Workflow and Implementation

The site selection and negotiation process of GW Medical Faculty Associate (GW MFA) research trials involves a collaborative process between the GW MFA study team, the clinical trial sponsor, MFA Business Operation Unit, and the OnCore Project Manager to ensure that the study is conducted efficiently, safely, and in compliance with all applicable regulations and guidelines.

This process typically includes the following steps:

1. *Site identification and assessment:* Clinical trial sponsor selects GW MFA as a suitable site for the research trial based on various factors, such as clinical capabilities, patient population, and experience with similar trials.

2. *Protocol shell creation:* In OnCore offers a template that contains the basic structure and framework of a study, including the study design, inclusion and exclusion criteria, treatment arms, study endpoints, and other essential elements. By starting with a pre-designed template, study teams can avoid starting from scratch and instead focus on customizing the template to meet the study's specific needs. This can help ensure consistency across studies and reduce errors or omissions.

3. *Task lists in OnCore:* This feature allows research staff to track and manage the tasks that must be completed for a specific study or protocol. Task lists can be customized to fit the needs of each study, and tasks can be assigned to specific individuals or groups. The task list can also include due dates, status updates, and comments to help keep the study team on track and ensure that tasks are completed on time. This feature helps streamline communication and collaboration within the study team and ensures that all necessary tasks are completed on time.

4. *Negotiation:* Formal negotiations typically involve discussions of the study budget, payment terms, and other contractual terms and conditions.

5. *Agreement execution*: Once the study team and GW MFA site have reached an agreement on the terms and conditions of the trial, a contract is executed. This contract outlines the roles and responsibilities of each party, as well as the terms of payment and other essential details.

6. *Calendar and budget build:* Advarra's clinical trial management consulting services can provide guidance and support for study calendar, and budget builds. Advarra can help create realistic study calendars, identify potential study expenses, and negotiate study budgets with sponsors. Advarra's team can also review and analyze study budgets to ensure they are comprehensive and accurate. Once the research coordinator signs the required builds off in OnCore, the study will be open to accrual by OnCore Project

Manager, triggering Epic activation.

7. *Participant recruitment and enrollment:* The study team and GW MFA site staff work together to identify potential study participants. This may involve recruiting participants from the site's patient population and other sources.

8. *Trial conduct:* After the contract is executed, the study team and GW MFA site work together to conduct the trial in accordance with the agreed-upon protocol and other study documents. This involves ongoing communication and collaboration to ensure the trial is conducted efficiently, safely, and in compliance with all applicable regulations and guidelines. Throughout the study, the study team and GW MFA site staff work closely to manage study activities, monitor participant visits, accurately collect and enter data, manage study finances, and communicate with participants and other stakeholders.

9. *Study closeout and reporting:* At the end of the study, the study team and GW MFA site staff work together to complete study closeout activities, such as finalizing data collection and analysis, submitting study reports, and archiving study materials.