F&MCW ONCORE DECISION TREE

Should Your Study Be in OnCore?

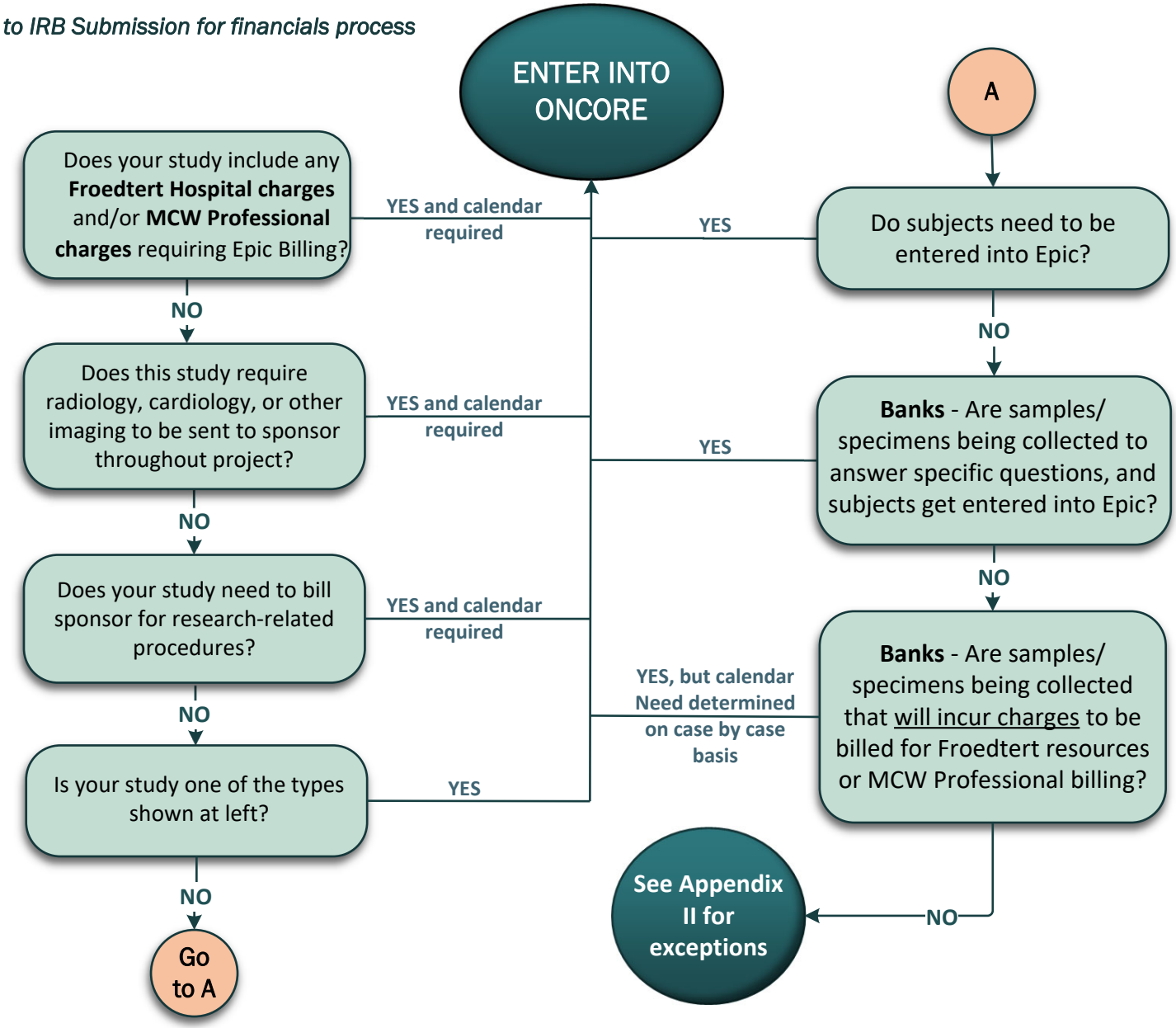
- *Determination required prior to Study Start-Up activities*
- *Purchase of calendar required prior to IRB Submission for financials process*

See Appendices for study definitions & OnCore exceptions

Study Types Available in OnCore:

- ANY study with a cancer focus (including healthy subjects)
- Epidemiologic/Observational (see Appendix II for exceptions)
- 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.

V. 9/15/23

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.

Epidemiologic/Observational (OBS): A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment. A patient registry is a type of observational study

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.