

NORTH TEXAS
REGIONAL

IRB

INVESTIGATOR GUIDEBOOK

NORTH TEXAS
REGIONAL IRB

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OVERVIEW

INVESTIGATOR GUIDEBOOK

ABOUT THIS GUIDEBOOK

This investigator guidebook, prepared by the North Texas Regional Institutional Review Board (NTR IRB), is intended to facilitate investigators with the creation and submission of IRB projects. The guidebook will provide information on specific types of projects as well as instructions on what needs to be submitted.

This guidebook will be updated regularly, and as needed, to ensure that all information remains current and active.

Should you have any questions please contact the North Texas Regional IRB:

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Visit the NTR IRB [website](#) for more information and resources

ARE YOU CONDUCTING HUMAN SUBJECT RESEARCH?



ABOUT THIS SECTION

This section provides guidance to investigators who may be uncertain if their study requires IRB review according to the definitions stated in the federal regulations for the protection of human subjects in research (45 CFR 46). The NTR IRB recognizes that the federal definitions may not always provide a straightforward answer.

The information provided below offers investigators an explanation of the definition for what would be considered "human subject research" (subject to 45 CFR 46), as well as examples of studies that do or do not meet this definition.

HUMAN SUBJECTS RESEARCH

Federal regulations provide definitions to help researchers and IRBs in determining which projects require IRB review. When considering a new project, the first question a researcher should ask with respect to IRB review is whether the research project fits the federal definition of human subjects research (HSR).

In light of the IRB's mission to protect human subjects, and the potential regulatory and ethical consequences of not obtaining IRB review and approval, investigators are generally required to submit all studies that involve human participants, information about humans, or biological samples to the IRB for an official determination as to whether the study fits the definition of HSR.



DEFINING RESEARCH

Federal Regulations define research as “a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**” (45CFR46.102(l)).

This rather complex definition can be broken down into two main concepts: one, whether a study is designed to be systematic in nature; and two, whether the investigator intends to use the study findings or conclusions to develop or contribute to generalizable knowledge.



Here is a deeper look at the two main concepts highlighted above:

1. **Systematic investigation**: Projects lacking a structured research design with pre-stated objectives, hypotheses, or specific questions to be answered are typically not HSR, even if humans are involved. As described in the [Belmont Report](#) “...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

However, investigators must note that there are many different kinds of systematic investigations that may involve nontraditional methodologies, especially with qualitative, phenomenological, and participatory action research studies. In addition, the secondary analysis of data or biospecimens collected for non-research purposes may itself be systematic even if the method of original data or sample collection was not.

2. Intention to contribute to **generalizable knowledge**: Even in cases when a project can be considered a systematic investigation, the study must also be “designed to develop or contribute to generalizable knowledge” to be considered HSR. Therefore, if the investigator does not intend to disseminate the study findings or conclusions in any way, or if the study conclusions by nature cannot be applied to populations or situations beyond that studied, the project is considered not to be HSR.

DEFINING HUMAN SUBJECTS

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research:

(1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” (45 CFR 46.102(e)(1))

Living individual – The specimen(s)/data/information collected must pertain to live subjects. Cadavers, autopsy specimens or specimens/ information from subjects now deceased are not human subjects.

“About whom” – a human subject research project requires the data received to be about the living individual.

Intervention includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes. Interaction includes any kind of communication between the investigator and the subject. This includes face-to-face, online, mail, and phone interaction as well as other modes of communication.

Private Information "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place" (such as a public restroom) "and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record)." (45 CFR 46.102(e)(4))

“Identifiable” private information means the information contains one or more data elements that can be **readily associated with the subject’s identity** (e.g. names, Social Security #), **or** that one or more data elements **can be combined with other reasonably available information to identify an individual** (e.g., job title, employer, zip code, etc.).

Observational studies of public behavior (including television and internet chat rooms) do not involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may not constitute human subjects research if individuals are not identifiable (e.g., data such as service statistics, school attendance data, crime statistics, or election returns).

Studies based on data that are individually identifiable but are also publicly available may not constitute human subjects research. However, the term “publicly available” is intended to refer to record sets that are truly readily available to the general public, such as census data, or federal health, labor, or educational statistics. An investigator should **not** assume information qualifies as “publicly available” merely because it has been posted on an electronic website and can be accessed without authorization.



IDENTIFYING HUMAN SUBJECT RESEARCH STUDIES

Certain studies may have several characteristics of human subjects research but may not meet the regulatory definition. From a regulatory perspective, a project can fall into one of two categories:

- **studies that do not qualify as human subjects research**
- **studies that do qualify as human subjects research**

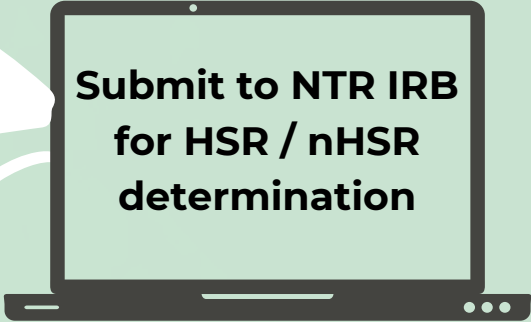
Any investigator who is planning to conduct a study that involves human participants, information about humans, or biological samples must submit the study to the IRB for an official determination. The IRB staff, IRB Chair, and/or designee will determine if the study is human subjects research. Federal regulations do not allow investigators to make this determination themselves.

Although studies that may include HSR must be submitted to the IRB for an official determination, the IRB is only required to review studies that meet the Federal definitions of “research” and “human subject,” or in certain instances when an institution would be considered “engaged in research” (see Office for Human Research Protections, Engagement of Institutions in Human Subjects Research (2008)). **A project that is determined to be Not Human Subjects Research (NHSR) is not subject to further IRB review or IRB requirements.**

If a study does not qualify as human subjects research, the IRB can issue a letter stating that the project does not require IRB review or approval. Grant offices, faculty advisors, or publications may require a copy of the determination letter from the IRB/designee.

North Texas Regional IRB Review Process: Not Human Subjects Research vs Human Subjects Research

Investigator designs project involving human participants, information about living humans, or biological samples



NTR IRB makes determination

HSR

nHSR

Project is HSR - further IRB review required

Project is nHSR - no further IRB Review



Quality Assurance/
Quality Improvement

Evidence Based Practice

Case Studies & Journalistic Activities

Exempt

Full Board

Expedited

STUDIES THAT ARE NOT HUMAN SUBJECTS RESEARCH (NHRSR)

- Survey Studies that fit any of the categories below do not need IRB review, but still must be submitted for an official determination.
- **Data collection** for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.
- **Service surveys** issued or completed by University personnel for the sole intent and purposes of improving services or programs of the University or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or University consortia. Note: If at a future date, an opportunity arises to contribute previously-collected identifiable or coded survey data to a research study that is producing generalizable knowledge, IRB review and approval will be required before the data could be released to the new project.
- **Information-gathering interviews** where questions focus on things, products, services, or policies rather than people or their thoughts regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.
- **Course-related activities** designed specifically for educational or teaching purposes, where data are collected from and about human subjects as part of a class exercise or assignment for the purpose of providing student education, but are not intended for use outside of the classroom. Example: instruction on research methods and techniques.
- **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- **Innovative therapies** for the purposes of medical treatment except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.) Note: When innovative therapies differ significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.

- **Quality Improvement (QI)** and **Evidence-Based Practice (EBP)** projects use data derived from individuals to improve or alter the quality of care or the efficiency of an institutional practice. Because the study design of QI and EBP is intended to implement validated improvements in the local setting and is not generalizable, QI projects are generally not considered research unless there is a clear intent to contribute to generalizable knowledge. However, since it is possible for a single project to contain elements of both QI and research, any investigator who is planning to conduct such a project must submit the study to the NTR IRB for an official determination. **Note that the determination must be made by the NTR IRB, not the investigator.** Additionally, if the data collected for QI is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, the project must be submitted to the IRB.
- **Case studies and patient histories** which are published and/or presented at national or regional meetings are not considered research if the case is limited to a description of the clinical features and/or outcome of a single (emphasis added) patient and do not contribute to generalizable knowledge.
- **Public health surveillance activities** conducted, supported, requested, ordered, required, or authorized by a public health authority.
- **Activities authorized by law or court order** solely for criminal justice or criminal investigative purposes.
- **Authorized operational activities** in support of intelligence, homeland security, defense, or other national security missions.
- **Research involving cadavers**, autopsy material or bio- specimens from now deceased individuals. Note: Some research in this category, such as genetic studies providing private or medical information about living relatives, may need IRB review. Please contact the IRB for further information.
- **Independent contracts for services or procedures** carried out for an external agency. Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.

- Some examples of Non-Engagement in Research include: when an institution's employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information; perform commercial services for the investigators; or inform prospective subjects about the availability of research. Note: the examples above are not an all inclusive listing. (<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>)

STUDIES THAT ARE HUMAN SUBJECTS RESEARCH

These projects must be submitted to the IRB for review and approval prior to the initiation of the project. Consult with the NTR IRB for additional guidance as needed for projects listed below.

1. Studies that utilize test subjects for **new devices, products, drugs, vaccines, or materials**.
2. Studies that systematically **collect data about living people through intervention or interaction with the individuals**. Examples of this type of research include drug trials; internet surveys about alcohol consumption; studies that involve deception or incomplete disclosure; research involving risky behaviors or attitudes; and open-ended interviews with minors.
3. Studies involving the **secondary use of private information or biological specimens** that were not collected for the currently proposed project. Note that these studies will generally qualify as Exempt status research if the investigator cannot link the coded data/specimens back to individual subjects, and the investigator will not be given access to any identifiable linking documents under any circumstances.
4. **Secondary research studies using private information** that can readily (or potentially) identify individual people, even if the information was not collected specifically for the study in question.
5. Studies that use **bodily materials** such as **cells, blood, urine, tissues, organs, hair, or nail clippings**, even if the investigator did not collect these materials for the present study. Note that such research may be considered exempt if the materials/data are coded and the investigator will not be granted access to the coding systems.
6. Studies that produce generalizable knowledge about categories or classes of **subjects from individually identifiable information**.
7. **Studies that use human beings to evaluate environmental alterations**, for example, weatherization options or habitat modifications to their living or working space or test chamber.

LEVELS OF IRB REVIEW

Human subjects research projects that are submitted to the IRB are classified into one of three regulatory classifications of review:

- **Exempt** projects, which involve minimal to no risks to subjects;
- **Expedited** projects, which may involve some risk but no greater than minimal risks to subjects; and
- **Full Board** projects, which may involve greater than minimal risks to subjects or which contain procedures that fall outside the scope of exempt and expedited review.

The federal regulations explicitly define the categories of human subjects research activities that can qualify for Exempt and Expedited review. **The IRB is required to review all research at the appropriate level mandated by the federal regulations.**

EXEMPT RESEARCH

The term “Exempt” can be somewhat misleading, as studies qualifying for this level of review **must be submitted to the IRB for an official verification of Exempt status** prior to the initiation of the project. However, unlike Expedited and Full Board projects, Exempt projects do not require ongoing IRB oversight (i.e., Continuing Review) due to their reduced level of risk. *Note that research which targets a prisoner population is not eligible for exempt review.*

Please note that if the IRB does determine a project to be Exempt, the NTR IRB does still require that any modifications to that project be submitted for review (and approval) to ensure that the project still meets criteria for Exempt level of review.

Studies involving only activities listed in one or more categories below are likely to qualify for Exempt review: (45 CFR 46.104)

1. Research in **commonly accepted educational settings involving normal educational practices** that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. Example: comparing the effectiveness of two well-known methods of math instruction in a third grade classroom.

2. Research that only includes **educational tests, survey procedures, interview procedures, or observation of public behavior** (including visual or auditory recording). Examples: administering an anonymous survey about personality characteristics to adults over the internet; conducting a focus group to assess opinions about local parks. *Note that research involving children typically does not qualify for this category; consult the NTR IRB with questions.*

3. Research involving **benign behavioral interventions when data will be collected from adult subjects through verbal or written responses or audiovisual recording**. To qualify for this category, subjects must provide consent before participating in the research, and the intervention must be brief in duration; harmless; painless; not physically invasive; not likely to have a significant adverse lasting impact on the subjects; and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Example: participation in an hour-long computerized, timed business decision making game; providing a 45-minute educational seminar to participants with the intention of changing their recycling behaviors. *Note that individuals who are unable to provide their own consent cannot qualify for this category; contact the NTR IRB with questions.*

4. **Secondary research uses of identifiable private information or identifiable biospecimens for which consent is not required**. This exemption allows for the re-use of data and specimens that have already been, or will be, collected from subjects for a purpose other than the current research study. Studies where data or specimens will be collected directly from subjects specifically for the current study are not eligible for this category. Examples: secondary analysis of identifiable blood samples collected during a previous research study; analysis of a publicly available dataset containing information about the sexual history of minors.

5. **Research and demonstration projects that are conducted or supported by a Federal department or agency and that are designed to study, evaluate, or improve public benefit or service programs**. Note that projects eligible for this exemption are required to be posted on a Federal website. Example: a government-led study examining whether welfare recipients have adequate access to nutrient-rich foods throughout rural areas across the United States.

6. **Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed** and the ingredients meet federal safety thresholds.

Note: the Revised Common Rule at 45 CFR 46.104 also includes the additional exempt categories 7 & 8 pertaining to broad consent for the storage and use of identifiable information and biospecimens. **These categories have been intentionally omitted from this document as the NTR IRB has chosen not to implement broad consent at this time.**

Visit [OHRP's website](#) for more information

Research projects involving procedures outside of the above categories or that involve greater than minimal risks to subjects are not eligible for Exempt review. These projects would instead be reviewed under the Expedited or Full Board classifications which will be addressed in subsequent chapters of the Investigator Guidebook.

NOT HUMAN SUBJECTS RESEARCH VS. EXEMPT RESEARCH

A common misunderstanding occurs when an investigator assumes that “exempt” studies are the same as studies which are not human subjects research. **Exempt studies DO fit the federal definition of human subjects research, and therefore are required to be reviewed by the IRB or designee prior to initiation.** In contrast, studies that are not human subjects research are entirely outside of the scope of IRB review; however, researchers should consult with the NTR IRB Office or submit such studies to the NTR IRB for an official Not Human Subjects Research (NSHR) determination.

How do I submit a project to the NTR IRB to receive an official NSHR determination?

1. Login to/register in IRBNet.org.
2. Follow instructions in the [IRBNet User Manual](#)
3. Create a new project (in IRBNet), and upload a brief project description (e.g., a signed memo that describes the purpose of the study, the study procedures, etc.) and any related documentation you feel would help aid in the IRB's review.
4. Submit the project for review.
5. The IRB will review the project description and reach out to the investigator if any additional documentation is needed to make an NSHR determination or if it seems that the project may be Human Subjects Research (in which case additional documentation will be required).



IRBNet URL:
irbnet.org.

Contact us with
any questions

THE USE OF CLINICALLY DERIVED DATA FOR SECONDARY USE



ABOUT THIS SECTION

This section provides guidance about how to develop and submit a project that intends to use data originally collected for clinical purposes.

These projects are commonly classified as a secondary data analysis, chart review, a data repository or data registry.

COMMON TYPES OF PROJECTS THAT USE CLINICALLY DERIVED DATA

Chart Review - A chart review evaluates patient data that exist within the patient's medical record (not a result of research activity, rather data that were collected as part of standard of care). There are two types of Chart Reviews, **Retrospective** (data that already exists in the patient's medical record) and **Prospective Chart Review** (evaluates patient data that does not yet exist in the patient's medical record at the time the project is submitted for initial IRB review).

Retrospective Chart Review- evaluates patient data that is existing at the time the protocol is submitted to the IRB for initial approval. This type of chart review uses information that has usually been collected for reasons other than research.

Prospective Chart Review- evaluates patient data that DOES NOT YET EXIST at the time the protocol is submitted to the IRB for initial review (i.e., future patient data).

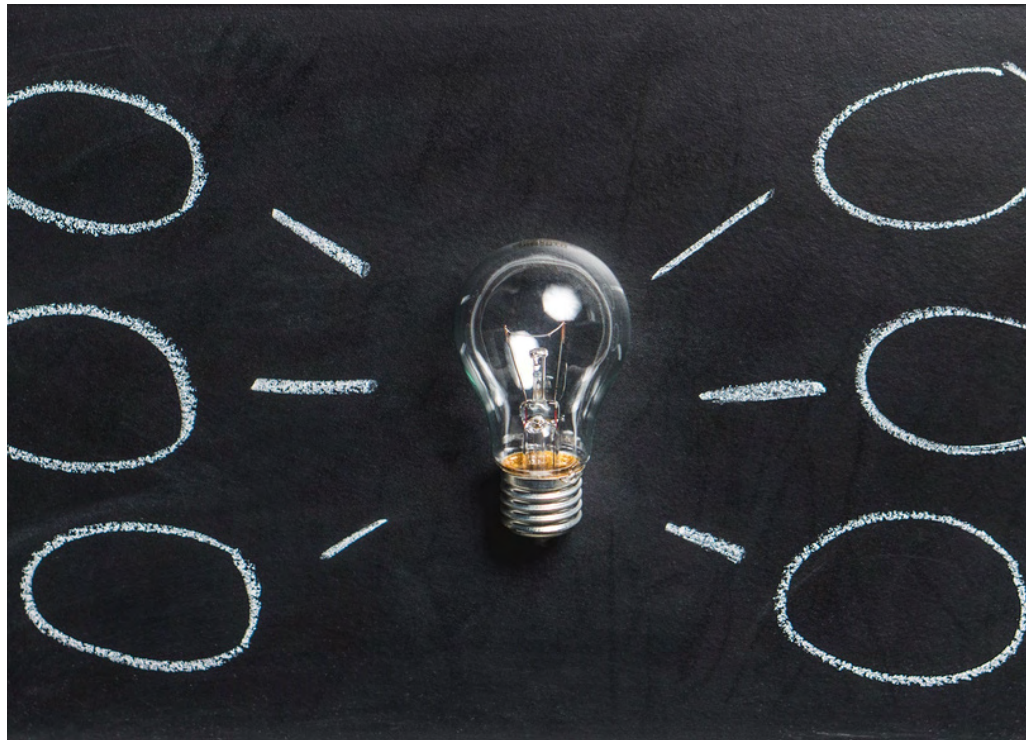


RESEARCHERS WHO ARE CONDUCTING A CHART REVIEW STUDY ARE USING DATA FROM THE MEDICAL RECORDS TO ANSWER ONE VERY SPECIFIC RESEARCH QUESTION. THIS IS DIFFERENT FROM A REGISTRY STUDY, WHICH IS OUTLINED BELOW.

Registry - A registry or data bank is a warehouse of data including a variety of data points such as contact information, demographic, health data. The Data steward (the person responsible for managing and tracking the registry) has the ability to provide access to authorized users. Investigators should be added as Key Personnel on the IRB protocol in order to use the data for their own studies or other research.

A registry is a collection of information elements or databases whose organizers:

1. Receive information from multiple sources
2. Maintain information over time;
3. Control access to the information;
4. Permit multiple individuals to use the information for a variety of purposes which may evolve over time
5. May (often) contain codes that link information and specimens to the donor's identity. When a key to the code is retained, the code may be maintained either by the registry or by the provider of the data.



Authorized users will be able to contact people who have opted into the registry (by providing their contact information). Other researchers can tap into this information to recruit for their own studies or other research purposes.

Registries may be publicly accessible or private. Examples of a few well-known public registries and data banks include:

- **State Cancer Registries**
- **The US Census Data Bank**

Repository- A repository or tissue bank is a collection of biological specimens (biospecimens) whose organizers receive specimens from multiple sources. The repository may be small or may be very large with thousands or millions of samples

CONSIDERATIONS FOR PROJECTS THAT USE CLINICALLY DERIVED DATA

Do the data contain **identifiers** that link research data to an individual? If so, the data are subject to the **HIPAA Privacy Rule**.

HIPAA Privacy Rule- protects most "individually identifiable health information" held or transmitted by a covered entity or business associate, whether electronic, on paper, or oral. The Privacy Rule calls this information protected health information (PHI) (45 CFR 160.130). Protected health information is information, including demographic information, which relates to:

- The individual's past, present, or future physical or mental health or condition,
- The provision of health care to the individual, or
- The past, present, or future payment for the provision of health care to the individual,

The 18 HIPAA Identifiers include:

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)



The HIPAA Privacy Rule, per the "minimum necessary standard" rule, does require that identifiers only be collected if they are needed/justified to achieve the intended purpose of the research.

OTHER KEY TERMS AND CONCEPTS

Deidentification of Other data- Data not including protected health information (PHI) but including other identifiers (e.g., name, date of birth, email, home address, IP address, audio recordings) can be deidentified through removal of identifying data variables. Audio recordings are by nature considered identifiable data and the method of deidentification would be destroying the audio recordings. If, for purposes of the research study, there needs to be a link to the identifiers (e.g., if a medical chart needs to be repeatedly reviewed to record data points), then the researcher may consider use of a master list.

Master List- A master list is a document that links participant identifiers (such as names or Medical Record Number) to the uniquely-generated code or ID number used to identify participants' data. In order to maintain confidentiality, Principal investigators need to ensure that the master list is stored on a secure, password-protected drive or in a locked, private office space and that only authorized personnel have access to it. Per NTR IRB policy, all study data must be deidentified at study closure. Most often this is done by destroying the master list.

Coded- means 1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and 2) A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Anonymized- The act of permanently and completely removing personal identifiers from data, such as converting personally identifiable information into aggregated data. Anonymized data are data that can no longer be associated with an individual in any manner. Once this data is stripped of personally identifying elements, those elements can never be re-associated with the data or the underlying individual.

Many of these projects qualify for a **Waiver of Informed Consent** if the following criteria is met:

- (i) The research involves no more than minimal risk to the subjects;
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

In addition, many of these projects also qualify for a **Waiver of HIPAA authorization**.

WHAT DO I NEED TO SUBMIT TO THE NTR IRB FOR REVIEW OF MY NEW RESEARCH PROJECT?



- Protocol Synopsis (will vary depending on the type of project you are submitting):
 - Chart Review Protocol Synopsis template (with embedded HIPAA Waiver and Informed Consent Waiver)
 - Protocol Synopsis Template (General) for all other types of projects
- Data collection sheet
- HIPAA Waiver (if not using Chart Review form)
- Informed Consent Waiver (if not using Chart Review form)

Need guidance on submitting in IRBNet?
Check out our **IRBNet User Manual** or **contact us.**

TIPS AND TRICKS FOR IRB SUBMISSIONS



ABOUT THIS SECTION

This section provides tips and tricks for developing and submitting your project to the IRB.

RESPONDING TO THE NTR IRB'S FEEDBACK

This section describes several methods that an investigator can use when responding to the NTR IRB's feedback.

Method #1: Responding via a Signed Memo. The investigator can copy and paste the IRB's feedback into a new MS Word document, which will be the investigator's memo. The investigator can then briefly describe (within the document) how each of the items has been addressed and/or clarified. (See example below; note that PI responses are included in italicized text.)



EXAMPLE RESPONSE MEMO:

Date:

Project Title:

To: NTR IRB

From: [principal investigator]

Response to NTR IRB's Feedback

I have responded to the IRB's feedback. My responses are provided below.

Items that the Principal Investigator Needs to Address and/or Clarify:

1. Submit a copy of Dr. Researcher's signed conflict of interest (COI) form.

The COI form has been submitted.

2. Describe (in the protocol synopsis) the potential risks of the study.

The potential risks of the study are now described in the protocol synopsis (on p.9).

RESPONDING TO THE NTR IRB'S FEEDBACK

CONTINUED

Method #2. Responding in Tabular Format (i.e., in a table).
The investigator can provide their responses in a MS Word document in a tabular format.

Click [here](#) for
example of signed
memo

Click [here](#) for
template of Tabular
Format Response



Additional Guidance:

- When available, a “tracked changes” copy and a “clean copy” of each of the revised documents should be submitted for review. (Note: If tracked changes cannot be provided, a reminder to please specifically outline the changes that have been made, and where they have been made, in your response document.)
- Once all of the required documents have been uploaded, the investigator must mark their revisions as complete in IRBNet. To mark revisions complete, the investigator needs to navigate to the Designer page, and then click on the blue text (at the top of the page; the text is small!) that reads, “Mark Revisions Complete”. The package will automatically be re-locked and returned to the IRB at that time.

HOW TO ACCESS IRB-RELATED DOCUMENTS IN IRBNET

This section describes how to access (within the IRBNet system) the IRB-related documents for a project, including IRB determination letters as well as how to access the IRB-approved, stamped versions of the research documents (if any).

Once the NTR IRB has issued a determination (aka “Board Action”) regarding a submission, the investigator will receive two IRBNet notifications: 1) “Board Action” (e.g., approved, acknowledged, etc.) and 2) “Board Document Published” (e.g., IRB approval letter, stamped research documents, etc.). Researchers can access their IRB determination letter and any corresponding stamped, IRB-approved, research documents by doing the following:

1. Login to www.irbnet.org using your username and password.
2. Select My Projects on the left side of the screen.
3. Select the project you wish to access.
4. Once you click into the study, click on "Reviews" (in the left column).
5. You should now see a “Board Documents” table that allows you to access the Board documents, including any stamped, approved research documents, for that package. To view the documents, you can either:

- a. click on the hyperlink (in the “Document” column”) that has the name of the document that you want to access (e.g., “Approval Letter”); or
- b. click on the paper icon (in the “View” column) that is associated with the document that you want to access.

Pro Tip:

Keep in mind that each project may have multiple packages. In most cases, the first package that you submit for a new study will be a “New Project” package (the exception for this would be those studies that started prior to the implementation of IRBNet.) The IRBNet ID number for the first package will always end in “-1”. The IRBNet ID for the project’s second package will end in “-2”, and so on.

HOW TO ACCESS IRBNet TRAINING RESOURCES

This section describes how to access resources that are helpful in learning how to navigate the IRBNet system.

IRBNet is a user-friendly, intuitive, on-line protocol submission, management, and review system.

Be sure to review the Training Energizer videos and material (you may want to print out the pdf files for future reference) to familiarize yourself with the system. Please follow the link provided in the "IRBNet Training Resources" section below to access the training resources.

IRBNet Training Resources

To access IRBNet training energizers (or "how to manuals") and videos, please follow this link and use the following institutional login information when prompted for login information:

Resource Link: <http://www.irbnetresources.org/tresources/training.html>

Institutional Login Information (User Name: unthsc; Password: training)

Note: In order to access the webpage, the system will automatically prompt you for the login information (provided above). Once you have landed on the page, you can simply click on hyperlinks for videos and energizers (pdf documents). Please note that you do NOT have to re-enter the login information in the Login section located on the right hand corner of the webpage.

Creating a New Project in IRBNet

After logging into your IRBNet account (at www.irbnet.org), go to "Create New Project" group in the left-hand navigation bar. This is the place to start...once it is saved, it will show up as a project in "My Projects". When you first create a new project, the "Designer" feature will appear. "Designer" is the home base for assembling the various forms and documents you will need for an IRB submission. This is where you will upload, complete and attach various documents from the Forms and Templates library.

HOW TO ACCESS IRBNet TRAINING RESOURCES *CONTINUED*

Adding Training and Credentials to IRBNet Account

If you have credentials to load in, such as medical license, curriculum vitae (COV), Human Subjects Research Training certificate (CITI), go to your USER PROFILE, scroll down to "Training & Credentials" and click on "Add a New Training & Credentials Record". Follow those instructions. Also, recall that the credentials may have their own expiration dates, so be sure to re-submit any renewed documents prior to protocol submission.

General Submission reminders:

- Some forms require a signature by the principal investigator (PI). Be sure to sign each form (if indicated), before scanning it in and saving as a pdf file.
- The **principal investigator must sign the initial IRB application and any required federal agency forms** (such as FDA documents). All subsequent forms may be signed by a co-investigator. However, unsigned documents will be returned unprocessed.
- Due to the size and placement of the approval stamp, please allow 1.5 inches at the bottom of each page. The stamp will be located at the bottom left-handed side of the page. Please note that this is a pre-determined location and cannot be reformatted or rearranged.
- Whenever a change is made to a submission (in response to a reviewer's feedback), be sure to "re-lock" the package by clicking the "Mark Revisions Complete" button (at the top right of the screen) so that it may be submitted for review and processing.
- Pre-Review findings: It is possible that you may receive the pre-review findings/comments for your study as a Board Document that is titled either "Other" or "Request for Information". Please be aware that if you receive a notification from IRBNet and see one of these types of documents published in the Board Documents for your study, you should open the document to review and address pre-review findings from the IRB.

North Texas Regional IRB – IRB Submission Quick Reference “Cheat Sheet”

This document is intended to be a quick-reference guide for researchers who are new to submitting studies to the NTR IRB. **The NTR IRB website has lots of additional guidance – visit <https://www.unthsc.edu/north-texas-regional-irb/> !**

1. If you do not already have an IRBNet user account, please visit <http://www.irbnet.org> and click the “New User Registration” link to create your IRBNet account. The website will walk you through the process – be sure to check the email addresses you used to register in order to confirm and verify your IRBNet account.
2. Once your IRBNet user account has been created, log into the IRBNet website with your credentials. Click the link on the left-hand sidebar to “Create New Project.” Enter the project title and the Principal Investigator’s name. All the other fields are optional.

On the next screen, it is suggested to start with Step 2 by clicking the “Start a Wizard” button at the bottom, then click the small link that says “North Texas Regional IRB – New Protocol Application Form.” Click next, and the Wizard will guide you through a series of dynamic questions about your project. Answer all the questions, clicking “Next” to proceed to the next screen. Once all the questions in the Wizard have been answered, you will reach a Principal Investigator Attestation page. Sign and complete the attestation. The final “Complete” page will provide a list of suggested Forms & Templates that may apply to your project. Click “Save & Exit,” and you will be taken to your project’s Designer page.

3. The Designer page in IRBNet is where you will upload all the required documents for your project, including completed forms and templates. To access blank, fillable Forms & Templates, visit the [NTR IRB Forms page](#).
4. Researchers are required to submit a completed Protocol Synopsis with every new project. The NTR IRB currently offers two versions of the Protocol Synopsis template: the [Chart Review Protocol Synopsis Template](#), which is used only for medical chart review studies; and the [“Protocol Synopsis Template \(General\),”](#) which must be used for all other types of projects. Download the version that applies to your project. **Note:** *A guidance document has been specifically prepared to assist you in completing the general Protocol Synopsis Template - the [“Master Protocol Synopsis Guidance Sheet.”](#)*
5. In addition to the Protocol Synopsis document, you will need to download any other [Forms or Templates](#) that apply to your project. Examples include Informed Consent templates; HIPAA Authorization Forms; requests for Waivers of HIPAA or the Informed Consent process; and more. Once you have downloaded all the required Forms and Templates to your computer, complete them with information that is applicable to your project. You will also need to create any other research-related materials that you intend to use in your project, like recruitment flyers or email scripts, surveys or questionnaires, data collection sheets, and so on.
6. Once all your needed Forms, Templates, and associated study documents are completed and ready to be uploaded, visit the Designer page in [IRBNet](#), and upload all the necessary documents to your project.
7. In addition to your study specific documents, be sure to upload all required trainings (including evidence of training in human subject research, such as [CITI](#), for all key personnel), licenses, the CV of the PI, etc. For studies that will be reviewed at the Expedited or Full Board level, the IRB also requires signed [Conflict of Interest forms](#) for all key personnel. Please upload one file for each different type of training; for instance, one file containing all Human Subject Protection Training for all key personnel, one file containing Conflict of Interest forms for all study personnel, etc.

If you will be working with any external collaborators who are not affiliated with UNT Dallas, UNTHSC, or JPS, please upload a transcript of the training modules that were completed so that the IRB can review the modules

and determine whether the modules are equivalent to the modules that are required by the NTR IRB.

8. Before submitting the project for IRB review, remember to share the project with key members of the study team and the appropriate personnel from your home institution. There are three levels of user access to projects in IRBNet: Full access, write access, and read only access. Choose the appropriate level of access depending upon the role of the individual personnel in your project.
9. The Principal Investigator is required to sign all projects in IRBNet prior to study submission. On the left-hand sidebar, click “Sign this package” to begin the signature process. *Please note that the IRB is not able to accept the signature of study personnel in place of the Principal Investigator.*
10. When the project is complete and ready to be submitted to the IRB, click “Submit this package” on the left-hand sidebar and follow the instructions to submit the package for IRB review.
11. After you have submitted your project in IRBNet, the IRB will conduct a preliminary completeness check of your submission within a few business days and will provide feedback about missing or incomplete documents.
12. Once you have uploaded all of the required documents and answered the IRB’s questions from the completeness check (if any), you must click the link to “Mark Revisions Complete”. **PLEASE NOTE that the IRB will not be informed that the project is ready without completing this important step.**
13. Once the IRB has received your updated project, the IRB will complete a more thorough review of your study documents. Please note that it is likely that the IRB will send detailed requests for revisions and clarifications. If this is the case, the IRB will unlock the package in IRBNet to let you know that your response is needed before continuing with the review of the project. IRBNet will send an email to notify you that the IRB has unlocked the package pending your response.
14. After reviewing the Board’s feedback, be sure to edit your study materials to address all of the IRB’s comments and questions. When your revisions are completed, log into IRBNet and go to “My Projects,” click on the appropriate project, and go to the Designer page. From the Designer page, you can delete study documents, upload new study documents, or use the pencil icon to upload a new version of a previously uploaded document. For each document that has been updated, be sure to upload two versions: one with tracked changes (if the document allows tracked changes), as well as a clean version to be stamped upon approval.
15. Be sure to create a separate memo which explains how each of the IRB’s requests was addressed, and have the memo signed by the Principal Investigator prior to submission in IRBNet.
16. Again (the same as when you’re responding to intake findings), once all of your revised study materials have been uploaded in IRBNet, you must click the link to “Mark Revisions Complete”. When you complete this step, the package will automatically be re-locked in IRBNet and the IRB will be notified that your project is ready for additional review. **The IRB will review your resubmission, and if the IRB has no further questions and all items were addressed sufficiently, you will receive emails from IRBNet noting that the Board has approved your study. Hooray!**

***Note:** The IRB may also request additional revisions and clarifications after reviewing your responses to the IRB’s feedback. For this reason, please submit your study **EARLY** to accommodate the full IRB review process.*

Please contact the North Texas Regional IRB at NorthTexRegIRB@unthsc.edu with any additional questions about the IRB submission process.