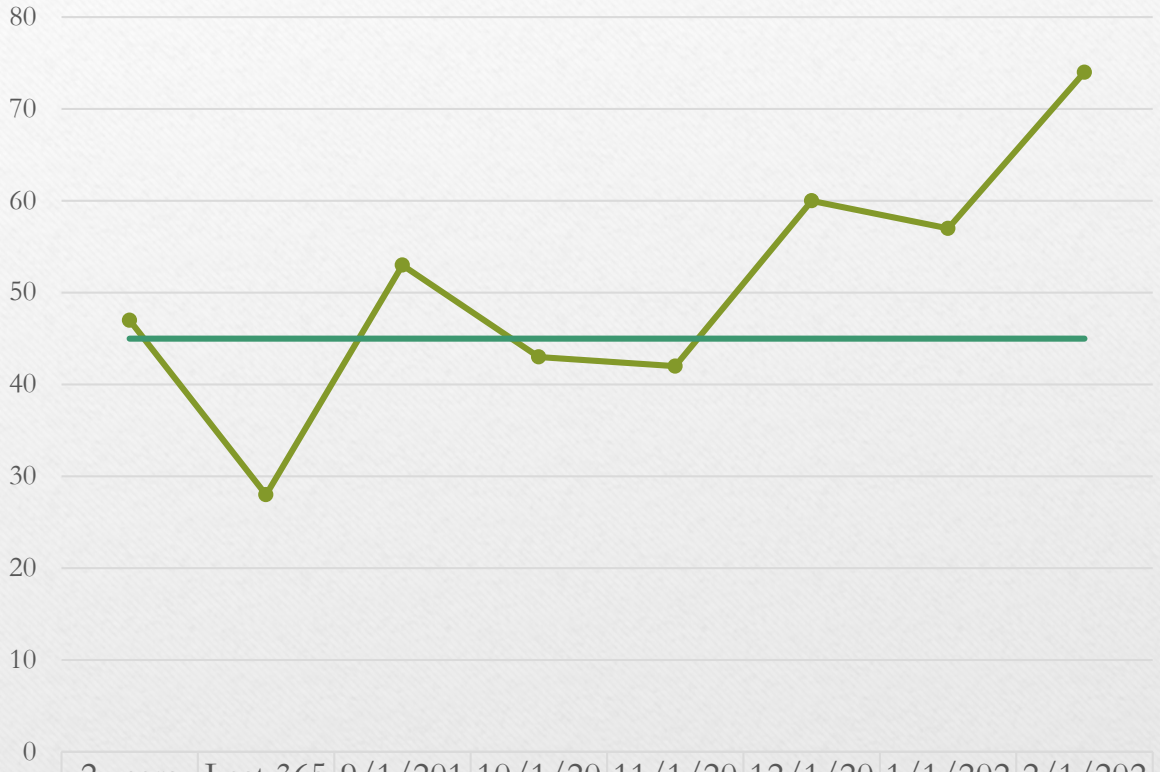
- Metrics
- Waivers of Informed Consent and HIPAA Authorization

Metrics: Volume

Total Items Approved

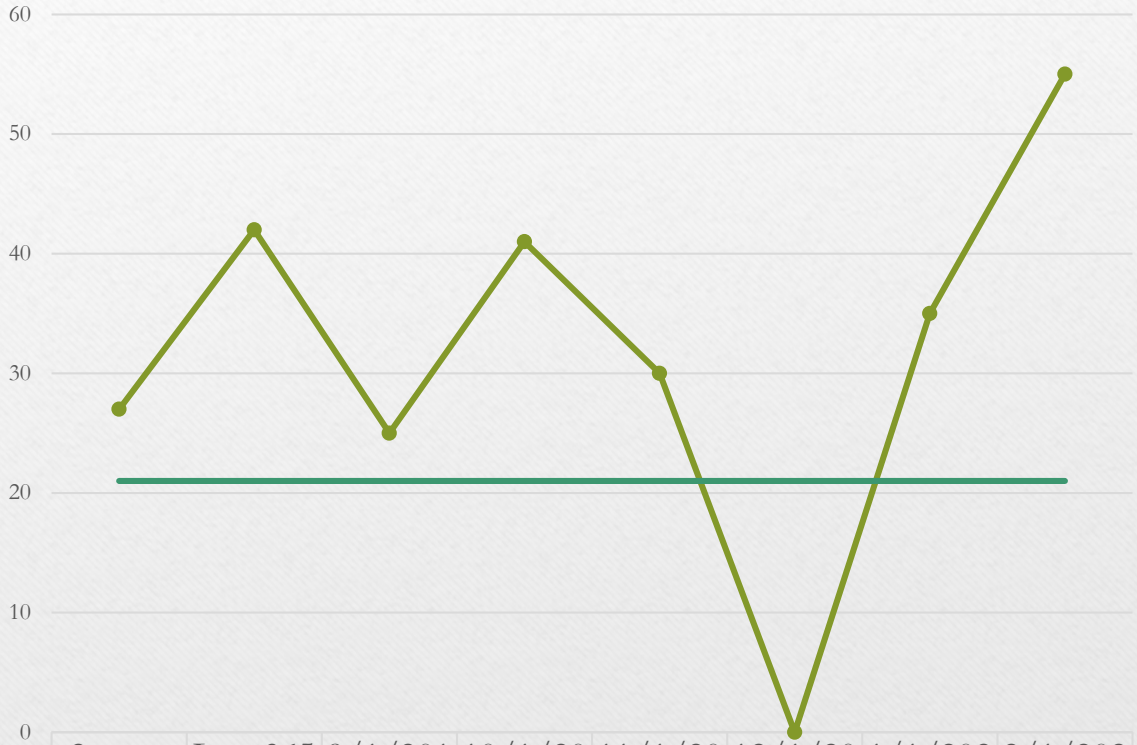
	Last 6 Months	Last 30 days
New Studies*	550	95
Continuing Review	1,265	363
Modifications	3,955	685
Reportable Events	175	19
Total	5,945	1,162

Full Board New Studies
Median Turnaround in Calendar Days
(Submission to Final Approval)



	2 years ago	Last 365 days	9/1/2019	10/1/2019	11/1/2019	12/1/2019	1/1/2020	2/1/2020
Full Board New Studies	47	28	53	43	42	60	57	74
Goal	45	45	45	45	45	45	45	45

Expedited New Studies
Median Turnaround in Calendar Days
(Submission to Final Approval)

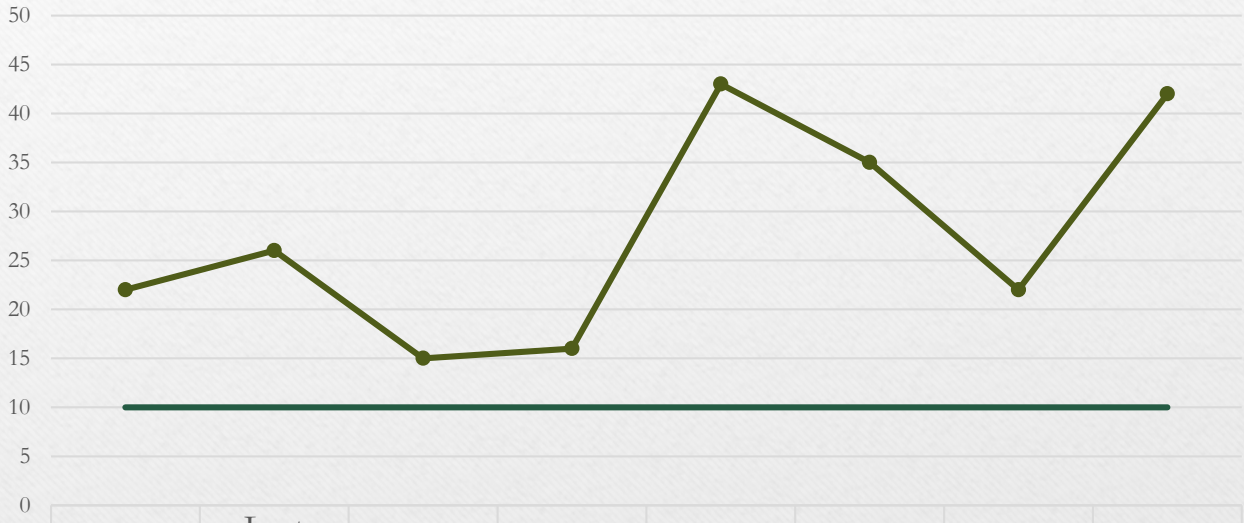


	2 years ago	Last 365 days	9/1/2019	10/1/2019	11/1/2019	12/1/2019	1/1/2020	2/1/2020
Expedited New Studies	27	42	25	41	30	0	35	55
Goal	21	21	21	21	21	21	21	21

Exempt New Studies
Median Turnaround in Calendar Days
(Submission to Final Approval)

	2 years ago	Last 365 days	9/1/2019	10/1/2019	11/1/2019	12/1/2019	1/1/2020	2/1/2020
Exempt New Studies	21	35	19	22	29	40	49	34
Goal	21	21	21	21	21	21	21	21

Reliance New Studies
Median Turnaround in Calendar Days
(Submission to Final Approval)



	2 years ago	Last 365 days	9/1/2019	10/1/2019	11/1/2019	12/1/2019	1/1/2020	2/1/2020
Reliance New Studies	22	26	15	16	43	35	22	42
Goal	10	10	10	10	10	10	10	10

Waivers of Informed Consent and HIPAA Authorization

Informed Consent and HIPAA are governed by the same regulations.

A. True

B. False

Informed Consent and HIPAA Authorization

- Federal regulations require that informed consent and HIPAA Authorization be obtained from research subjects
  - Informed consent – 45 CFR 46.116
  - HIPAA Authorization – 45 CFR 164.508

Informed Consent 45 CFR 46.116

- "Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative."

Informed Consent 45 CFR 46.116

- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:
  - (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

HIPAA Authorization 45 CFR 164.508

- "*Standard: Authorizations for uses and disclosures*—(1) *Authorization required: General rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization."

Informed Consent and HIPAA Authorizations

- Two sets of regulations
- Two sets of regulations on types of waivers
- Two unique requirements for IRB/Privacy Board to approve waivers

Informed Consent Waivers or Alterations

If informed consent can be obtained, the IRB cannot approve a waiver of informed consent.

- True
- False

Types of Informed Consent Waivers or Alterations

1. General waiver or alteration of consent (Form G1)
2. Waiver or alteration for screening, recruiting, or determining eligibility
3. Waiver of documentation of informed consent (Form G3)
4. Waiver or alteration in research involving public benefit and service programs conducted by or subject to the approval of state or local officials (Form G)
5. Waiver of consent for emergency research (Form G4)
6. Waiver of assent or parental permission (Form G)

Waiver vs. Alteration

- Waiver – "An IRB may waive the requirement to obtain informed consent for research…"

- Alteration – "An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent…"

Types of Informed Consent Waivers or Alterations

FORM G

IRB Protocol Number	

HUMAN USE RESEARCH
WAIVER OR ALTERATION OF CONSENT

Note: additional rules apply to research involving investigational drugs/devices. See instructions for details before proceeding.

Type of request *(Select all that apply):*		**Explanation**
☐	**Waiver** of Informed Consent *Complete sections 1 and 2*	Consent will not be sought by the investigator for some or all subjects enrolled. The waiver may apply to only part of the study or the entire study.
☐	**Alteration** of Informed Consent *Complete sections 1 and 2*	Some or all of the elements of informed consent normally required by the IRB are changed or omitted.
☐	Waiver of **Documentation** of Informed Consent *Complete sections 1 and 3*	Consent will be obtained, however a consent document will not be signed. This waiver may apply to only part of the study *(e.g., screening phase)* or the entire study.

General Waiver or Alteration of Consent

- Waives or alters informed consent process
- Primarily for chart review studies

General Waiver or Alteration of Consent

- The IRB must find and document:
  - Research involves no more than minimal risk

Section 1 – For all requests, describe how the risk in this research is minimal:
[Click once here to type your answer]

  - The research could not practicably be carried out without the requested waiver or alteration

b. Explain why it is not practicable to carry out the research without the waiver or alteration *(CHOOSE ONE)*		
☐	Design issues:	[Click once here to insert your justification based on study design issues]
☐	Feasibility issues:	[Click once here to insert your justification based on study feasibility issues]

General Waiver or Alteration of Consent

- The IRB must find and document (cont.):
  - The research could not be carried out with using identifiable private information or biospecimens, if applicable

c. Explain why it is not practicable to carry out the research without using identifiable private information or biospecimens, if applicable *(CHOOSE ONE)*		
☐	Design issues:	[Click once here to insert your justification based on study design issues]
☐	Feasibility issues:	[Click once here to insert your justification based on study feasibility issues]

  - Waiver will not adversely affect rights and welfare of subjects

a. Without the protection of informed consent, how are the rights and welfare of the participants protected (not adversely affected),
[Click once here to type your answer]

  - Subjects/legally authorized representative (LAR) will be provided with additional pertinent information, when appropriate

d. If it may be appropriate to provide subjects with additional pertinent information after the study is done, explain what type of information you anticipate giving the subjects and how it would be handled.
[Click once here to type your answer]

Form G1 – Waiver of Informed Consent

Section 1 – For all requests, describe how the risk in this research is minimal:

This waiver is needed for collection of data from records for use in this chart review study activity. In order identify potentially eligible subjects for the research; the researchers must review records for patients meeting the basic eligibility criteria.

The risk of this activity is minimal to the subjects, because the information collected will be limited only to information which was recorded in records for purposes other than for this research study. Only the minimum information necessary to complete the research will be recorded.

Section 2 - For Waiver of consent or alteration of consent requests – address the following questions

a. Without the protection of informed consent, how are the rights and welfare of the participants protected (not adversely affected).

Researchers have been granted access to the record data by the institution(s) and will protect the data they use and record for this activity according to institutional and HIPAA standards for protecting privacy and maintaining confidentiality. If the records identified do not meet eligibility criteria for inclusion in the study, the data used (under this waived activity) will not become part of the research data. If records are eligible for inclusion in the research, the identifiable data collected will become part of the subjects' research records and will be stored according to the research confidentiality plan.

Form G1 – Waiver of Informed Consent

b. Explain why it is not practicable to carry out the research without the waiver or alteration *(CHOOSE ONE)*		
☐	Design issues:	**[Click once here to insert your justification based on study design issues]**
☑	Feasibility issues:	It would be very difficult, if not impossible, to contact the individuals, although some of them may have been recalled a few times over the years. Thus, contact information may be outdated for a large number of the subjects. Without this waiver, the research would not be practicable as the eligible subjects would likely not be identified, contacted and recruited in time to complete the required sample.

c. Explain why it is not practicable to carry out the research without using identifiable private information or biospecimens, if applicable *(CHOOSE ONE)*		
☑	Design issues:	To answer the research question, the researchers must have access to the individual's medical record. This may include the individual's name and/or medical record number in order to be sure that the appropriate information is reviewed and collected.
☐	Feasibility issues:	**[Click once here to insert your justification based on study feasibility issues]**

d. If it may be appropriate to provide subjects with additional pertinent information after the study is done, explain what type of information you anticipate giving the subjects and how it would be handled.
N/A

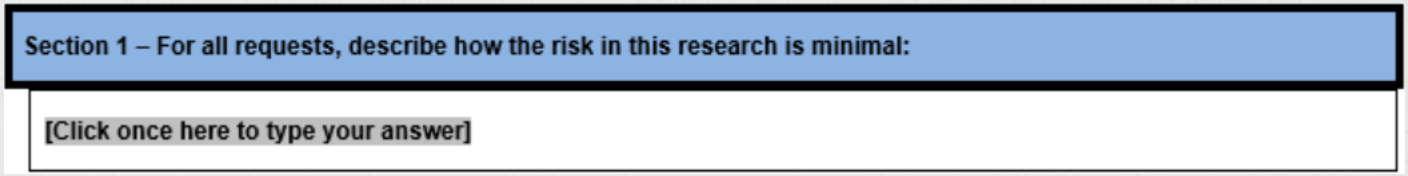
Screening, Recruiting, or Determining Eligibility

- IRB can approve study where study will obtain information or biospecimens without consent if:
  - Obtained through oral or written communication with the subject/LAR
  - Obtained by accessing records or stored biospecimens

Waiver of Documentation of Consent

- Waives the requirements to obtain signatures on the document ("verbal consent")

- Research must be minimal risk (or research procedure to be conducted before written consent is obtained)



Waiver of Documentation of Consent

- Three additional justifications
  - Consent document would be only link between research and subject and primary risk is loss of confidentiality; OR
  - Research involves no procedures for which written consent is required outside research context; OR
  - Subjects/LAR are from distinct cultural group for which signing forms is not normal and there is another mechanism for documenting consent was obtained
- IRB may require a written summary be provided to subjects

Waiver of Documentation of Consent

- Three additional justifications

a. **Acceptable justification for waiver of documentation** - *Important note: Only justification A, B, or C are accepted by the IRB – select the most appropriate justification.*		
☐	**Justification A** *(Check the applicable statements)*	*Both statements must be applicable to use this justification. This justification is not acceptable for FDA regulated research (investigational drug/device studies)*
	☐ 1. The only record linking the subject and the research would be the consent document	
	☐ 2. The principal risk of the study would be potential harm resulting from a breach of confidentiality if a consent form were required.	
☐	**Justification B**	The research involves no procedures for which written consent is normally required outside of the research context.
☐	**Justification C**	The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm.

Waiver of Documentation of Consent

- IRB may require a written summary be provided subjects

b. Plan for providing information relevant to the research when documentation is waived If it may be appropriate to provide subjects with a written statement regarding the research before participation. If so, provide a plan for providing subjects with information about the research. Include a description of the type of information you anticipate providing the subjects (e.g., an information letter). (See Information Sheet Template)
[Click once here to type your answer]

- Informed consent must still be obtained ("verbal consent") and documented (e.g., research note in research record)

c. Plan for documenting that verbal consent was obtained. *(CHOOSE ONE)*		
☐	Person obtaining consent will write a research note for each subject and place it in the subjects' research record. An example of a research note for consent is: *On [DATE], subject was provided information about the study including: purpose, risks, benefits, procedures, etc; subject was provided an opportunity to ask questions and have them answered; and verbal consent was obtained/not obtained to participate in the study.*	
☐	Other	Describe: [Click once here to type your answer]

Form G3 – Waiver of Documentation of Informed Consent

Section 1 – For all requests, describe how the risk in this research is minimal:
Select/Edit/Add as applicable: **Fasting:** This waiver of documentation and alteration is needed to allow for subjects to present at screening visit in a fasting state to allow for baseline determination of glucose and insulin concentrations. Subjects will be provided information about the study and verbally consented over the telephone to participate in the fasting screening visit. Fasting for the screening visit poses no more than minimal risk to the subjects and fasting is not something that would normally require written consent outside of the research context. Subjects will be asked to sign a full informed consent document for the study before participating in any additional research procedures. Risks to subjects with fasting may include lightheadedness, dizziness, and/or weakness.

b. Plan for providing information relevant to the research when documentation is waived If it may be appropriate to provide subjects with a written statement regarding the research before participation. If so, provide a plan for providing subjects with information about the research. Include a description of the type of information you anticipate providing the subjects (e.g., an information letter). (See Information Sheet Template)
Potential subjects will be informed about the study via a verbal phone script. Potential subjects will be given an informed consent document at the in person visit to review and sign if interested, prior to any additional research activities/procedures taking place.

Waiver of Consent for Emergency Research

- Life-threatening situation
- Informed consent is not feasible
- Research holds out direct benefit
- Research is not practicable without waiver
- Research defines treatment window and attempts to obtain informed consent
- Community consultation is conducted

Waiver of Assent or Parental Permission

- Waiver of assent
  - Capability of some/all children is so limited they cannot be consulted; OR
  - Research holds out prospect of direct benefit and is only available in the context of research; OR
  - According to the requirements for general waivers of informed consent

Waiver of Parental Permission

- Waiver of parental permission
  - Parental permission is not a reasonable requirement to protect subjects (e.g., research on abused children) with appropriate mechanism to protect children subjects; OR
  - According to the requirements for general waivers of informed consent

Informed consent does not need to be waived for exempt studies.

- True
- False

HIPAA Authorization Waivers or Alterations

Types of HIPAA Authorization Waivers

- Full Waiver
  - Authorization will not be sought; primarily for chart review studies
- Partial Waiver
  - Identify eligible subjects for recruitment; PHI will only be kept by subjects who provide authorization
- Alteration of Authorization
  - Changes or omits elements of authorization (including physical signature of subject)

Full Waiver or Alteration of HIPAA Authorization

- Use or disclosure involves no more than minimal risk based upon:
  - A plan to protect identifiers
  - A plan to destroy identifiers at the earliest opportunity
  - Protected Health Information (PHI) will not be reused or disclosed to another person, entity, or for other research

Full Waiver or Alteration of HIPAA Authorization

- Research can not be practicably conducted without waiver or alteration
- Research could not be practicably conducted without access to and use of PHI
- IRB must document PHI for which use or access is necessary (minimum necessary)

1. Explain why it is **not practicable** to carry out the research without this waiver. *Select all that apply.*		
☐	**Identify/recruit** – access to records is needed to identify eligible subjects (e.g., chart reviews, partial waiver for recruitment, etc.)	
☐	**Limited Means/Resources–** resources needed to identify and contact eligible subjects for recruitment are limited	
☐	**Large number of subjects projected** – potential subject population includes a large number of records to review and it is not feasible to attempt contact with all subjects	
☐	**Outdated records** – This is a retrospective study involving subjects who may have moved or expired and researchers cannot feasibly attempt to contact required sample	
☐	**Risk of breach of confidentiality** – The only record linking the subject and the research would be the signed authorization and a breach of confidentiality is the principal risk in this study (e.g., verbal consent)	
☐	**Other:**	[Click once to type here]

3. Provide details of the information to be accessed, collected or disclosed without written authorization.	
3a. Institution / Covered Entity *(List the institution(s) which maintains materials for this activity)*	**3b. Type of materials being used** *(List the type(s) of materials to be used, such as electronic medical records (e.g., EPIC), paper records, etc.)*
[Type the Institution name here]	[Click once to type]
3c. Nature of the Health Information *Provide a summary of the actual health information you will be accessing and/or collecting under this waiver/alteration)*	
[Click once to type summary - (for example "current medications, treatment and medical history relating to hypertension")]	

3d. Will you assign study codes to allow the research team to link subjects to the health information listed above or collect other information allowing you to re-identify subjects?

☐	No (delete 3e. and skip to 4)
☐	Yes (complete 3e, then answer 4)

3e. Identifiers Collected with Health Information

*Using the 18 HIPAA identifiers below, select those collected **that can also be linked** to the health information in 3c.*
(delete those you will not collect)

- Any unique identifying number, characteristic, or code (e.g., assigned study code)
- Names
- Address
- Dates (except year)
- Ages over 89 (except those grouped as age 90 or older)
- Phone numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Fax numbers
- Account numbers
- Certificate/license numbers
- Health plan beneficiary numbers
- Vehicle identifiers and serial numbers, or license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric Identifiers, including finger and voice prints
- Full face photographic images and any comparable images

4. Describe the plan to protect the identifiable health information and indicate where it will be stored and who will have access to it. Indicate all safeguards which will be used to protect identifiers to ensure minimal risk of improper use or disclosure of the subject's identifiable information.

4a. DURING ACCESS TO SOURCE RECORDS:

Describe the measures to protect health information during the time the researcher will be viewing health records:

Select all that apply:

☐	All HIPAA regulations as well as institutional privacy policies will be followed during the time the researchers have actual access to the source data (health records)
☐	Information (paper and/or electronic) will be viewed in a private/secure area (i.e., medical records room, behind covered entity firewall, etc.)
☐	Only personnel authorized by the covered entity will access health record data. These individuals are also approved to review PHI as part of this research study
☐	**Other:** [Click once to type here]

4b. RECORDED DATA:

Measures to protect the recorded data:

The information obtained will be stored in the following location:	[Click once to type]
Only personnel approved in this research study will have access to the recorded identifiable data:	☐ *Check to confirm your understanding*
The identifiable data **collected** will not be disclosed to persons outside of the covered entity unless:	☐ Required by law ☐ Approved by the IRB as part of the protocol ☐ Other: [Explain here]
The key to decipher the code/identifiers will be permanently destroyed at the earliest opportunity consistent with the conduct of the research which is (*select*):	☐ Upon completion of the study ☐ After publication acceptance ☐ Other: [Explain here]

4c. DISCLOSURE OF DATA:

Protection measures while transmitting PHI (disclosing) from one covered entity to another location:
Will you **disclose** the recorded identifiable information outside the covered entity?

(*i.e., Parkland/Children's medical record data stored on UTSW servers; identifiable health data sent to sponsor, etc.*)

☐	**No** - this study is not collecting identifiable health information	
☐	**No** - this study is not disclosing PHI collected under this waiver/alteration	
☐	**Yes** - Describe steps taken to securely transmit identifiable health information (PHI) outside the covered entity:	[Click once to type]

5. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. **Are you obtaining *only* the minimum information necessary to complete the waived activities?**

☐	Yes
☐	No (explain/justify why not): [Click once to explain]

Alteration of HIPAA Authorization – Short Forms (Form H.SF)

- When using a short form, the English consent document is presented orally to subjects
  - This includes HIPAA Authorization
- Form H.SF allows IRB to waive requirement for physical signature

Partial Waiver of HIPAA Authorization

- Use or disclosure is to review PHI to prepare a research protocol
- No PHI is to be removed from the covered entity in the course of review
- PHI is necessary for the research purposes

Coding data sets and removing identifiers is a standard method to protect PHI.

- True
- False

Questions?