PennState

Office for Research Protections
Human Research Protection Program
Office of The Senior Vice President for Research
The Pennsylvania State University
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University Park, PA 16802

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research.psu.edu/irb

EXEMPTION DETERMINATION

Date: September 26, 2024

From: Stephanie Flohr, PhD, IRB Analyst

To: Yaxian Dong

Type of Submission:	Initial Study
Title of Study:	Examining current practices of offsite and onsite coordination for prefabricated construction projects
Principal Investigator:	Yaxian Dong
Study ID:	STUDY00025624
Submission ID:	STUDY00025624
Funding:	Not Applicable
Documents Approved:	• HRP-591 - Protocol for Human Subject Research-Yaxian (September 24, 2024), Category: IRB Protocol • Interview questions (0.02), Category: Data Collection Instrument

The Human Research Protection Program determined that the proposed activity, as described in the above-referenced submission, does not require formal IRB review because the research met the criteria for exempt research according to the policies of this institution and the provisions of applicable federal regulations.

Continuing Progress Reports are **not** required for exempt research. You must notify the IRB when the exempt research study is closed/completed by completing a continuing review in CATS IRB.

Changes to exempt research only need to be submitted to the Human Research Protection Program in limited circumstances described in the below-referenced Investigator Manual. If changes are being considered and there are questions about whether IRB review is needed, please contact the Human Research Protection Program.

You will receive annual reminder notifications from CATS until the study is closed.

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Investigators are required to follow the requirements listed in the HRP-103 – Investigator Manual, which can be found by navigating to the IRB Library within CATS IRB (http://irb.psu.edu).

Investigators are also responsible for reviewing the History tab of their STUDY in CATS to ensure that any administrative HRPP requests are addressed in a timely manner.

This correspondence should be maintained with your records.

HRP-591 - Protocol for
Human Subject Research

Protocol Title:

Provide the full title of the study as listed in item 1 on the "Basic Information" page in CATS IRB (http://irb.psu.edu).

Examining current practices of offsite and onsite coordination for prefabricated construction projects

Principal Investigator:
Name: Yaxian Dong
Department: Architectural Engineering
Telephone: 8143251832
E-mail Address: yzd5221@psu.edu

Version Date:

Provide a version date for this document. This date must be updated each time this document is submitted to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

September 24, 2024.

Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable. See "HRP-103- Investigator Manual", under "ClinicalTrials.gov" for more information.

Not applicable

Important Instructions for Using This Protocol Template:

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. **GENERAL INSTRUCTIONS[1]:**
   - Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
   - Do not change the protocol template version date located in the footer of this document.
   - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
   - **GRAY INSTRUCTIONAL BOXES:** Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
     - **Do NOT delete the instructional boxes from the final version of the protocol.**
   - The protocol should be written in lay language. Do **NOT** copy and paste grant proposal information into the protocol.
   - Add the completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page.

2. **CATS IRB LIBRARY:**

[1] This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D

- Documents referenced in this protocol template (e.g., SOP's, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3. **PROTOCOL REVISIONS:**
   - When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the guides available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.
   - Update the Version Date on page 1 each time this document is submitted to the IRB office with revisions.

If you need help…

All locations:
Human Research Protection Program
Office for Research Protections
101 Technology Center
University Park, PA 16802-7014
Phone: 814-865-1775
Fax: 814-863-8699
Email: irb-orp@psu.edu
https://www.research.psu.edu/irb

Table of Contents

1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims, or objectives. State the hypotheses to be tested.

The goal of this study is to examine the current state of coordination management practices for prefabricated construction projects and identify directions for efficiency improvement clearly: 1) understand how to conduct each construction coordination task and the time consumed in each task. 2) identify implementation barriers in practice via semi-structured interviews with construction professionals, including project leaders, cost managers, etc.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study.

Research typically has a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

Researchers from the Department of Architectural Engineering, Penn State University will interview industry professionals, including cost managers, market managers, and project managers, to examine the current state of coordination management practices for prefabricated construction projects and identify directions for efficiency improvement clearly. Specifically, through a series of interviews, this study aims to understand how to conduct each construction coordination task and the time consumed in each task. In addition, this study aims to identify implementation barriers in practice via semi-structured interviews with construction professionals, including project leaders, cost managers, etc. The findings can contribute to the development of future automation technologies to facilitate coordination among offsite and onsite activities for prefabricated construction projects in practice.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

[Type protocol text here or indicate as not applicable]

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the study procedure is available to patient without taking part in the study.

For buildings, compared with traditional cast-in-situ construction, prefabricated construction has several advantages, such as a shorter construction period, better quality control, low pollution, low energy consumption, and safety improvement. Hence, as an alternative, it provides a viable solution to promote the industrialization of construction. Meanwhile, compared with traditional projects, prefabricated construction projects involve many assets manufactured from prefabricated factories at diverse

locations and subsequently transported to the construction site for assembly. Therefore, prefabricated construction projects thus have a high requirement for offsite and onsite coordination. However, in the real world, several uncertainties occurred, such as weather and natural disasters, logistical issues, worker strikes, and poor inventory, which might cause offsite and onsite activities' delays and schedule changes. If any delays happen during offsite asset deliveries, they will generally exert ripple effects on other offsite and onsite activities due to the interdependency and sequential nature of activities. Correspondingly, the overall construction progress might be impacted, such as postponement and even disruption. This could result in change orders, determination of liability, financial losses, and claims. Therefore, to avoid these potential issues, there is a need to examine the current practices of offsite and onsite coordination process to make the improvement areas clear. Existing studies have categorized the coordination tasks during this process. However, they only assessed the levels of time-consuming like high or low. In addition, how they coordinate each task is underexplored. Nevertheless, understanding how they conduct these coordination tasks and associated time consumed is important to make the process more effective. Therefore, examining the current practices and time consumed for the offsite and onsite coordination process in prefabricated construction projects is worthy of discussion.

2.2 Previous Data

Describe any relevant preliminary data.

None

2.3 Study Rationale

Provide the scientific rationale for the research.

This project will generate significant impacts on the U.S. construction industry. The investigated data through semi-structured interviews will help make the improvement areas clear by examining the current practices and time consumed for the offsite and onsite coordination process in prefabricated construction projects. More importantly, this study will promote construction project performance such as progress and cost management perspectives.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

Vulnerable Populations:

You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.
The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

- **Children –**Review "HRP-416- Checklist - Children"
- **Pregnant Women** – Review "HRP-412- Checklist - Pregnant Women"
- **Cognitively Impaired Adults-** Review "HRP-417- Checklist - Cognitively Impaired Adults"
- **Prisoners-** Review "HRP-415- Checklist - Prisoners"
- **Neonates of uncertain viability or non-viable neonates-** Review "HRP-413- Checklist - Non-Viable Neonates" or "HRP-414- Checklist - Neonates of Uncertain Viability"

[Do not type here]

3.1 Inclusion Criteria

Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.)

1. Construction industry professionals are allowed. They need to have basic knowledge and work experience in construction projects.
2. Professionals in different departments are welcomed, such as cost, project, and market. They do not need to have experience in all of these areas.
3. Project managers are preferred.
4. Aged 18 years and older.

3.1.1 Does this research involve collecting data from individuals residing outside of the US?

☒ No
☐ Yes – identify the countries where data collection will take place
[Type protocol text here]

3.2 Exclusion Criteria

Create a numbered list of the exclusion criteria that define who will be excluded in your study.

1. Less than 18 years old
2. Participants unable to provide consent.
3. Participants not belonging to the construction industry.

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

subject consent withdrawal

3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; the follow-up for subjects withdrawn from investigational treatment.

Subjects can withdraw from the study at any time. No data will be collected for withdrawn subjects. Subjects will not be replaced. There will not be a follow up with withdrawn subjects.

4.0 Recruitment Methods

- Upload recruitment materials for your study in CATS IRB (http://irb.psu.edu). **DO NOT** include the actual recruitment wording in this protocol.
- StudyFinder: If StudyFinder (http://studyfinder.psu.edu) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
- Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (http://irb.psu.edu).

[Do not type here]

4.1 Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

- If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, include this method in this section.
- Information provided in this protocol, including the description of study procedures, compensation, and recruitment, needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For research utilizing **Penn State Health patient data**, please note the following:

- Submissions using **Enterprise Information Management (EIM)** for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form in CATS IRB (http://irb.psu.edu). See "HRP-103- Investigator Manual, Study Recruitment" for additional information.
- Direct contact with patients for research recruitment that does not occur in person will require review of the contact list by Penn State Health's contracted mail company, **Allegra**. See the following for additional information: https://pennstatehealth.sharepoint.com/COM-IT%20Resources/SitePages/Data%20&%20Analytic%20Services.aspx (Penn State Health ePass login required).

DO NOT include the actual recruitment material or wording in this protocol.

We will recruit them from our collaborative industry partners, including "Penn State Office of Physical Plant" and "The Partnership for Achieving Construction Excellence".
Penn State Office of Physical Plant: https://www.opp.psu.edu/
The Partnership for Achieving Construction Excellence: https://pace.psu.edu/

4.2 Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate 'not applicable' if subjects will not be prospectively recruited to participate in the research.
Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio).

If applicable, state whether the study team will access medical records before or after engaging the potential subject.

DO NOT include the actual recruitment material or wording in this protocol.

[Do not type here]

4.2.1 How potential subjects will be recruited.

Researchers in Penn State University will contact our industry partners by emails and phone numbers to recruit industry professionals. Partners can forward recruitment information to their employees. The employees who accept the interview invitations will reach out to our study team by the email address we attach in the recruitment information.

We use snowball techniques to recruit more subjects. Research participants can share recruitment information with others and share contact information of potential participants with the study team. To avoid ethical issues, during recruitment, the study team will not share the referred persons about who referred them and provided their contact information.

4.2.2 Where potential subjects will be recruited.

At participating the institution of Penn State University.

4.2.3 When potential subjects will be recruited.

August 2024 and Fall 2024.

4.2.4 Screening and determining eligibility

Screening involves the process of assessing whether or not a potential subject is eligible for a study based on the inclusion and exclusion criteria. This process only involves assessing the eligibility and collecting information/data/biospecimens that is not related to eligibility does not meet the definition of screening and requires prior written consent.

There are some specific situations in which consent is not required prior to screening activities, and otherwise, consent is required prior to screening. Answer the following items in order to describe the screening process and determine if prior consent is required.

4.2.4.1 For the purpose of screening/determining eligibility, is the potential subject providing information through oral or written communication (e.g. survey or verbally responding to answers)?

☒ Yes

To determine eligibility, the potential subject needs to provide these information (age, position, department, and years of work experience) through oral communication at the beginning of the interview (verbally respond to answers).

☐ No

4.2.4.2 Is eligibility being determined by obtaining identifiable private information or biospecimens by accessing records or stored identifiable biospecimens?

☐ Yes [NOTE: HIPAA authorization or a waiver of HIPAA authorization may be necessary – see section 6.0]

[Describe what is being accessed here]

☒ No

4.2.4.3 Is the potential subject being asked to do any activity for screening and eligibility purposes beyond what is described above (e.g. fast, blood test)?

☐ Yes [NOTE: consent process or waiver of consent is required – see section 5.0]

[Describe the activity here]

☒ No

4.2.4.4 Is the screening data to be used for purposes other than eligibility or recruitment (e.g. retained for data analysis or for other purposes)?

☐ Yes [NOTE: consent process or waiver of consent is required – see section 5.0]

[Describe the other purposes here]

☒ No

5.0 Consent Process and Documentation

Refer to the following materials:

- The "HRP-090- SOP - Informed Consent Process for Research" outlines the process for obtaining informed consent.
- The "HRP-091– SOP - Written Documentation of Consent" describes how the consent process will be documented.
- The "HRP-314- Worksheet - Criteria for Approval" section 7 lists the required elements of consent.
- The "HRP-312- Worksheet - Exemption Determination" includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
- The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
- Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu). Links to Penn State's consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

5.1 Consent Process:

Check all applicable boxes below (at least one of the first four boxes must be checked):

☐ **Informed consent will be sought and documented with a written consent form** *[Complete Sections 5.2 and 5.6; If this is the only box checked, mark Sections 5.3, 5.4 and 5.5 as 'Not applicable']*

☒ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent)** *[Complete Sections 5.2, 5.3 and 5.6; If this is the only box checked, mark Sections 5.4 and 5.5 as 'Not applicable']*

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).** *[Complete section 5.2, 5.4 and 5.6; If this is the only box checked, mark Section 5.5 as 'Not applicable']*

☐ **Informed consent will not be obtained** *[Complete Section 5.5; If this is the only box checked, mark Sections 5.2, 5.3, 5.4 and 5.6 as 'Not applicable']*

If you believe that the research activities outlined meet one or more of the criteria outlined in "HRP-312- Worksheet- Exemption Determination", check the following box in addition to a consent checkbox above.

☒ **Exempt Research - By checking this box, you are verifying that the consent process will disclose the following:**

- **For all research**: Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; permission for use of data can be withdrawn for research activities involving the collection and use of identifiable data.

- **For research that uses student educational records:** the records that may be used; the purpose of using those records; the party or class of parties to whom the records may be shared; and that if an adult student (or a parent of a student who is not an adult) requests, the school will provide them with a copy of the records shared. Additionally, the parent or adult student will *sign and date* the consent.

Note: If this box has been checked, mark Sections 5.3, 5.4, 5.5, and 5.6 as "Not applicable." If the investigator's assessment is inaccurate, an IRB Analyst will request revision to the protocol and ask that consent forms and recruitment materials be submitted. Except for exemptions where Limited IRB Review is required (see "HRP-312- Worksheet- Exemption Determination") or where otherwise requested by the IRB, consent forms and recruitment materials are generally not reviewed nor approved by the PSU HRPP for research undergoing exempt review.

5.2 Obtaining Informed Consent

5.2.1 Consent Process

Describe the consent process (when, where, and how), including how subjects indicate consent. If there are multiple consent processes, describe each process separately.

The consent form and the interview questions will be sent to subjects by email for review in advance. Subjects will verbally agree prior to the beginning of the interview.

5.2.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

No payment will be given to industrial professionals.
Recruitment materials will be addressed to subjects and the study team at Penn State University to minimize potential for coercion / undue influence in their decision to participate.

5.3 Waiver of Written Documentation of Consent

Review "HRP – 411 – Checklist – Waiver of Written Documentation of Consent."

5.3.1 Indicate which of the following conditions applies to this research:

☐ The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

For distinct cultural groups, describe the alternative mechanism for documenting that informed consent was obtained:

[Type protocol text here]

5.3.2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, or implied consent form)

The consent form and the interview questions will be sent to subjects by email for review of this research in advance.

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.4.1 Indicate the elements of informed consent to be omitted or altered

Not applicable.

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

Not applicable.

5.4.3 Describe why the research involves no more than minimal risk to subjects.

Not applicable.

5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

Not applicable.

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

Not applicable.

5.4.6 Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

Not applicable.

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

Not applicable.

5.5.2 Describe why the research involves no more than minimal risk to subjects.

Not applicable.

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

Not applicable.

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

Not applicable.

5.5.5 Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation.

Not applicable.

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review "HRP-091 –SOP- Written Documentation of Consent" and "HRP-103 -Investigator Manual" to ensure that you have provided sufficient information.

Not applicable.

5.6.2 Cognitively Impaired Adults

Refer "HRP-417 -CHECKLIST- Cognitively Impaired Adults" for information about research involving cognitively impaired adults as subjects.

5.6.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

Not applicable.

5.6.2.2 Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual's authority to consent to research.

For research conducted in the state of Pennsylvania, review "HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "legally authorized representative."

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013 - SOP- Legally Authorized Representatives, Children, and Guardians."

Not applicable.

5.6.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Not applicable.

5.6.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual's authority to consent to each child's general medical care.

For research conducted in the state of Pennsylvania, review "HRP-013-SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "children."

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians."

Not applicable.

5.6.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

Not applicable.

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See "HRP-103 -Investigator Manual" for a list of the 18 identifiers.

[Do not type here]

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ **Not applicable, no identifiable protected health information (PHI) is accessed, used, or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Signed authorization will be obtained and documented.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver for recruitment purposes only (e.g. if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration to waive requirement for written documentation of authorization (e.g. verbal or implied authorization).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

This section is about the disclosure of PHI as it relates to the requested authorization waiver and/or alteration. Complete each item in this section in relation to each requested waiver of authorization and/or alteration (the last three boxes in Item #6.1). For example, if requesting a partial waiver for recruitment, these items need to address the PHI for recruitment rather than addressing the use of PHI for the entire study.

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER
If the research does not involve a waiver or alteration of authorization, <u>remove</u> the statement and indicate as <u>not applicable</u>.

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol or in "HRP-598 – Research Data Plan Review Form".
Not applicable.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers (associated with the waiver and/or alteration of authorization) at the earliest opportunity that is consistent with the conduct of the research. Include when and how identifiers will be destroyed.

If identifiers are to be retained, provide the legal, health or research justification for retaining the identifiers.

Not applicable.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide reasons why this research could not practicably be carried out without access to and use of PHI (that is requested in the waiver and/or related to the alteration of authorization).

Not applicable.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide reasons why this research could not practicably be carried out without the waiver and/or alternation of authorization. If more than one waiver and/or alteration of authorization (e.g. waiver for recruitment and alteration for verbal authorization) is requested, make sure to provide reasoning for each request.

Not applicable.

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER.
If the research does not involve a waiver or alteration of authorization, remove the statement and indicate as not applicable.

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

Not applicable.

7.0 Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (http://irb.psu.edu). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions).

[Do not type here]

7.1 Study Design

Describe and explain the study design.

We use the semi-interview method to examine the five aspects of construction coordination tasks: 1) identifying or gathering information on ambiguities in drawings; 2) identifying variances from the schedule; 3) coordinating and rescheduling the sequence of onsite work; 4) communicating project progress, plans, schedules, and changes, to all relevant participants; 5) resolving conflicts and differences among participants). The five aspects of interview questions are based on the scenario set (4th-floor precast beams delay 2 days; 4th-floor precast slabs delay 1 day). Participants are required to recall the typical time, common methods, effectiveness, and current challenges of completing each coordination task. We list the interview questions and upload them into the system as supplementary material.

7.2 Study Procedures

Provide a step-by-step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

- HOW: (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.) For surveys, indicate if subjects are able to skip questions that they don't want to answer.

- WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

Interview will be conducted in hybrid models. In-person interview will be selected first at the conference room in Department of Architectural Engineering, Penn State University. If interviewees cannot make it work, the online model will be used as an alternative model by video call or voice call through Zoom. Participants can skip questions if needed. After getting the permission of interviewees, we will type interviewees' responses to the interview questions in Penn State OneDrive file to record their interview contents using electronic notes as records, instead of directly recording audio or video in the zoom meeting or physical meeting. Content analysis will be conducted to these responses to identify the main time-consuming coordination tasks. The process will keep the same for subjects with different positions.

7.2.1 Visit 1 or Day 1 or Pre-test, etc.

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and delete 7.2.2.

Before the interview, we will obtain consent in advance. We will also share interview questions in advance. After the interview, the thank messages will be sent to the participant.

7.2.2 Visit 2 or Day 2 or Post-test, etc. (If applicable)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.). If your study involves only one session or visit, delete this section.

Not applicable.

7.3 Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

Half an hour to an hour per interviewee.

8.0 Number of Subjects and Statistical Plan

8.1 Number of Subjects

Indicate the maximum number of subjects to be accrued/enrolled, to include all persons who sign consent for the study. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

More than 5 interviewees will be recruited. The maximum number is 15.

8.2 Sample Size Determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

More than 5 participants are required since we need to ensure that the insights are not based on an individual's experience but are representative. The maximum number of 15 is because in most qualitative research, saturation point is typically reached after around 10-15 participants, which indicates that more participants stop revealing new insights and thus are unnecessary.

8.3 Statistical or Analytic Methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Content analysis will be used to analyze interview content and descriptive analysis will be conducted to summarize main time-consuming coordination tasks that interviewees identified.

9.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects as defined in "HRP-001 SOP- Definitions."

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Please complete each section below if the research involves more than minimal risk to subjects or indicate not applicable.

[Do not type here]

9.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Not applicable as this does not meet criteria for minimal risk.

9.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

Not applicable.

9.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

Not applicable.

9.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

Not applicable.

9.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Not applicable.

9.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

Not applicable.

9.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

Not applicable.

9.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

Not applicable.

10.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. **Note: Loss of confidentiality is a potential risk when conducting human subject research and must be listed here.**

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

Loss of confidentiality is a potential risk.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.

None

11.2 Potential Benefits to Others

Describe the potential benefits to society or others.

Identifying existing practices and barriers can help to advance a more efficient coordination process in the offsite and onsite activities of prefabricated construction projects, which will benefit everyone within the project and foster trust among all parties.

12.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how information will be shared.

Research results, e.g., conference and journal papers, will be shared with subjects. These results will not include any confidential information.

13.0 Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

No payment

14.0 Economic Burden to Subjects

14.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

Not applicable.

14.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

Not applicable.

15.0 Resources Available

15.1 Facilities and locations

Identify and describe the facilities, sites, and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

The interview will be conducted in the local areas of Penn State. Online interviews are conducted via Zoom.

15.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

More than 5 subjects are required with the maximum number of 15.

15.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Consider outside responsibilities as well as other on-going research for which the PI is responsible. Please only provide a response for the principal investigator – do **not** include information about any other study team members.

PI, as a PhD candidate, has completed all courses and currently devoted all her work time to research topics. This research is one important part of her research topics. With no other outside responsibilities, the PI can allocate the majority of her work time to this study. Although PI does have other research work, this study is prioritized due to its foundational nature as the examination of current industry practices, with some findings directly influencing subsequent research direction. Therefore, PI has a sufficient amount of time to conduct and complete the research.

15.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study.

Not applicable.

15.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties.

Before recruiting participants and conducting interviews, a meeting will be organized by the main researcher Yaxian Dong to communicate the protocol with other team members.

16.0 Other Approvals

16.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

[Type protocol text here or indicate as not applicable]

16.2 Internal PSU Ancillary Reviews

DO NOT ALTER OR DELETE:
Ancillary reviews are reviewed by other compliance groups or individuals within Penn State that inform the IRB's review of a new study or a modification to an existing study.

PSU IRB may set applicable ancillary reviews for your study. Please refer to the "HRP-309 Worksheet – Ancillary Review Matrix" for more information (found in the CATS Library).

[Do not type here]

17.0 Multi-Site Study

If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and **the Penn State PI is the lead investigator**, describe the processes to ensure communication among sites in the sections below.

[Do not type here]

17.1 Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

Not applicable.

17.2 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results, and closure of the study.

Not applicable.

17.3 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

Not applicable.

17.4 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

Not applicable.

17.5 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

Not applicable.

17.6 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

Not applicable.

18.0 Adverse Event Reporting

18.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

19.0 Study Monitoring, Auditing, and Inspecting

19.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

20.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting **identifiable** data and/or specimens that will be banked for **future undetermined research**, please describe this process in the sections below. This information should not conflict with information provided in section 22 below OR the "HRP-598 – Research Data Plan Review Form" regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If there are no plans to use identifiable data/specimens for future, undetermined research, then this section is **NOT applicable**.

[Do not type here]

20.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored, and the data associated with each specimen.

Not applicable.

20.2 Location of storage

Identify the location where the data and/or specimens will be stored.

Not applicable.

20.3 Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate such.

Not applicable.

20.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

Not applicable.

20.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

Not applicable.

20.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

Not applicable.

21.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

Not applicable.

22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598 Research Data Plan Review Form." In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form."

In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all sub-sections of section 22.

For all other research: Complete the following section. Please refer to PSU Policy AD95 for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State's Policy AD95 or standards or need a consultation regarding data security, please contact Penn State IT – Information Security at security@psu.edu.

22.1 Which of the following identifiers will be recorded for the research project? Check all that apply. If none of the following identifiers will be recorded, do not check any of the boxes.

	Hard Copy Data	Electronic Stored Data
Names and/or initials (including on signed consent documents)	☐	☒
All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes,	☐	☐
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	☐	☐
Telephone numbers	☐	☒
Fax numbers	☐	☐
Electronic mail addresses	☐	☒
Social security numbers	☐	☐
Medical record numbers	☐	☐
Health plan beneficiary numbers	☐	☐
Account numbers	☐	☐

Certificate/license numbers	☐	☐
Vehicle identifiers and serial numbers, including 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	☐	☐
Any other unique identifying number, characteristic, or code (such as the pathology number)	☐	☐
Study code number with linking list	☐	☐
Genomic sequence data	☐	☐
State ID numbers	☐	☐
Passport numbers	☐	☐
Driver's license numbers	☐	☐

22.2 If storing paper records of research data, answer the following questions:

We use electronic notes as records rather than paper records.

22.2.1 Where will the paper records, including copies of signed consent forms, associated with this research study will be stored?

Not applicable

22.2.2 How will the paper records be secured?

Not applicable

22.2.3 How will access to the paper records be restricted to authorized project personnel?

Not applicable

22.3 If storing electronic records of research data, indicate where the electronic data associated with this research study will be stored. Check all that apply.

☒ Penn State-provided database application. Check which of the following database applications are being used (check all that apply):

- ☐ Penn State REDCap
- ☐ Other – Specify - provided and approved database application:
  [Type protocol text here if box checked]

- ☐ Penn State, College, or Department IT file server
- ☒ Penn State OneDrive or SharePoint
- ☐ Penn State GoogleDrive
- ☐ Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:
  [Type protocol text here if box checked]

☐ Other – Specify the database application or server:
[Type protocol text here if box checked]

Provide details about the data security features or attach security documentation provided by sponsor or group:

[Type protocol text here if box checked]

Please visit datastoragefinder.psu.edu and https://security.psu.edu/awareness/storage/ for assistance with identifying appropriate data storage options. If the software to be used does not appear on that site, please visit https://procurement.psu.edu/electronic-click-through-contracts to consider whether a software request form must be completed.

If there is a list/key that links indirect identifiers (code numbers, participant IDs, etc.) to direct identifiers, that list must **not** be comingled (i.e., stored in the same location) as the identifiable data, including copies of signed informed consent forms. Additionally, access to that list/key must be restricted to authorized project personnel.

22.4 Is there a list/key that links code numbers to identifiers?

☐ Yes - explain how the list that links the code to identifiers is stored separately from coded data:
[Type protocol text here if box is checked]

☒ Not applicable, there is no list that links code numbers to identifiers. Skip to section 22.6.

22.5 Is there a list of people who have access to the list/key?

☐ Yes – explain how access to that list is restricted and why certain persons require access.
[Type protocol text here if box is checked]

☐ No – explain why not:
[Type protocol text here if box is checked]

22.6 Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).

☐ Password-protected files
☒ Role-based security
☐ Specify all other mechanisms used to ensure only permitted users have access to the stored research data:

We use Penn State OneDrive to store research data. Only study team members can have access to the files containing the electronic records of research data.

The use of mobile devices or wireless activity trackers to collect identifiable research data may have to be approved by Penn State IT - Information Security.

22.7 Will research data be collected and/or stored on a wireless activity tracker or mobile application or will the study team enter research data on a mobile device, such as an electronic tablet or cell phone?

☒ No – skip to 22.8
☐ Yes - answer the following questions:

22.7.1 Specify the provider of the tracker or mobile devices(s)/application

☐ Supplied by the sponsor
☐ Penn State owned device
☐ A personal device
☐ Other – Please specify source: [Type protocol text here if box is checked]

22.7.2 Specify the type(s) of tracker or mobile device(s)/application that will be used to capture data and all identifiers captured on the mobile device(s)/application. Please list all devices, and if more than one, the identifiers to be collected on each.

[Type protocol text here]

22.7.3 Specify the type of data collected on the tracker or mobile devices(s)/application.

[Type protocol text here]

22.7.4 Specify the application or website used to collect the data from the tracker or mobile device, if applicable.

[Type protocol text here]

22.7.5 Describe the measures taken to protect the confidentiality of the data collected on the tracker or mobile device(s)/application. Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 22.3.

[Type protocol text here]

The use of online survey tools and email to collect or send research data containing identifiers that represent more than minimal risk to subjects may have to be approved by Penn State IT - Information Security.

22.8 Will any research data be directly entered/sent by subjects over the internet or via email (e.g., data capture using on-line surveys/questionnaires, surveys via email, observation of chat rooms or blogs)?

☒ No – skip to 22.9
☐ Yes - answer the following questions:

22.8.1 Specify the identifiers collected over the internet or via email (Including IP addresses if IP addresses will be collected).

[Type protocol text here]

22.8.2 Specify the type of data collected over the internet or via email.

[Type protocol text here]

22.8.3 Describe the measures taken to protect the confidentiality of the data collected?

[Type protocol text here]

22.8.4 Describe how the research team will access the data once data collection is complete.

[Type protocol text here]

22.8.5 If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s) (e.g., REDCap, Penn State licensed Qualtrics, Survey Monkey,

Zoomerang)? (Note: The IRB strongly recommends the use of REDCap for online surveys that obtain sensitive identifiable human subjects data.)

☐ Penn State REDCap
☐ Penn State Qualtrics
☐ Penn State Microsoft Forms
☐ Penn State Google Forms
☐ Other - Please specify:
Application: [Type protocol text here]
URL (If applicable): [Type protocol text here]

Depending on the nature of the subject matter involved, certain security requirements must be in place for the audio and/or video recording or photographing of subjects. Subject matter that presents more than minimal risk to subjects may have to be approved by Penn State IT - Information Security.

22.9 Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study?

☒ No - skip to section 22.10
☐ Yes - answer the following questions:

We do not record any type of information for subjects themselves. Although we conduct the interviews either in-person or online Zoom meeting, we do not directly record the meetings (e.g., audio or video). We take notes for participants' responses to interview questions through Penn State OneDrive.

22.9.1 What will be used to capture the audio/video/images? Give a brief description of content.

☐ Audio – Describe the intended content of the audio recording:
[Type protocol text here]

☐ Video – Describe the intended content of the video recording:
[Type protocol text here]

☐ Photographs of the subjects – Describe the intended content of the photographs:
[Type protocol text here]

☐ 3-D Images – Describe the intended content of the of 3-D images:
[Type protocol text here]

☐ Other - Specify:
[Type protocol text here]

22.9.2 How will the recordings/photographs/images be stored (electronically or physically)?

[Type protocol text here]

22.9.3 Where will the recordings/photographs/images be stored?

[Type protocol text here]

22.9.4 Who will have access to the recordings/photographs/images?

[Type protocol text here]

22.9.5 Will any of the recordings be transcribed?

☐ Not applicable
☐ No
☐ Yes – indicate who will be doing the transcribing?
[Type protocol text here]

22.9.6 Will the recordings/photographs be used for purposes other than this research study?

☐ No
☐ Yes - specify purpose(s) (e.g., publication, presentations, educational training, future undetermined research):
[Type protocol text here]

22.10 Certificate of Confidentiality (COC) - Is the research biomedical, behavioral, clinical or other research that is funded by the National Institutes of Health (NIH)?

☐ Yes - check one of the following:
- ☐ The research involves human subjects as defined by the DHHS regulations (See Worksheet HRP-310).
- ☐ The research involves collecting or using biospecimens that are identifiable to an individual.
- ☐ If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
- ☐ The research involves the generation of individual level, human genomic data.

Note: If <u>any</u> of the 4 items above are checked, a COC is automatically issued by NIH and applies to the research. Information about the COC must be included in the consent form.

☒ No - answer the following question.

If the research is not funded by NIH, will the investigator apply for a COC for this research study?

☒ No
☐ Yes

Note: For research not funded by NIH, the IRB may require a COC if the research is collecting personally identifiable information and the information is sensitive and/or the research is collecting information that if disclosed could significantly harm or damage the subject.

22.11 What steps will be taken to protect subjects' privacy interests? (Check all that apply.)

☒ Identification and recruitment of potential subjects follows procedures consistent with privacy standards
☒ Consent discussion and research interventions will take place in a private setting
☒ Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes
☒ Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process
☐ Other – Specify:
[Type protocol text here]

22.12 What is the process for ensuring correctness of data entry?

☒ Double data entry to reduce risk of errors
☐ Electronic edit checks to ensure data being entered are not obviously incorrect

☐ Random internal quality and assurance checking of research data
☐ Direct entry by subjects
☐ Other - Specify:
[Type protocol text here]

22.13 Does this research involve the generation of large-scale human genomic data as defined in NIH Genomic Data Sharing Policy (http://gds.nih.gov)?

☒ No
☐ Yes – describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.
[Type protocol text here]

Note: Data sharing with an NIH-designated data repository may require execution of an institutional certificate. Please review the 'Institutional Certification for NIH Genomic Data Sharing' section of the Investigator's Manual for information about seeking institutional certification.

22.14 Does this research involve data sharing to public/restricted data repositories or as part of a journal requirement?

Data sharing is an important part of rigorous scientific discovery and the validation of results. Planning for data sharing is *strongly recommended*.

Data sharing includes sharing of identifiable, coded, or de-identified data. The data can be shared with public or restricted data repositories. Increasingly, journals require the sharing of data as a stipulation for publication. NIH-funded studies **require data sharing**, unless explicitly granted an exception from the NIH.

☐ No
☒ Yes (*strongly recommended* as may be required for publication and future grant submission)

22.14.1 What type of data will be shared: De-identified, identifiable (if identifiable, list the identifiers that will be shared)

De-identified data:
For participants, we just share their position, type of organization (general contractor, design and construction service providers, etc.,), and work experience (year).

We need to share participants' responses to the interview questions, including the typical time, common methods, effectiveness, and current challenges of completing the five coordination tasks. 1) identifying or gathering information on ambiguities in drawings; 2) identifying variances from the schedule; 3) coordinating and rescheduling the sequence of onsite work; 4) communicating project progress, plans, schedules, and changes, to all relevant participants; 5) resolving conflicts and differences among participants.

22.14.2 What type of repository will be used to share the data: Public, controlled, etc. Note: The specific name of the repository is not necessary.

The data will be shared through a controlled-access repository.

22.15 Does this research involve transfer or disclosure of data and/or specimens to and/or from Penn State?

☒ No - skip the remainder of section 22.15

☐ Yes - answer the following questions:

Check all that apply:

22.15.1 ☐ **Data** are being transferred or disclosed **to** Penn State

What is the name of the third party(ies) (the institution, sponsor, etc.) sending or providing the data?

[Type protocol text here]

22.15.1.1 Is the third party requiring us to sign a contract regarding the data?

☐ Yes - this contract must go through the Office of Sponsored Programs
https://www.research.psu.edu/osp/overview-pages/data-use-agreements

☐ No

22.15.2 ☐ **Data** are being transferred or disclosed **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving or accessing the data?

[Type protocol text here]

Note: Data transfers or disclosures may require a Data Use Agreement (DUA).

22.15.3 ☐ **Specimens** are being transferred **to** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) sending the specimens?

[Type protocol text here]

22.15.4 ☐ **Specimens** are being transferred **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving the specimens?

[Type protocol text here]

Note: All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA). Please contact the Office of Technology Management for more information.

22.15.5 Describe how the data/specimens will be securely transferred or disclosed to/from the third party(ies).

We use Penn State OneDrive to store the interview data and only study team members can have access to the file containing these data.

22.15.6 How are the research data/specimens being transferred from and/or sent to the third party(ies)? Complete the appropriate section(s) and check all that apply within each completed section.

22.15.6.1 Data being transferred or disclosed **to** Penn State**:**

- ☐ Data are being received in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded research data without any identifiers are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7 aside from Study Code) are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7) are being received and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being received
- ☐ Other – Specify:
  [Type protocol text here if box is checked]

22.15.6.2 Data being transferred or disclosed **from** Penn State**:**

- ☐ Data are being sent in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded research data without any identifiers are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7 aside from Study Code) are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7) are being sent and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being sent
- ☐ Other – Specify:
  [Type protocol text here if box is checked]

22.15.6.3 Specimens being transferred or disclosed **to** Penn State**:**

- ☐ De-identified specimens are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded specimens without any identifiers are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7 aside from Study Code) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list
☐ Coded specimens with identifiers along with the linking list are being received
☐ Other – Specify:
[Type protocol text here if box is checked]

22.15.6.4 Specimens being transferred or disclosed **from** Penn State**:**

☐ De-identified specimens are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
☐ Coded specimens without any identifiers are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7 aside from Study Code) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.7) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list
☐ Coded specimens with identifiers along with the linking list are being sent
☐ Other – Specify:
[Type protocol text here if box is checked]

22.15.7 If transferring data/specimens with identifiers to or from Penn State, which of the following identifiers will be included with the data/specimens? Check all that apply:

☐ Names	☐ Medical record numbers
☐ Initials	☐ Health plan beneficiary numbers
☐ Street address	☐ Account numbers
☐ City	☐ Certificate/license numbers
☐ Driver's License numbers	☐ Passport numbers
☐ State	☐ State ID numbers
☐ Zip Codes	☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ County	☐ Device identifiers and serial numbers
☐ Geocodes	☐ Web Universal Resource Locators (URLs)
☐ Precincts	☐ Internet Protocol (IP) address numbers
☐ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death	☐ Biometric identifiers, including finger and voice prints
☐ Ages > 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	☐ Full face photographic images and any comparable images

☐ Telephone numbers	☐ Any other unique identifying number, characteristic, or code (such as the pathology number) Specify: [Type protocol text here if box is checked]
☐ Fax numbers	☐ Study code numbers
☐ Electronic mail addresses	☐ Master list linking study code numbers to subject(s)
☐ Social security numbers	☐ Genomic sequence data
	☐ Other – specify: [Type protocol text here if box is checked]

Construction coordination tasks

Interview questions: (Scenario: 4th-floor precast beams delay 2 days; 4th-floor precast slabs delay 1 day.)

1. Identifying or gathering information on ambiguities in drawings

    What methods do you use to identify and clarify these ambiguities?

    How much time do you typically spend resolving ambiguities in drawings?

    How effective are the current processes in resolving drawing ambiguities?

    What are the challenges in identifying or gathering information on ambiguities in drawings?

2. Identifying variances from the schedule

    How do you detect these variances?

    How much time do you spend identifying schedule variances?

    Where do you usually find schedule variances?

    What are the challenges in identifying variances from the project schedule?

3. Coordinating and rescheduling the sequence of onsite work

    What tools or processes do you use when coordinating and rescheduling the sequence of onsite work?

    How much time does it typically take to reschedule and coordinate the sequence of onsite tasks?

    How effective is rescheduling the sequence of onsite work due to certain offsite assets' delivery variances?

    What are the challenges in rescheduling onsite work due to offsite asset delivery variance?

4. Communicating project progress, plans, schedules, and changes, to all relevant participants

    How do you currently communicate project progress, plans, schedules, and changes to all relevant participants?

    How much time is spent on communicating the updated schedule to all relevant participants?

    How effective are the current communication practices in keeping everyone updated?

    What challenges do you face when informing all relevant participants?

5. Resolving conflicts and differences among participants

    How do you resolve conflicts or differences arising among project participants?

    What processes are in place more likely to cause these conflicts or differences?

    How much time does it usually take to resolve conflicts and differences among participants?

    What are the challenges in resolving conflicts and maintaining project progress?

HRP-509 Study Team Member Qualifications

Template Version 11/2/2021

Instructions

DO NOT ENABLE TRACK CHANGES WHEN MODIFYING THIS DOCUMENT. Effective 09/01/2021, the PSU HRPP no longer requires completion of this form for all study team members. Examples of when this form may be required include but are not limited to:

- Those study team members who will perform research procedures requiring special expertise or credentials above and beyond what is typically expected in the course of research conduct and/or clinical care;
- Individuals conducting biomedical procedures in a non-clinical setting;
- Student and faculty advisor for those projects that designate the student as Principal Investigator;
- Individuals participating in the research via execution of an Individual Investigator Agreement.

Note, all study team members will still need to be listed in Question #1 on the Study Team Member page of CATS. The Principal Investigator (PI) should be listed on the Basic Information page of CATS.

Please note: If you will be listing more than four (4) Study Team Members, duplicate the questions below and extend the template to provide the information for each additional member. Likewise, if you will be listing fewer than four (4) Study Team Members, remove the additional un-needed questions below.

Instructions for Individuals Using Visual Assistive Technology (e.g., JAWS)

- There are form fields and instructional text that are outside of the form fields, so the best way to navigate through this document is to use the down arrow key.

- To navigate through the checkbox options, after hearing "select all that apply," down arrow once for the list of options. When reaching an individual checkbox, use the Home button to move to the front of the line and right arrow once to hear the properties of the form field. Use the spacebar to check or uncheck the box. You may need to down arrow and then up arrow again for confirmation on whether the checkbox is checked.

- This document includes entry fields for the PI and up to four study team members. If you are using visual assistive technology (i.e., a screen reader) and more than four team members need to be added, email ORP@psu.edu to request a new version of this document. Do not complete this document until the new version is provided. If you are not using a screen reader, you may simply copy and paste any additional fields needed.

Principal Investigator

1. **Full Name (First Name followed by Last Name).**

   Yaxian Dong

2. Provide the individual's responsibilities for this research study (e.g., recruitment, protocol development, data analysis/management, performing tests/procedures). Check all boxes that apply.

☒Involved in consent
☒Recruitment activities, including identification of potential subjects/records
☒Protocol development
☒ Data analysis/management at any time in the course of the study
☒ IRB submissions
☒Data collection, e.g., survey, interviews, focus group, at study visits
☐Collection of biological specimens by non-invasive means, e.g., urine without a Foley catheter, hair/nail clippings, uncannulated saliva, mucosal and skin cells collected by buccal scrapping or swab, etc.
☐Research laboratory testing
☐Procedures/tests requiring clinical degree, certification, licensure, or demonstrated competency such as ECG, EEG, physical exams/assessments, venipuncture, etc.
☐Procedures/tests not requiring clinical degree, certification, or licensure
☒Review/assessment (severity, attribution, etc.) of data collected as part of the study, e.g., adverse event data, ECGs, laboratory test results, radiographic scans, etc. (check only for appropriately qualified study team members). Note: Final review must be completed by Principal Investigator.
☐Oversight of student investigator
☐Other responsibilities: If other, please specify:
Specify PI's other responsibilities here.

3. Describe the individual's qualifications related to this individual's responsibilities (e.g., years of education, certification, license, degrees, etc.).

Yaxian possesses qualifications in the construction domain. She holds a Master degree in Civil Engineering from National University of Singapore and a Bachelor degree in construction cost from Chongqing University, completed over 6 years of studies in construction domain. Currently, as a graduate research assistant and 3rd-year PhD candidate at Penn State, she passed the qualification exam in Department of Architectural Engineering. She has the necessary skills and knowledge to construction domain.

4. Describe the individual's research experience or training related to this individual's responsibilities.

Yaxian has conducted research about prefabricated construction projects for 2 years. Currently, She has completed and published some related papers. "BIM and Blockchain-Based Automatic Asset Tracking in Digital Twins for Modular Construction": this paper is about how to improve the automation of offsite and onsite construction tasks in modular construction. Additionally, she has another published paper which involved survey design, required IRB, data collection, and analysis. "Building Diversity in the Construction Industry: Examining Hiring and Performance Evaluation Practices for Equipment Operators under the Trend of Technology Transformation". In summary, she has qualified knowledge and relevant qualitative research experience with design of survey, questionnaire etc., and data collection and analysis.

Study Team Member #1

1. Full Name (First Name followed by Last Name).

Yuqing Hu

2. Provide the individual's responsibilities for this research study (e.g., recruitment, protocol development, data analysis/management, performing tests/procedures). Check all boxes that apply.

☒Recruitment activities, including identification of potential subjects/records
☒Protocol development
☒Data analysis/management at any time in the course of the study
☒IRB submissions
☐Data collection, e.g., survey, interviews, focus group, at study visits
☐Collection of biological specimens by non-invasive means, e.g., urine without a Foley catheter, hair/nail clippings, uncannulated saliva, mucosal and skin cells collected by buccal scrapping or swab, etc.
☐Research laboratory testing
☐Procedures/tests requiring clinical degree, certification, licensure, or demonstrated competency such as ECG, EEG, physical exams/assessments, venipuncture, etc.
☐Procedures/tests not requiring clinical degree, certification, or licensure
☒Review/assessment (severity, attribution, etc.) of data collected as part of the study, e.g., adverse event data, ECGs, laboratory test results, radiographic scans, etc. (check only for appropriately qualified study team members). Note: Final review must be completed by Principal Investigator.
☒Oversight of student investigator
☐Other responsibilities: If other, please specify:
Specify other responsibilities for team member 1 here.

3. Describe the individual's qualifications related to this individual's responsibilities (e.g., years of education, certification, license, degrees, etc.).

Dr. Hu is an Assistant Professor at the Department of Architecture Engineering at Pennsylvania State University. Her general research interests lie in using Building Information Modeling (BIM) and graph-based artificial intelligence to improve design and construction automation. Dr. Hu holds a doctorate in Building Construction, and a Master's in Computational Science & Engineering from the Georgia Institute of Technology and earned Bachelor's and Master's of Science degrees from Tongji University in Engineering Management and Management Science & Engineering. She completed her studies about 11 years in the construction domain.

4. Describe the individual's research experience or training related to this individual's responsibilities.

Dr. Hu has been an Assistant Professor at the Department of Architecture Engineering at Pennsylvania State University for over 4 years. She has a good ability to guide PhD students and Master students to do research work. She has solid understanding and experience in qualitative research and construction domain. Her responsibility in this study is mainly oversighting the PhD student, including reviewing all documents and providing revision suggestions throughout whole process. The papers mentioned above are guided by Dr. Hu.

At the completion of this document, please attach document to Question #2 on the Study Team Member page in CATS IRB.