University of Wisconsin-Madison
MR IRB Application

Study # : 2022-1012

Principal Investigator:
Victoria Zhang

Basic Study Information

1. Formal Title

This is the title that will appear in correspondence.

* Provide the full, formal study title.

> Provider networks, hospital systems, and changes in practice in response to regulations

2. Transferred Study

Answer Yes to this question only if:

a) the principal investigator (PI) for this application is coming to UW-Madison, UW Health, or the Madison VA from another institution and,

b) they plan to open a study here that is already IRB-approved at their previous institution.

* Is this study being transferred from another institution?

○ Yes ◉ **No**

3. Principal Investigator

* Identify the Principal Investigator.

Victoria Zhang

Type of Research Application

1. Type of Research Application

* Select one of the following: Health care records research

PI Information

1. Principal Investigator

PI : Victoria Zhang

2. Primary Appointment

* Is the PI's primary appointment through the University of Wisconsin – Madison?

(•) **Yes** ( ) No

2.1. Appointment Details

* Identify the appointment under which the PI will conduct this research.

	Title	Type	UDDS	Department Combined Name
(•)	**Assistant Professor**	**FA**	**A123800**	**WSB/MANAGEMENT & HR**
( )	Assistant Professor	FA	A123800	WSB/MANAGEMENT & HR

2.2. Appointment Not Found

Check if the appointment is not listed above. ☐

Study Team

1. Points of Contact Selection

Points of contact can edit the application and will receive email notifications about this submission.

If the PI is serving as the only study point of contact, indicate that here.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

* Identify the points of contact for this study (limit of four).

Name	Email
Victoria Zhang	victoria.zhang@wisc.edu

2. All Other Study Team Personnel

List ONLY UW-Madison, UW Health, or Madison VA personnel. External personnel will be listed elsewhere in the application.

Study team members listed below will have read-access only and will not be able to edit the application. They also will not receive email notifications.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

List all the other members of the study team (not including the PI or points of contact).

Name	Email

Study Team Roles

1. Primary POC

If the PI is serving as the primary point of contact, indicate that here.

* Identify the primary point of contact for this study.

Victoria Zhang

2. Human Subject Involvement

* Does this study involve recruiting, consenting, or interacting with human subjects?

○ Yes ◉ **No**

Funding

1. Funding Administered by UW Madison

Answer no to this question if this study will only be supported by VA funding; you will have the opportunity to add VA funding later in the application.

* Do you have pending or approved funding administered through Research and Sponsored Programs (RSP) or Business Services to support this project?

○ Yes ◉ **No**

2. Other Funding

* Do you have pending or approved funding NOT listed on this page?

◉ **Yes** ○ No

2.1. Sponsor

* Provide the name of the funder or sponsor (e.g., ICTR, WPP).

> OVCRGE

2.2. Description

* Provide a brief title or description of the funding award.

> Research Startup Fund through OVCRGE

Conflict Of Interest

Please review the study team member Outside Activities Report (OAR) and

managed entities data below before answering the questions on this page.

All study team members have completed their Ouside Activities Report for the year.

*NOTE: Per **campus policy** all study team members must **submit an OAR** every year and keep it up to date.*

No study team members have any managed entities at this time.

1. Intellectual Property

* Do any study team members involved in the design or conduct of the research (including their spouses and dependent children) own intellectual property that will be used in the study or project?

Yes **No**

2. Other Entities

* Besides the sponsor(s) of this project or entities listed above, do any study team members have a fiduciary or financial relationship with entities that will be involved in this study or that may be significantly affected by it?

Yes **No**

3. Incentives

* Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

Yes **No**

VA Status

All studies that fall under Madison VA purview must be reviewed and approved by the VA Research and Development (R&D) Committee in addition to being reviewed by the Health Sciences IRB. VA R&D Committee must first endorse the proposed study prior to submission to the IRB. For information about the VA R&D Committee review process, please contact **VHAMADRDCoordinator@va.gov**. If the study or project rents or uses Madison VA (Wm. S. Middleton VA Hospital) facilities, contact the Madison VA Research Office to ensure the appropriate permissions are in place.

1. VA Status

* Indicate if any of the following apply to this study or project.

☐	There are key personnel engaged in human subjects research for this project or study under their Madison VA appointment.
☐	The study or project enrolls, uses specimens obtained from, or involves the use of medical records from Madison VA patients.
☐	The study is conducted at the UW-Madison VA. (The study or project uses Madison VA facilities for more than administrative or sample processing activities. VA space that is rented by the University does not apply)
☐	The project or study is supported by VA funds.
☑	**None of the above.**

Scientific Review: Protocol Review Monitoring Committee

1. Cancer Related

* Is the scientific question of the protocol cancer related?

○ Yes ◉ **No**

2. Targeting Cancer Patients

* Are you specifically targeting cancer patients for enrollment in this study?

Yes **No**

3. Use of Cancer Data or Images

* Does this study involve the review and/or use of biological specimens/data/images/records from cancer patients?

Yes **No**

External Collaborations

1. Outside UW Activities

* Will any UW/UW Health or Madison VA personnel conduct any of the following study activities at locations outside the UW/UW Health or Madison VA: subject recruitment, obtaining informed consent, or interacting or intervening with subjects?

Yes **No**

Sharing Data Outside UW

1. Sharing Data Outside UW Madison

* Will subject data, images, or specimens be shared outside the UW Madison?

Yes **No**

Study Procedures and Special Populations

1. Study Procedures Involved

Select "Review or use of information from health care records"

* If your study involves any of the following special procedures or considerations, additional information may be needed. Select all that apply. If none apply, check Not Applicable.

Review or use of information from health care records, which includes information within:
*Medical records
*Appointment schedules
*Billing records
*Databases
*Registries

Secondary use of information not included in health care records for research purposes (e.g., additional use of research data).

2. Special Populations

If you will collect data points identifying individuals as any of the following, select the corresponding box(es).

* From the list below, select those populations you will target for inclusion in this study. Targeting means you will enroll and/or use data or specimens from a specific population. Select Not Applicable if you are not targeting any of the populations below.

Individuals who are receiving inpatient or outpatient services for mental illness, developmental disability, or alcohol and other drug abuse (AODA)

Research Design and Procedures

1. Overall Purpose

Describe the research questions or gap in knowledge the study proposes to address or contribute to in language that someone who is educated but not an expert in the field can understand.

* What is the overall purpose and aim of this project or study?

> The proposed study has the following objectives: (1) Examine how provider characteristics and provider patient-sharing networks are associated with high-risk professional practices; (2) Examine how patient-sharing networks are associated with changes in high-risk practices before and after new policies and regulations are introduced; (3) Examine how provider networks shape the prescribing of buprenorphines for treating opioid-use disorders (4) Examine how formal forms of organizations – the type of hospital systems and insurance networks – shape

> provider networks; (5) Examine how providers change their practices in response to new regulations; (6) Examine how adverse events change collaboration patterns between providers; (7) Identify the social network structures and processes that amplify learning at the physician-community-level.

2. Pre-Existing Information/Background Knowledge

* What prior information or knowledge exists to support the conduct of this project or study?

> Past studies has shown that provider networks transmit information and advice between physicians (Barnett et al. 2011). Provider networks have been shown to hold substantial predictive power for explaining variations in health care practices. They predict the diffusion of expertise and medical innovations (Pollack et al. 2015) and the spread of fraudulent health care activity (O'Malley et al. 2021) as well as collaboration, teamwork, information sharing, health care integration, learning, and teamwork (Everson et al. 2018; Funk et al. 2018; Ghomrawi et al. 2018; Hollingsworth et al. 2016; Zhang and King 2021).
>
> This body of work lays the groundwork and motivation for the first two objectives of this study – that provider networks likely also play important roles in shaping the extent to which providers change their practices in response to new regulations.
>
> Prior research has also highlighted the interplay between formal organizations (e.g. hospitals) and informal networks (e.g. patient-sharing networks) (Barnett et al 2011). This informs the last objective of the study – that formal hospitals may also shape informal networks and inform how providers change their practices in light of new information, regulations, and guidelines.

3. Study Procedures and Interventions

Provide an overview of the types of records that will be reviewed, what information from these records will be collected, and the kinds of analyses that will be performed on the study data. If data from multiple sources will be used describe this here (e.g., medical record information connected to imaging or billing information or data from multiple institutions collated).

* Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved. Do not include information on recruitment or consent.

> The proposed study will use administrative claims data and medical health records from the Colorado all payer claims data (APCD). CO APCD is a database that includes health care insurance claims information representing the majority of covered lives in the state of Colorado across commercial health insurance plans, Medicare (Fee-for-Service and Advantage), and Health First Colorado (Colorado's Medicaid program).
>
> To model how provider network structures and communities are associated with changes in prescribing, I will construct longitudinal provider social networks using

patient-sharing records. This method of social network construction has been widely applied in prior health care services research, which has shown that provider networks transmit information and advice between physicians (Barnett et al. 2011), predict the diffusion of expertise and medical innovations (Pollack et al. 2015) as well as collaboration, teamwork, information sharing, health care integration, learning, and teamwork (Everson et al. 2018, Funk et al. 2018, Ghomrawi et al. 2018, Hollingsworth et al. 2016, Zhang and King 2021). I will subsequently construct physician communities using community detection algorithms.

To understand the extent to which network position or prescriber characteristics are associated with changes in prescribing, a difference-in-difference approach will be used to assess changes in prescribing for the physicians who are in states with regulations ("treated") and observationally similar physicians who were not subject to regulations ("control"). I will also use network analytical tools to model the social influence practice across physician community and organizational environments.

4. Instruments Involved

This question is intended to identify projects involving the development or use of medical devices. This does not apply to surveys or questionnaires.

* Are there instruments of any kind, including software, tests run on samples, and algorithms, used in the study?

(•) **Yes** ( ) No

4.1. Health-Related Purpose

* Are any instruments used for health-related purposes including diagnosis or treatment?

( ) Yes (•) **No**

4.2. Specific Medical Mobile Application

* Does this study involve a medical mobile application focused on specific health related conditions and not just general wellness activities?

( ) Yes (•) **No**

4.3. Instrument Assessment

Please contact the FDA Regulated Research Oversight Program if you are unsure whether your project involves assessing the safety and/or efficacy of an instrument.

* Do any aims of the study involve assessing the safety and/or effectiveness of those instruments?

Yes **No**

4.4. Data Submitted to FDA

* Will data from the proposed activity be submitted in an application to the FDA?

Yes **No**

Subject Identification: Medical Records

1. Medical Record Use

* Will medical records be used to identify subjects or records?

Yes **No**

Risks and Benefits

1. Potential Benefits to Society

Describe how the research might help future patients.

* Describe the importance of the knowledge reasonably to be gained from this study and what benefit the research may provide to society.

> This research will provide insight into the role of provider networks in the efficacy of regulations. The study will also be able to link patterns of excessive overprescribing with provider network characteristics. The findings will provide insight for designing social network interventions and policies that are best suited to curb high-risk prescribing. The study result will be published and shared broadly with state and federal health policymakers and healthcare organizations.

2. Potential Psychosocial Risks

For this type of research the risks to subjects are generally limited to the risk of breach of confidentiality. The response to this question, "There is a risk of breach of confidentiality", would be acceptable.

* Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation, economic risks, and legal risks).

> If providers' practices were revealed it could affect their employment or reputation.

3. Procedures to Minimize Risks

The response to this question should address how the risk of breach of confidentiality will be minimized. For example, it could be described that the study team has several measures in place to protect against a breach of confidentiality, such as limiting the number of people who view identifiable information, coding study instruments, storing study data in restricted areas and on computers that are password-protected, only transmitting coded data outside the institution (if data will be shared), and using a secure web-interface to transmit data off-site (if data will be shared).

* Describe the procedures in place to minimize risks from all interventions performed for research purposes. This should include activities in place to identify, monitor, mitigate, and eliminate risks to the degree possible.

> Sensitive or identifiable information about providers and the organization is necessary to answer the research question(s). Data will be stored securely according to campus policy.

Privacy and Confidentiality

1. Privacy Plan

Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. In the context of research, this primarily pertains to methods used to obtain information about subjects or the setting in which research takes place.

* Explain how the subjects' privacy will be protected. (e.g., research intervention is conducted in a private room).

> This research does not involve interaction with subjects.
>
> Data collection will be limited to the amount necessary to achieve the aims of the research.

2. Level of Identifiability

This question is trying to obtain information about how subject data will be maintained. Generally, the options of "indirectly" or "anonymous" are preferred for medical records research because informed consent is often waived for these types of studies.

- If the study team will maintain a code for the duration of the study, choose "indirectly".
- If the study team will not maintain a code, choose "anonymous".
- If the study team chooses "directly", justification must be provided as to why a coding system cannot be implemented to further minimize risk of breach of confidentiality.

* Select how subjects are identified in the data. Check all that apply.

Coded or Indirect Identifiers: data includes a link to direct identifiers (e.g., name, initials, phone number, SSN, or medical record number linked to data but stored separately)

2.1. Necessity of Data

* Explain the necessity of collecting or maintaining data linked to subjects' identities.

> Provider NPIs are required to link to public information on provider characteristics (gender, graduation year, specialties), which will serve as important controls in the model.
> Organizational names are required to link to public information on hospital characteristics which will be important moderators in the model.
> Patient date of birth is required for determining patient age, which is a key control in the model. Note that all patients will be de-idenfied from the data.

2.2. Retaining Data

* How long will data linked to subjects' identities be retained?

> Provider NPIs and organization names will be retained indefinitely.

3. Data Protection Plan

Records and data include informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordings of subjects, labeled specimens, data about subjects, subject identifiers, etc.

The study team should describe how data confidentiality will be protected. Some measures that are often used and acceptable to the IRB are: using codes so that no direct subject identifiers are recorded on data collection sheets; creating codes for data that are not based on subject identifiers (i.e., avoiding codes that include subject initials or are based on birth dates); and destroying the link to the code as soon as possible.

* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss, or destruction? Include how and where the data and/or specimens will be stored.

> Only approved personnel will have access to study data.
>
> Electronic files will be stored on a Social Science Computing Cooperative's (SSCC) Silo environment, a restricted data environment for working with HIPPA or other sensitive data.

Retention of Data and or Specimens

1. Future Research Plans

* Will data and/or specimens collected for this study be banked for future research outside the scope of the current project?

(•) **Yes** ( ) No

1.1. Retention Optional

If this research does not involve enrolling and consenting subjects, select No.

* Is the retention of data and/or specimens optional?

( ) (•)

Yes **No**

1.2. Limits and External Sharing

* Explain whether there will be limits on the intended future use of the data and/or specimens (e.g., for cancer research only) and whether data and/or specimens will be shared with investigators outside the study team. If there will be no limits, state that.

> There will be no limits on the intended future use of the data.

1.3. Retention and Security Details

Responses in other sections of the application that address storage and security provisions do not need to be repeated here.

* Describe where the data and/or samples will be banked and the security provisions in place.

> Only approved personnel will have access to study data.

1.4. Anonymized Data and/or Samples

* Will all data and/or samples be anonymized prior to being banked?

○ Yes ◉ **No**

1.4.1. Confirm Future Research Policy

* Do you confirm that any future research utilizing these banked data and/or specimens will be submitted as a separate application to the IRB prior to their use?

◉ **Yes** ○ No

Waiver of Informed Consent

1. Waiver of Consent Process

If the research is limited to retrospective review of medical records or images with no interaction with subjects, select "Yes". Note: If the record review involves a small number of patients, the study team may be required to obtain informed consent.

* Are you requesting a waiver of informed consent for all components of the study?

(•) **Yes** ( ) No

2. Waiver Justification

Provide a justification for how the following criteria for a waiver of informed consent will be met:

2.1. Minimal Risk

* The study involves no more than minimal risk to the subjects.

> The study likely poses minimal risk to subjects because the activities are limited to use of data or specimens collected for another purpose and there are sufficient measures in place to protect the data.

2.2. No Adverse Effects

* The waiver will not adversely affect the rights and welfare of the subjects.

> The research likely does not adversely affect the subjects' rights and welfare because access to study data will be restricted to the study team and the use of the data is not expected to affect the subjects from whom the data are derived.

2.3. Waiver Justification

* The study could not practicably be carried out without the waiver.

> Given the number of records to be reviewed it would likely be difficult for the study team to contact the subjects in order to obtain informed consent for the use of their records for research purposes.
> Names of patients are not collected in this study.

2.4. Identifiable Data

* Can the research be practicably carried out without identifiable information or identifiable biospecimens?

○ Yes ◉ **No**

2.4.1. Identifiable Data Justification

* Please explain why the research could not be practicably carried out without identifiable information or identifiable biospecimens.

> Identifiable information on providers and hospitals will be needed to identify hospitals in order to address the research question.

HIPAA

1. Identifiable Information

* Will the research involve identifiable health information for any reason?

◉ **Yes** ○ No

1.1. UW Madison Health Care Component or Madison VA

The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; and Waisman Center (clinical units only). Ensure the PI or any study team members are covered under HIPAA Privacy Rule regulations as part of their appointment.

* Are you or any member of the study team conducting the study under an appointment that is within the UW-Madison Health Care Component (HCC) and/or Affiliated Covered Entity (ACE) or the Madison VA?

○ Yes ◉ **No**

Outside UW Madison HCC or ACE

1. Health Information Source(s)

* Select all sources of health information used, received, or analyzed in the study using the checkboxes below.

☐	Directly from subjects
☐	UW-Madison HCC or ACE
☑	**External non-federal entity holding PHI (e.g., community hospital; tertiary care center; private health insurance company)**
☐	External federal entity holding PHI (e.g., Centers for Medicare/Medicaid Services (CMS), includes ResDAC; Healthcare Cost and Utilization Project (HCUP))
☐	Other

1.1. Data Source Details

* Please describe how you will obtain this information.

> The data will be provided by the Colorado APCD CIVHC.

2. Access to Fully Identifiable Information

Fully identifiable information is data that includes direct identifiers such as name, medical record number, SSN and date of birth.

* Will you access or obtain fully identifiable health information?

○ Yes ◉ **No**

Review of Health Care Records

1. Contacting Subjects

Research conducted under this application type should be limited to a review of health records. If you will contact subjects to gather more information (e.g. via a survey or interview), a full application is required.

* Will the study involve contacting subjects to obtain additional information for this study?

○ Yes ◉ **No**

2. Data Source

Student UHS records are subject to FERPA. Please see the Investigator Manual for more information on FERPA requirements.
If accessing fully identifiable information from external sources without subject authorization, a waiver of authorization is required.

Most retrospective medical records studies involve accessing HealthLink and many extract data from departmental databases or clinic/departmental paper records.
If accessing fully identifiable information from external sources without subject authorization, a waiver of authorization is required.

* Select all of the sources of the records/data/images and, if applicable, protected health information that will be used for this study.

- ☐ HealthLink (i.e., UW Hospital & Clinics electronic medical records system, includes Swedish American)
- ☐ University Health Services records
- ☐ VA Electronic Records System
- ☐ Clinic or Departmental database
- ☑ **Other source(s) (including external sources such as UnityPoint Health-**

Meriter, ACHC)

2.1. Database or Other Source Details

* Specify the clinic/departmental database or the other sources involved.

> Provider and hospital characteristics will be linked to publicly available data on hospitals and providers.

2.2. Non-Clinical Source(s)

* Will other sources include non-clinical data?

(•) **Yes** ( ) No

3. Identification Process

Describe the patient population from whom the information from the research will be derived, such as patients undergoing X procedure at Y clinic(s).

* Describe the conditions of interest used to identify eligible records.

> The population will include all patients who were prescribed with controlled substances of abuse potential or buprenorphines and physicians who prescribed these medications in the state of Colorado.

Review of Health Care Records Cont.

1. Date Range

Full dates should be provided. When collecting data under waivers of consent and authorization, an end date is required.

* Provide the date range of the data to be collected (e.g., 1/1/1990 - 12/31/2000).

1/1/2012 - 12/31/2020

2. Data Collection Sheet

Different regulations and laws apply to different records. If you will record sensitive information like HIV status or extract free text fields (e.g. notes), it is especially important that this be reported to the IRB.

* Upload a data collection sheet or a list of all data elements that will be collected.

CIVHC_Data_Request_Form_v11_FINAL_April2023.xlsx

3. Number of Records

The number of records accessed may be more than the number of records ultimately used for the research because the study team may need to review records to determine if the desired data are in the record.

* Provide the estimated number of records/data/images that will be accessed for this project.

50000000

Secondary Use of Information

1. Identify Source(s)

Source means where the research team will obtain the data, such as from another research study or a repository.

Identify the source(s) of the data that the study team plans to obtain for a secondary use (e.g., data are being collected or exist for another purpose than for what the research team completing this application will use the data). Select all that apply.

1.1. Collected by Current Study Team

* The information was collected as part of a study or studies conducted by members of the current research team.

○ Yes ◉ **No**

1.2. Collected by Other Study Team

* The information was collected as part of a study or studies conducted by members of a different research team that will be shared with the current study team.

Yes **No**

1.3. Repository or Registry Use

* The information will be obtained from a repository or registry.

Yes **No**

1.4. Publicly Available

"Publicly available" is defined as information/biospecimens shared without conditions on use. Answer "No" if your research involves a Data Use Agreement or Material Transfer Agreement.

* The information is publicly available.

Yes **No**

1.5. Other Source(s)

* The information will be obtained from another source or sources not listed above.

Yes No

1.5.1. Other Source Details

* Identify and describe the source(s).

> Information on provider and hospital characteristics will be obtained from public online databases such as dealookup.com based on provider DEAs.

1.5.2. Information Details

* Specify the information to be obtained form the source(s).

> Information on provider characteristics, including gender, graduation year, specialty, and medical school, and hospital characteristics, including type, ranking, etc. will be obtained

1.5.3. Number Estimate

* Approximate number of individuals from whom the data were derived from the source(s).

> 1,000,000

2. IRB Review Requirements

Full committee or expedited review is often required for studies using data from dbGaP.

* Does the data or specimen provider require full committee or expedited review?

○ Yes ◉ **No**

3. Identifiable Data/Specimens

This means that the information accessed or received includes direct identifiers (name, address, email, phone number, social security number, student ID, medical record number), indirect identifiers (i.e. data elements that could be combined to identify an individual, such as dates, employment history, etc.), or a code that can be linked back to the subject.

* Can subject identity be readily ascertained (directly or through links) in the data/biospecimens accessed or received by study team members on this project?

◉ **Yes** ○ No

3.1. Type of Identifiers

Even if the study team plans on removing these identifiers and re-coding the information before the secondary analysis occurs, the study team should describe which identifiers will be included in the original data set they receive.

* Describe what identifiers you will receive along with the information (e.g., names, email or home addresses, medical record numbers, dates of service for medical procedures).

> Names and addresses of providers and hospitals will be included in the original dataset received.

3.2. Consent Upload

This question is collecting information to help the IRB determine whether the secondary use of the identifiable private information is either a) consistent with what the individuals from whom the information was derived may have agreed to or b) if individuals did not specifically agree to a secondary use of their private identifiable information, whether the additional use could be objectionable to them.

Please attach the consent form used for the original collection of the data.

There are no items to display

Supplemental Information

1. Additional Documents

Provide any additional relevant documents (e.g., data sharing agreements, letters of support, MOUs, site permission letters), if applicable.

There are no items to display

Final Page

1. Assurance

The information presented in this application is accurate;
If the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement; and
The specific aims and description of research (including subject population, subject interventions, collaborators, performance sites, and general scope of work) in this IRB application are consistent with those described in the sources of support listed as providing financial and/or material resources to conduct this study.

* Do you certify the above statements?

(•) **Yes** ( ) No

2. Complete and Submit Application Instructions

To complete and submit this application to the IRB office, please follow the steps below:

1. Select Ready to Submit or Exit on this page to be directed to the application workspace.
2. In the application workspace, click the Submit activity to send the application to the IRB office. NOTE: The Submit activity is only available to certain study team members.