Protocol Review

CREW Training Series

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Research

University of Mississippi Medical Center

Objectives

- Define the purpose of a protocol
- Identify protocol components
- Critically read a protocol and understand the implications for study conduct

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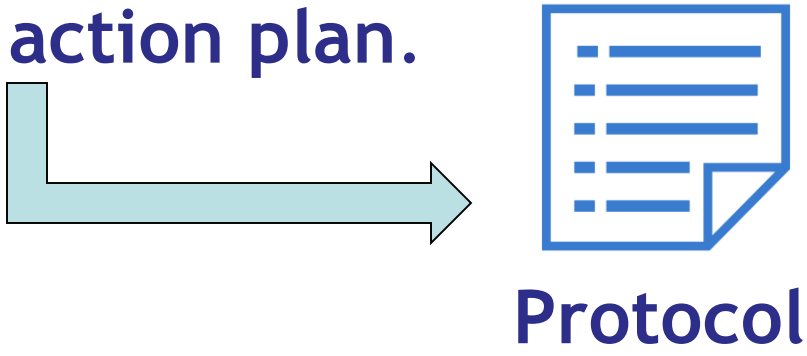
What is a Protocol?

- Clinical research is conducted according to a **plan or an action plan.**



Protocol

- The protocol demonstrates the guidelines for conducting the study.
  - Provides the details of the study.
  - Explains how the study will be conducted.

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What is the Purpose of a Protocol?

- Ensures that the research study procedures are consistently carried out.
- Helps the study team to prepare for the conduct of the study and to determine required resources and services.
  - Eligibility of the participants
  - Length of the study
  - Treatments/Interventions involved
  - Related tests required

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What are the Protocol Components?

CLINICAL TRIAL PROTOCOL	
General Information	Statistics
Background Information	Direct Access to Source Data/Documents
Trial Objectives and Purpose	Quality Control and Quality Assurance
Trial Design	Ethics
Selection and Withdrawal of Subjects	Data Handling and Record Keeping
Treatment of Subjects	Financing and Insurance
Assessment of Efficacy	Publication Policy
Assessment of Safety	Supplements

Adopted from the ICH Good Clinical Practice Guidelines

Note: *Each IRB or Sponsor will have their own protocol template.*

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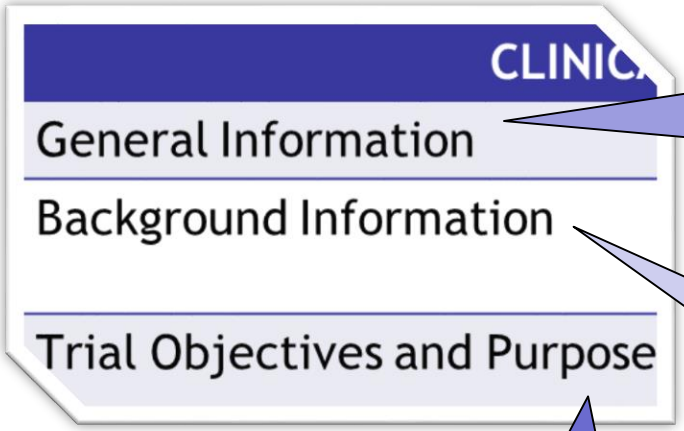
Role of Protocol Components



- Provides basic information regarding the study.
  - Protocol title
  - Contact details of the sponsor, monitor, or PI

- Provides the goals of the study.
- Explains why the study is being conducted.

- Provides the relevance of the study.
  - Description of study drug or intervention
  - Potential risks or benefits
  - Population to be studied
  - References to literature

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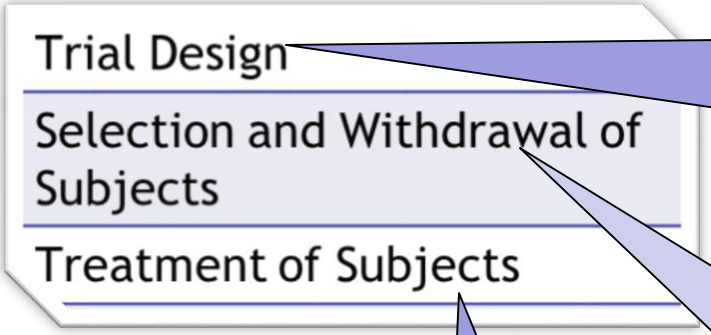
Role of Protocol Components



- Explains how the study will be conducted.
  - Methodology (procedures, treatment, measurements, etc.)
  - Data Collection
  - Timelines

Describes who will be a part of the study, inclusion and exclusion criteria.

Describes the treatment or intervention method, schedule, and other details.

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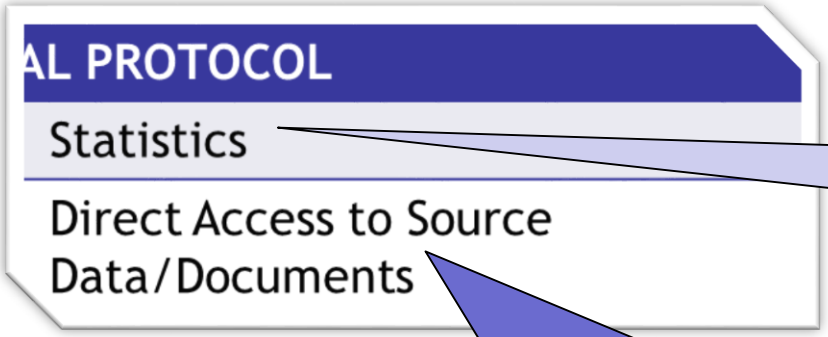
Role of Protocol Components

Specifies procedures and measurements to evaluate the safety and effectiveness of the study.



Describes how data will be analyzed.

Specifies sponsor monitoring, audits, IRB/IEC review, regulatory inspection(s), and access to source data/documents.

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UMMC IRB Research Protocol Template

RESEARCH PROTOCOL

Title	
Principle Investigator/Co-investigators	
Abstract	A brief (200 words or less) description of your project featuring research question, significance, design, and outcome determination
Background	What work exists that has led up to your research question? Has anything similar been done before? How would your work contribute to the knowledge base and possibly affect clinical practice? Do not exceed one page. Use no more than ten references and list the references in the reference section below.
Purpose	This should include your research question and could include a hypothesis, if appropriate.
Specific Aim(s)	Specific aim(s) is(are) the objective(s) of your research – what you want to accomplish. Specific aim(s) should be driven by your hypothesis.
Study Period (inclusive years)	Over what period of time will the study be conducted?
Data Generation Period	For record review only studies, identify the period of time (beginning and ending dates) during which the records were generated (day/month/year)
Study Design	What type of study are you designing? Cohort, case-controlled, case series? How is the study designed to answer your hypothesis and specific aim(s)?

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UMMC IRB Research Protocol Template

Inclusion Criteria	Criteria that will identify the study population
Exclusion Criteria	List all exclusion criteria* *exclusion is a subset of inclusion – identify anything that will exclude those who meet inclusion
Number of Participants/ Records to be reviewed (anticipated)	
Outcome Measures	How will the results be interpreted? How will your outcomes be measured?
Study Endpoints	At what point will you measure outcomes?
Protected Health Information (PHI)	Protected Health Information is any information (identifiers and personal health information) that was created, used or disclosed in the course of providing a health care service and that can be used to identify an individual. Describe the PHI that will be accessed. If PHI will also be collected, describe the PHI that will be collected. NOTE: HIPAA requires the PHI accessed/collected/used be the minimum necessary to accomplish the purpose. How will private health information (PHI – identifiers plus personal health information) be protected? Who will have access? How will PHI be maintained and in what format (de-identified, coded, with identifiers)? If PHI will be collected with identifiers, at UMMC it must be maintained in REDCap. Please contact the Center for Informatics and Analytics for more information. If PHI will not be collected with identifiers, how will your database be secured?

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UMMC IRB Research Protocol Template

Statistical Methodology	This is important. You will want to consult with a statistician on this part. You want to reduce confounding variables, particularly in retrospective studies. A statistician will help you do this. Also, the statistician can help you determine the desirable study population and design outcome measures that will lend themselves to statistical inference.
References	Pertinent references should be listed. Make sure your study has not already been done recently. If so, you must explain why your study is different and should be done.
Data Collection Sheet	This is a form that is used to record the information that will be collected and used in outcome measurements. The data collection sheet should be included in your proposal. If a separate key with identifiable information will be used, that sheet should also be included. If questionnaires/surveys will be used, they should be included in your proposal.
Funding Source	Is funding necessary? If so, to what funding source have or will you apply/who will cover costs?

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Key for Protocol Review

- When you look through a protocol, keep in mind what specific information you need from the protocol for study planning and activation.
  - Participant Selection
  - Treatment/ Intervention Details
  - Study Treatments
  - Study Procedures and Guidelines
  - Adverse Event Reporting and Documentation
  - Data Collection/ Management

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Usefulness of a Protocol

EXHIBIT A-1 - CLINICAL TRIAL BUDGET

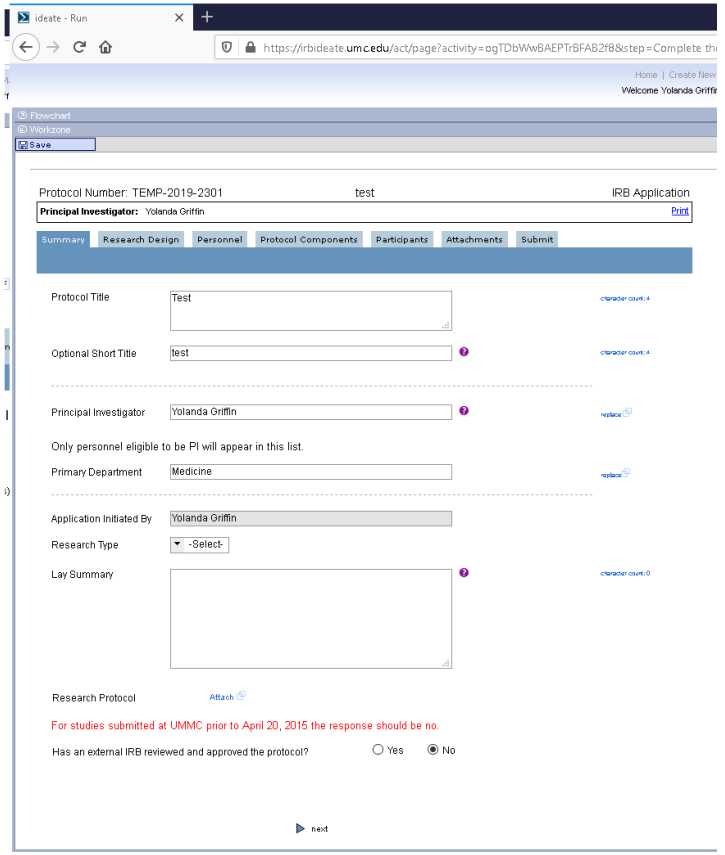
Study Details

Protocol Number
Protocol Title
Phase
Indication Bronchopulmonary dysplasia (BPD) in preterm infants
Institution Name / PI* University of Mississippi Medical Center
Institution Overhead Percentage 31%

*PI listed is PI assigned as time of contract execution, institution may update from time to time with no need to amend this Exhibit A-1.

Subject Visit Costs	Overhead	Total Quantity	Cost	Post Treatment Phase									Long Term Outcome Phase		STUDY TOTAL
				Screening Visit	Baseline Visit	Combined Screening/ Baseline[1]	24 Hours Post Dose	72 Hours Post Dose	7 Days Post Dose	Weekly (Until 36 Weeks PMA)	36 Weeks PMA	40 Weeks PMA/ Hospital Discharge/ Early Term	6 Month Phone Contact	1 Year Visit	
Study Day				-45 Hours to Baseline	1	1	2	4	8	15, 22, 29, 36, 43, 50, 57, 64, 71, 78, and 85	80 up to 88	78 up to 116			
Procedure Costs															
Parental Informed Consent	31%	2	150.00	150.00		150.00									150.00
Subject Eligibility	31%	3	65.00	65.00	65.00	65.00									130.00
Medical History and Demographics	31%	2	114.50	114.50		114.50									114.50
Maternal History	31%	2	114.50	114.50		114.50									114.50
Length, Head Circumference	31%	5	15.25		15.25	15.25					15.25	15.25		15.25	61.00
Blood Draw and Clinical Lab Assessments	31%	4	279.00		279.00	279.00		279.00			279.00				837.00
Predefined Complications of Prematurity	31%	8	30.00		30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00			210.00
Vital Signs, including weight	31%	9	30.50	30.50	213.50	213.50	30.50	30.50	30.50	30.50	30.50	30.50			427.00
Physical Examination	31%	3	225.00		225.00	225.00					225.00				225.00
Oxygen Saturation - Pulse Oxemitry	31%	8	25.00		25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00			175.00
Tracheal Aspirate	31%	2	95.00		95.00	95.00									95.00
Concomitant Medications	31%	8	44.00		44.00	44.00	44.00	44.00	44.00	44.00	44.00	44.00			308.00
Adverse Events	31%	9	60.00	60.00	60.00	60.00	60.00	60.00	60.00	60.00	60.00	60.00			480.00
UNICAP/Placebo Administration - Infusion	31%	2	150.00		150.00	150.00									150.00
Incidence and Severity of BPD	31%	1	30.00								30.00				30.00
Assessment of General Health and Serious Adverse Reactions	31%	2	100.00										100.00	100.00	200.00
Non-Procedure Costs															
Study Coordinator / Nurse - Per Visit	31%	10	155.50	233.25	311.00	388.75	155.50	155.50	155.50	155.50	155.50	155.50		155.50	1,632.75
Data Entry	31%	11	60.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	1,200.00
Principal Investigator - Per Visit	31%	10	225.00	225.00	225.00	225.00	225.00	225.00	225.00	225.00	225.00	225.00		225.00	2,025.00
Pharmacy Dispensing Fee - Per Visit (study drug)	31%	2	120.00		120.00	120.00									120.00
Subject Visit Costs Sub Total (US$)				$1,112.75	$1,977.75	$2,434.50	$690.00	$969.00	$690.00	$690.00	$1,239.25	$705.25	$220.00	$615.75	$8,909.75
Overhead				$344.95	$613.10	$754.70	$213.90	$300.39	$213.90	$213.90	$384.17	$218.63	$68.20	$190.88	$2,762.02
Total Subject Visit Costs with Overhead(US$)				**$1,457.70**	**$2,590.85**	**$3,189.20**	**$903.90**	**$1,269.39**	**$903.90**	**$903.90**	**$1,623.42**	**$923.88**	**$288.20**	**$806.63**	**$11,671.77**
Total Cost Per Patient (US$)[1]												$10,576.94		$1,094.83	$11,671.77

Note 1: For purposes of calculating per subject total, the combined screening/baseline has been removed and total assumes those will occur separately. If this is done as combination visit the total cost per patient will be reduced accordingly.



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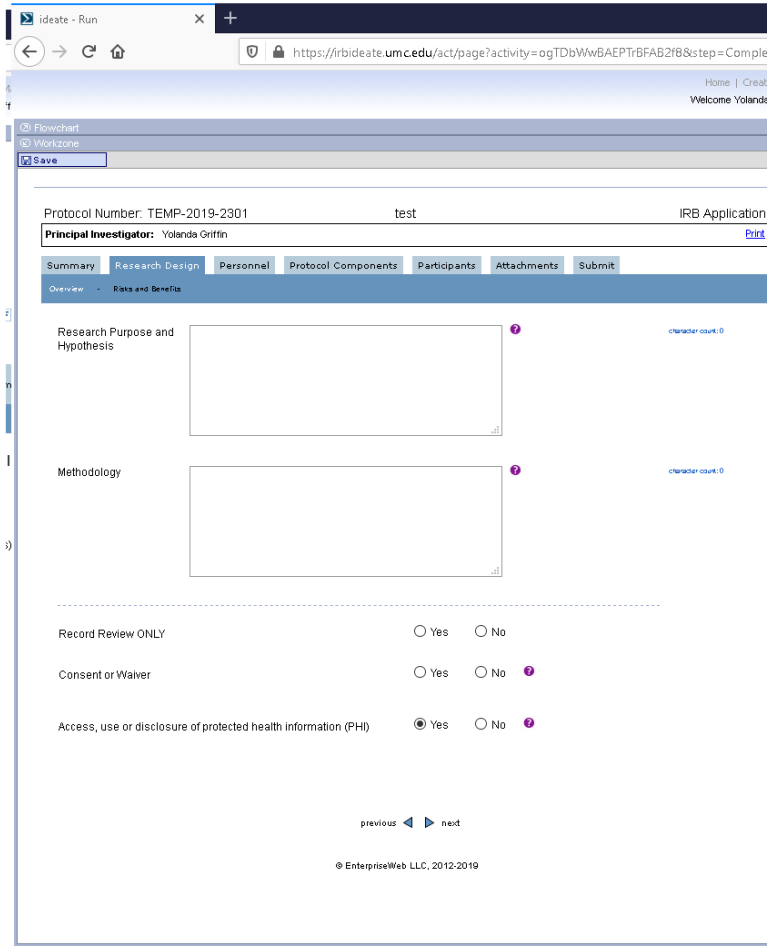
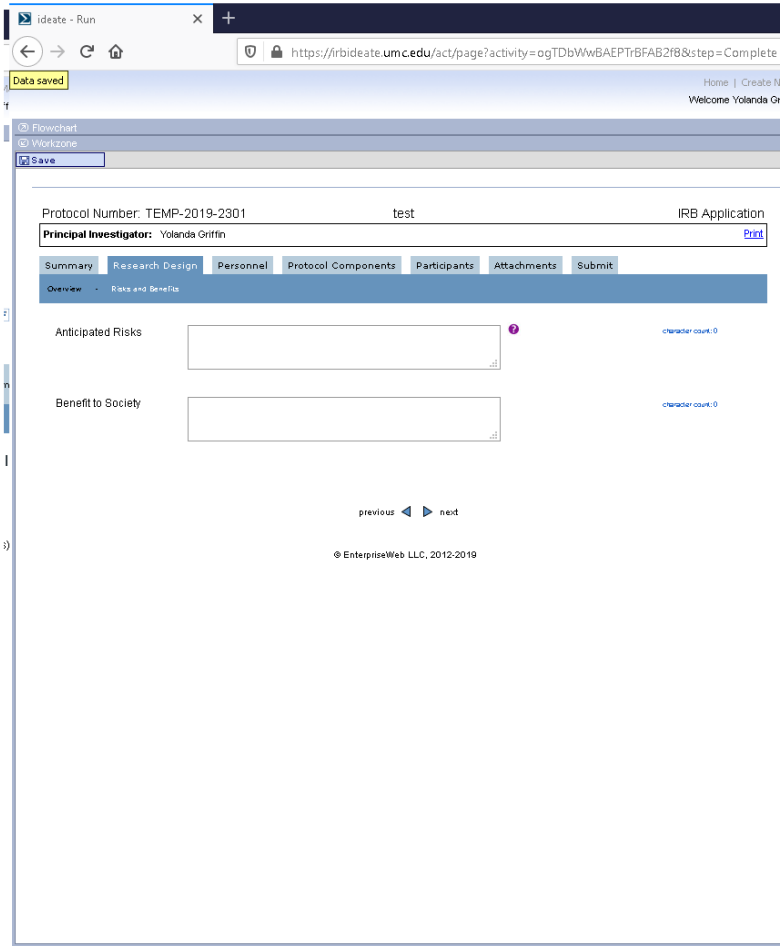
Usefulness of a Protocol





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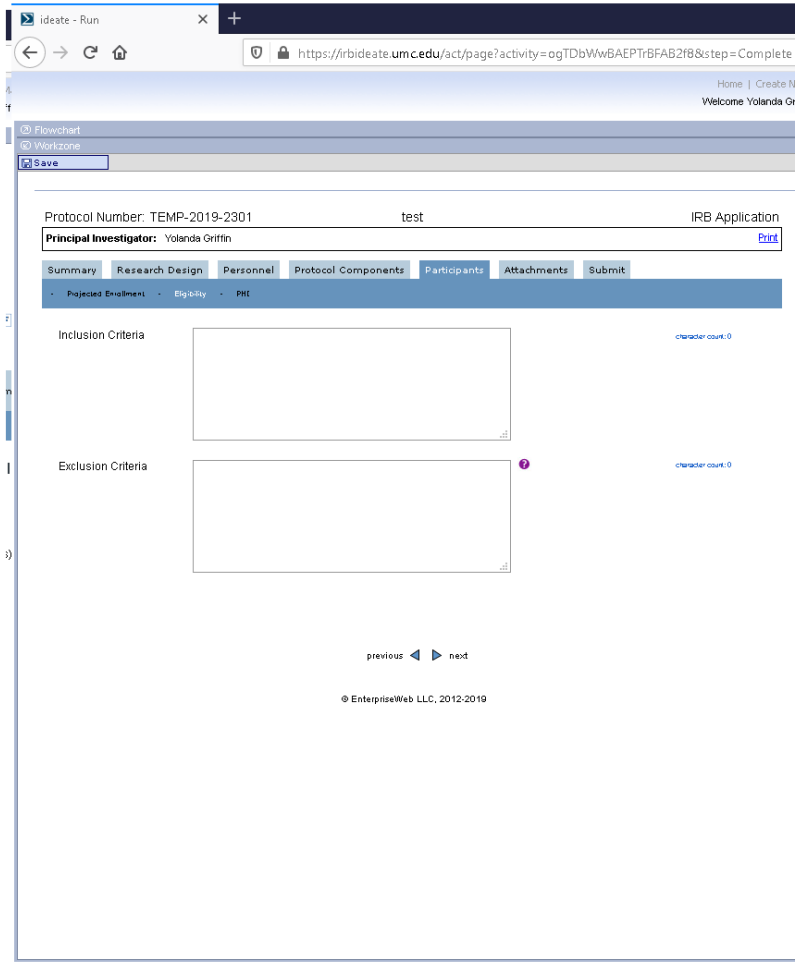

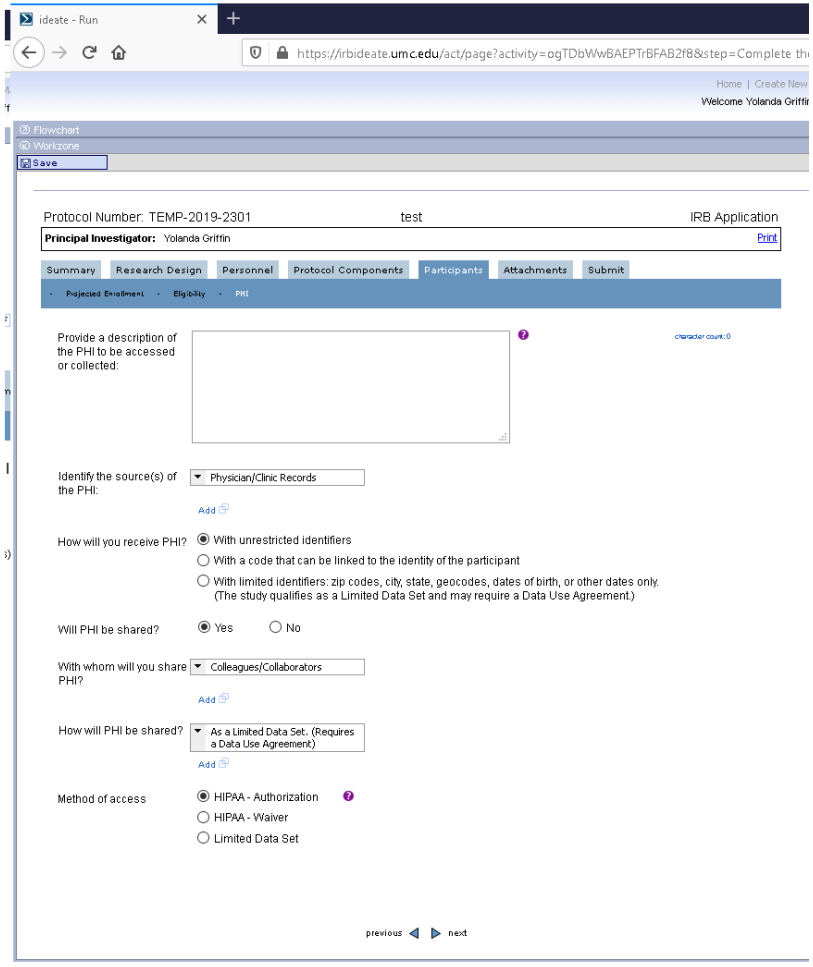

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Wrap-Up

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