Should Your Study Be in OnCore?

- Determination required prior to Study Start-Up activities
- Purchase of calendar required prior to IRB Submission for financials process

See Appendices for study definitions & OnCore exceptions

Study Types Available in OnCore:
- ANY study with a cancer focus (including healthy subjects)
- Epidemiologic/Observational
- Screening
- Prevention
- Basic Science
- Device Feasibility
- Diagnostic
- Genetic
- Correlative
- Health Services Research
- Supportive Care
- Ancillary or Companion
- Treatment/interventional
- MCW-sponsored (IITs) IND/IDE
- Industry-sponsored Expanded “retrospective chart reviews or registries”***

**If sponsor calls study a retrospective chart review/registry, but requires consenting and subject visits, this is a clinical trial that goes into OnCore (and subject visits require a calendar)

NOTE: Studies entered in OnCore are NOT dependent on sponsor type. Investigator-Initiated and NIH-sponsored studies should still be put in OnCore with a calendar to manage budget and subject visit tracking.
Appendix I: OnCore Primary Study Purpose Definitions

Assign the appropriate Primary Purpose to Interventional or Non-Interventional (Observational or Ancillary/Correlative) Clinical Research Categories.

**Basic Science (BAS):** Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.

**Device Feasibility (DEV):** An intervention of a device product is being evaluated in a small clinical trial (generally fewer than 10 participants) to determine the feasibility of the product; or a clinical trial to test a prototype device for feasibility and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.

**Diagnostic (DIA):** Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.

**Health Services Research (HSR):** Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

**Prevention (PRE):** Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.

**Screening (SCR):** Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).

**Supportive Care (SUP):** Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant’s health or function. In general, supportive care interventions are not intended to cure a disease.

**Treatment (TRE):** Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in previous versions of the guidelines.

*Expanded Access Trials* – Facilitates access to drugs or devices where the subject(s) may not be eligible to go on a trial but could benefit from the therapeutic option: EXPACC-Drug Company Name-Sponsor Protocol Name, e.g. EXPACC-JANSSEN-SAR-3002.

*Treatment Use Only Trials (Compassionate Use Trials)* – Subject(s) who were enrolled on a study are given IRB permission to continue to use the study drug(s) even though they have gone off-study: TXUSE-Drug Company Name-Sponsor Protocol Name, e.g. TXUSE-GLOBE-G14000-14.

*Emergency Investigative Drug or Device Use Trials* – Subject(s) are given IRB permission to emergently use an experimental therapeutic option, not on-study, for a particular disease/diagnosis/symptom: E-IND-Drug Company Name-Drug Name, e.g. E-IND-ANSUN-DAS181.

*Note:* Access/Compassionate Use IND/IDE and Emergency-Use IND/IDE are under consideration.

**Other (OTH):** Not in other categories
Appendix II: Exceptions for OnCore entry

If you have worked through the Decision Tree and you don’t feel your study meets criteria for entry into OnCore, determine if it can be described/fit into one of the seven scenarios below:

1. **Registries**: Registry studies are observational, they look retrospectively at what was done without dictating a treatment plan. If considered a registry study and:
   - Does not consent subjects with HIPAA authorization to release PHI
   - Does not track subject visits for reporting
   - Does not need subjects to be in EPIC
   Then, registry **should NOT be entered** into OnCore

2. **Banks**: Determination of whether the protocol is hypothesis driven or not.
   - If specimens/data are being collected for the sake of building a repository for future unspecified research AND subjects do NOT get entered into EPIC, then it is a bank and **should NOT be entered** into OnCore.

3. **Community Engagement studies**: (for example, a hypertension screening at Miller Park)
   - If no subjects need to be entered into EPIC, study **should NOT be entered** into OnCore

4. **Observational/survey studies**:
   - Where subjects are not Froedtert patients, and no gender/ethnicity/race information is collected
   - Where the only data available to enter is number of subjects enrolled (but no details about those subjects)
   Then study **should NOT be entered** into OnCore

5. Studies using MCW medical students and/or residents **should NOT be entered** into OnCore
6. Enhancing Education or Quality Improvement studies **should NOT be entered** into OnCore
7. Perspective based surveys/observations **should NOT be entered** into OnCore

If you have additional questions, please contact oncore@mcw.edu.