Research 201

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School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

Departmental Protocol Feasibility Assessments

New SMPH/ICTR-mandated Departmental Protocol Feasibility assessment will be implemented for all non-exempt protocols:

- Research conducted by UW SMPH faculty and fellows, and students will undergo departmental-level feasibility assessment prior to IRB review
- Feasibility Reviews will require Chair (or designee) sign-off, attesting that the study is operational feasible
- Mandatory once implemented: IRB will send the submission back if submitted without approved feasibility form
- Some divisions have this type of review during protocol development, which is ideal

Protocol Feasibility: What is it?

It is a mechanism to assess every non-exempt human subjects protocol prior to submission to the HS- IRB to ensure that it is operationally feasible, based on the following domains:

Table 1: Required Feasibility Domains	
• Scholarly merit	• Stakeholder Endorsement (Collaborators)
• Fiscal (Funding)	• Acceptable Clinical Practice
• Personnel (Appropriate and trained)	• Recruitment (Cohort Analysis)
• Space and Facilities	• Multi-Site Investigator Initiated Research
• Equipment and Test Articles	* **HIPAA privacy and data security considerations**

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Protocol Feasibility as a Shared Mission

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Departmental Role

Can the study investigator and site successfully conduct the project?

- **PI has the necessary skills, experience and time**
- **Available resources**
- **Other personnel skills, expertise, and available effort**
- **Feasible plan for successful patient recruitment**
- **Key local stakeholder commitment**
- **Strong local implementation plan**

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Scientific Review Committee Role

Does the protocol represent "good science?"

- Appropriate study design
- Sufficient objectives and outcomes
- Scientifically meritorious; adequate rationale
- Eligibility criteria
- Statistical analysis and sample size
- Data management and monitoring
- PI and study site qualifications and resources
- Subject population is appropriate to answer the scientific question
- Statistical considerations (i.e., sample size/justification, estimated accrual and duration) are adequate to meet study objectives

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IRB Role

Is the study ethically sound?

- **Social or Scientific Value**
- **Scientific Validity**
- **Fair Subject Selection**
- **Favorable Risk - Benefit**
- **Independent Review**
- **Informed Consent**
- **Respect for Potential and Enrolled Subjects**

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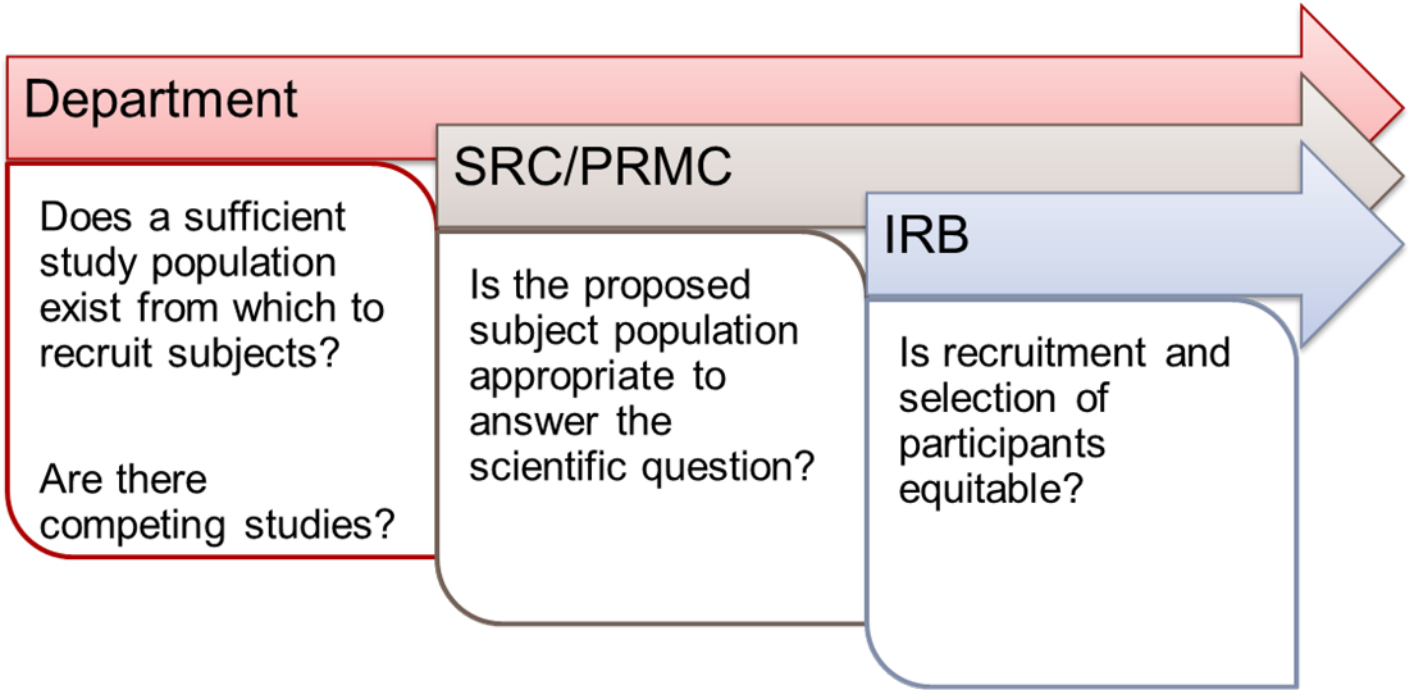
Assessing subject selection and recruitment: Example of collaborative approach



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Protocol Feasibility: WHO?

- The Chair (or designee(s)) is required to complete the feasibility review and sign off on a ‘Feasibility Attestation Form’ that will be uploaded into the ARROW protocol application under ‘Protocol Feasibility’ before the submission can be submitted.

- IN DOM, Shari Zeldin is the Chair designee for protocol feasibility attestation sign-off

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RESEARCH FEASIBILITY ATTESTATION FORM

PRINCIPAL INVESTIGATOR	
Name *(Last, first)*	**Title** Choose an item.
Department	**Email**
POINT OF CONTACT (IF OTHER THAN PI)	
Name *(Last, first)*	**Email**
STUDY TITLE	

Feasibility Domain	Feasible (Agree)	N/A
Department & Scholarly Merit		
The study aligns with department priorities or has the potential for scholarly output (e.g., publications).	☐	☐
Fiscal		
External/internal funding sources have been/will be secured and are/will be sufficient to cover total study budget expenses inclusive of regulatory (e.g., IRB) and non-departmental ancillary program/service fees (e.g., UW Health; Pharmaceutical Research Center; Clinical Research Unit, Office of Clinical Trials).	☐	☐
Personnel		
All personnel engaged in this study: • have appropriate experience, credentials, and training; • have sufficient time available to conduct the research; • are performing study activities commensurate with their job description and scope of practice; and • are appropriately supervised and monitored.	☐	☐
Space/Facility		
Appropriate approvals and safeguards are in place for both clinical and non-clinical space and facilities where study activities may occur. Type and risk-level of procedures have been accounted for when selecting space and facilities.	☐	☐
Equipment and Test Articles		
• Equipment used in the study will be appropriately housed, inventoried, certified, and returned, as applicable. • Investigational and commercially available test articles (e.g., drugs, devices) will be procured, inventoried, stored, secured, dispensed, labeled and disposed of in accordance with FDA regulations and institutional policies.	☐	☐
Constituent Endorsement		
Departments, clinics, and other operational units that may be impacted by, or provide services for, the research (e.g., informatics, pharmacy, nursing, laboratory, and imaging) have been informed of and support the conduct of this study.	☐	☐
Acceptable Clinical Practice		
The proposed research utilizes acceptable practice for the discipline.	☐	☐

Feasibility Domain	Feasible (Agree)	N/A
Recruitment		
• If there are similar studies that will draw from the same subject population, there is a plan in place to address competing recruitment goals.	☐	☐
• A sufficient study population pool exists from which to recruit and the recruitment plan proposed supports achievement of target recruitment goals.	☐	☐
Multi-Site Investigator-Initiated Research		
If SMPH will serve as the lead institution of a multi-site investigator-initiated study, the other performance sites have/will be vetted. If performance sites have not yet been selected, the study is likely to solicit the interest of a sufficient number of investigators.	☐	☐
Data Security and EHR Considerations		
• For studies requiring automated electronic health record data extraction (EHR), modification(s) to EHR functionality or complex data transformation, ICTR Biomedical Informatics has been informed and agreed to support.	☐	☐
• Safeguards are present for the secure collection, storage and retention of protected health information, and necessary data agreements (e.g., Data Use Agreement, Business Associate Agreement) have/will be obtained.	☐	☐
• ICTR Biomedical Informatics has pledged support for Research Computing Platform.	☐	☐
• Safeguards are present for the secure data transfer for multi-site studies.	☐	☐

OTHER

Is this a multi-site, investigator-initiated study in which UW is the lead institution?

☐ Yes
☐ No

Will this study involve data exchange or data extraction from Health Link or other sources of patient data (e.g., MyChart, tumor registry)?

☐ Yes
☐ No
☐ Unsure (for assistance making this determination please contact *ICTR Biomedical Informatics*)

COMMENTS

The signature(s) below indicate the proposed research study has underwent feasibility assessment by the PI and appropriate individuals in accordance with departmental procedures, and the necessary resources are available to successfully implement and complete the study.

Principal Investigator (Optional)	**Department Chair or Designee (Required)**
Signature Date	Signature Date
Name	Name
Title	Title

DOM Protocol Feasibility Intake Form

Resize font:

DOM Research Protocol Feasibility Intake Form

Please complete the survey.

Principal Investigator

Name (Last, first)
* must provide value

Title
* must provide value

Divisions/Institutes
* must provide value

Email
* must provide value

Point of Contact (If other than PI)

Name (Last, first)

Email

Study Details

Study Title
* must provide value

Will this study be going through the Office of Clinical Trials?

- Yes
- No

reset

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Atttachments

Protocol

Upload document

Attach Additional document?

(i.e. Division protocol review form, if applicable)

- Yes
- No

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Protocol Feasibility Considerations

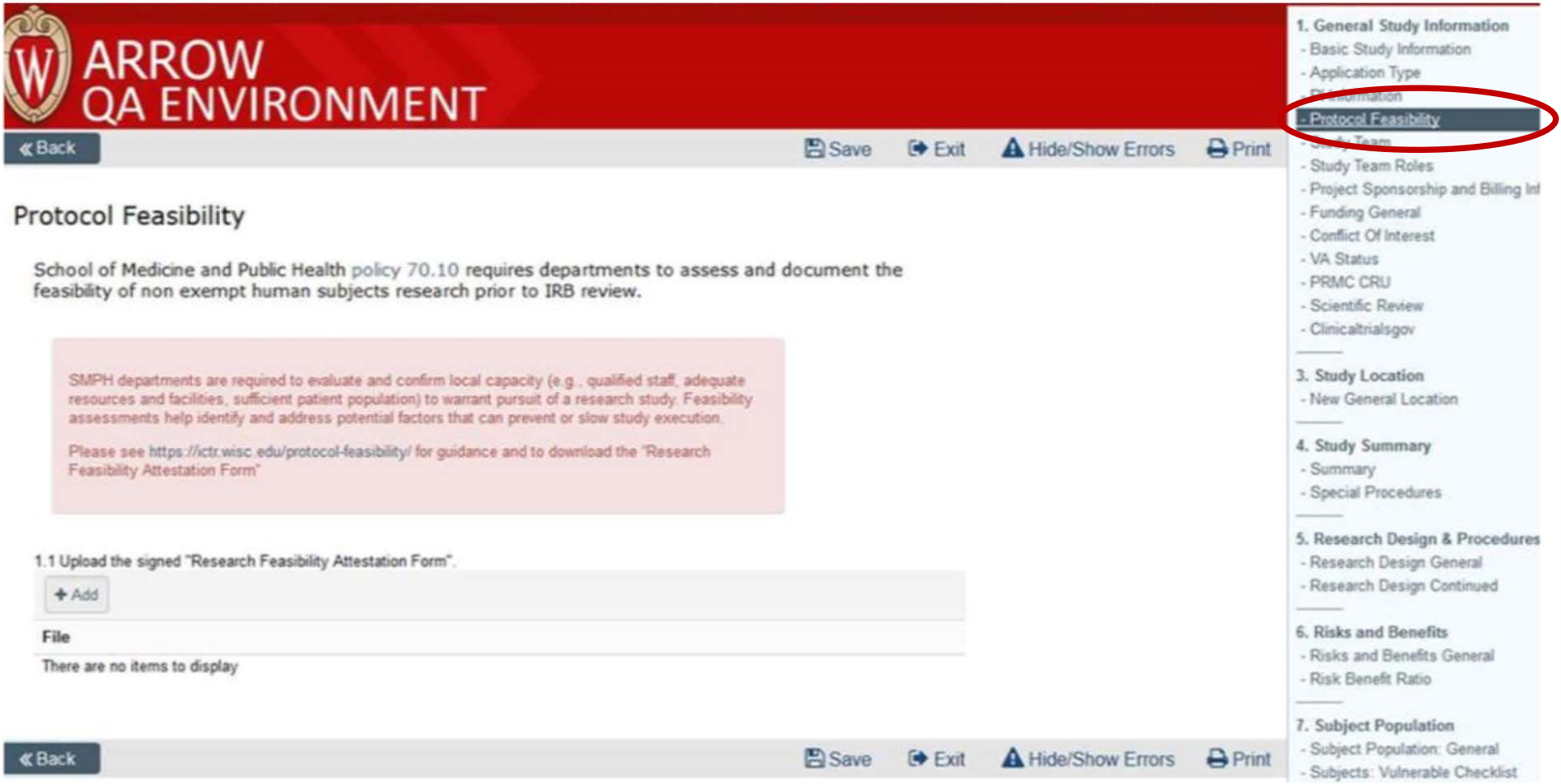
	Yes	No	Unknown	N/A	
1. Is external and/or internal funding sufficient to cover total study budget expenses inclusive of regulatory and non-departmental ancillary program/services?					reset
2. Have other departments, clinics, or operational units that may be impacted by, or provide services for, the research (e.g., Clinical Research Unit, Office of Clinical Trials, informatics, pharmacy, nursing, laboratory, and imaging) been informed and agreed to support the conduct of the study?					reset
3. Are similar studies open to enrollment or under consideration that will draw from the same subject population?					reset
⇨ If there are similar studies that will draw the same subject population, is there a plan in place to address competing recruitment goals?					reset
4. Is there empirical data that a sufficient study population exists from which to recruit subjects?					reset
5. Are the following data and/or sample issues identified: ⇨ How the data and/or samples are securely collected, stored and shared?					reset
6. Does the investigator possess the adequate time commitment to oversee the study?					reset

How to access DOM Protocol Feasibility workflow and intake form:

Medicine.wisc.edu>Research> Protocol Feasibility

http://www.medicine.wisc.edu/research/protocol-feasibility

ARROW after June 1



Tips:

- You can continue past the protocol feasibility page in ARROW to complete your application.
- When you have received the signed attestation form from Shari for the protocol, you go back into application and upload the form in the protocol feasibility section before submitting.
- If your division has a mechanism to assess and document feasibility, there is a document upload function on the intake form that will allow you to include the feasibility documentation.

Resources to learn more about Protocol Feasibility

SMPH Policy:
https://uwmadison.app.box.com/s/hanufyhktjs4ppyiuh09518mko93wokh

SMPH/ICTR Feasibility Assessment webpage:
https://ictr.wisc.edu/protocol-feasibility/

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