

# Other Event Decision Chart

**For any event involving a compliance issue, make sure you include your root cause analysis and your corrective and preventive action plan. For safety issues, please include your safety plan. Include details about reconsenting or contacting subjects if applicable.**

Choose from the following options according to the event you are assessing:

- [Reporting Other Events in studies reviewed by an External IRB](#)
- [Safety event](#)
- [Loss or mismanagement of identifiable information](#)
- [Complaints](#)
- [Deviation from IRB approved protocol](#)
- [Submission requested by the sponsor that does not meet our reporting criteria](#)
- [Consent process errors](#)
- [Errors involving drug administration or REMS requirements deviations](#)

# Reporting Other Events in studies reviewed by an External IRB

## **What and How to Report to the External IRB**

When assessing the need to report an Other Event, please follow the external and the Emory IRB reporting requirement, whichever is *more stringent*.

**All events** should be reported to the external IRB as they are your IRB of record.

Follow the external IRB's SOP's for how to report (either directly, or via the lead study team or coordinating center).

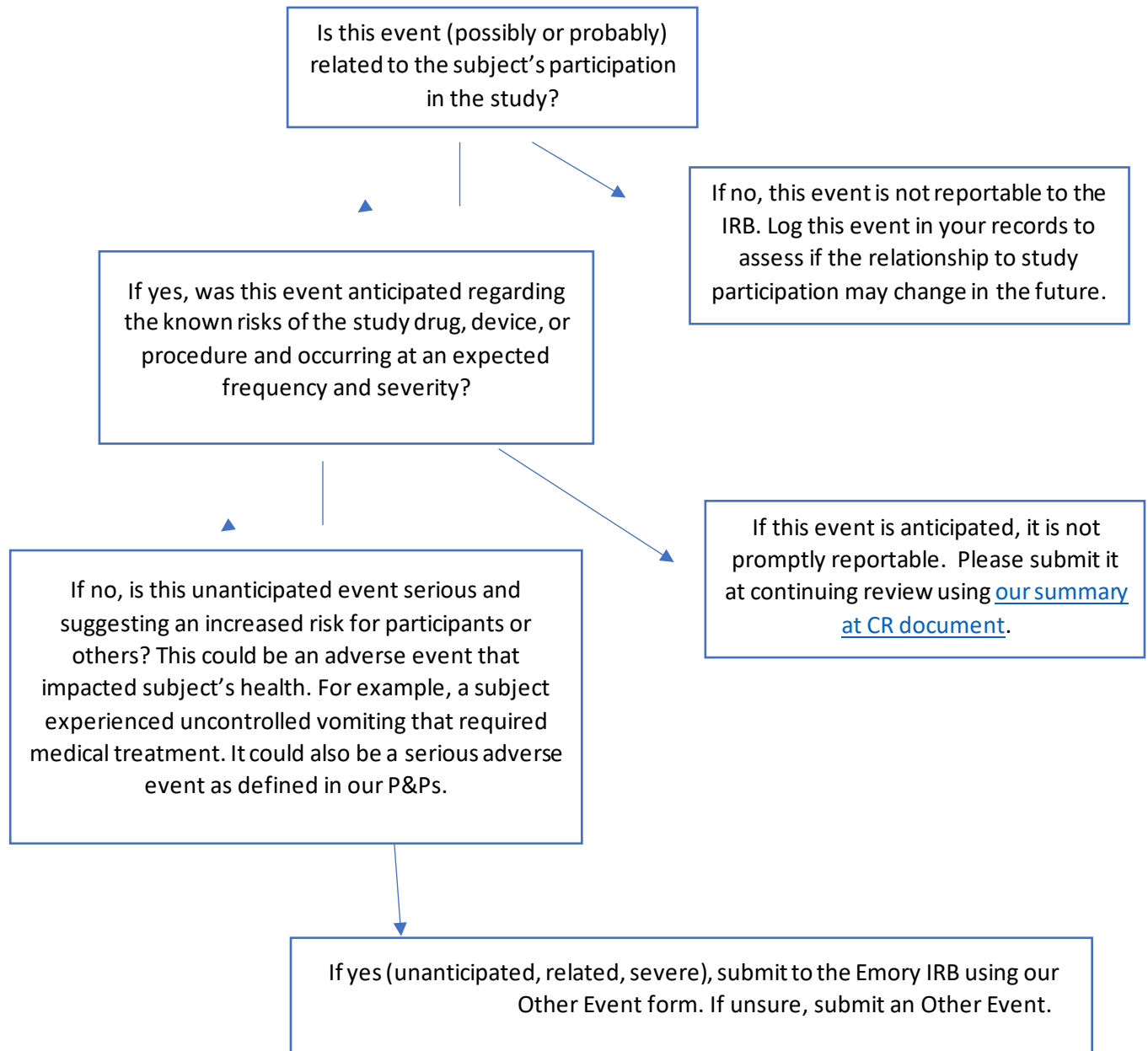
## **What and How to Report to the Emory IRB**

In addition, you are **required** to report the following egregious events to the Emory IRB **promptly** via an Other Event submission, as well as report them to the [Emory Office of Research Integrity and Compliance](#) and the Emory Risk Management offices(Emory Healthcare):

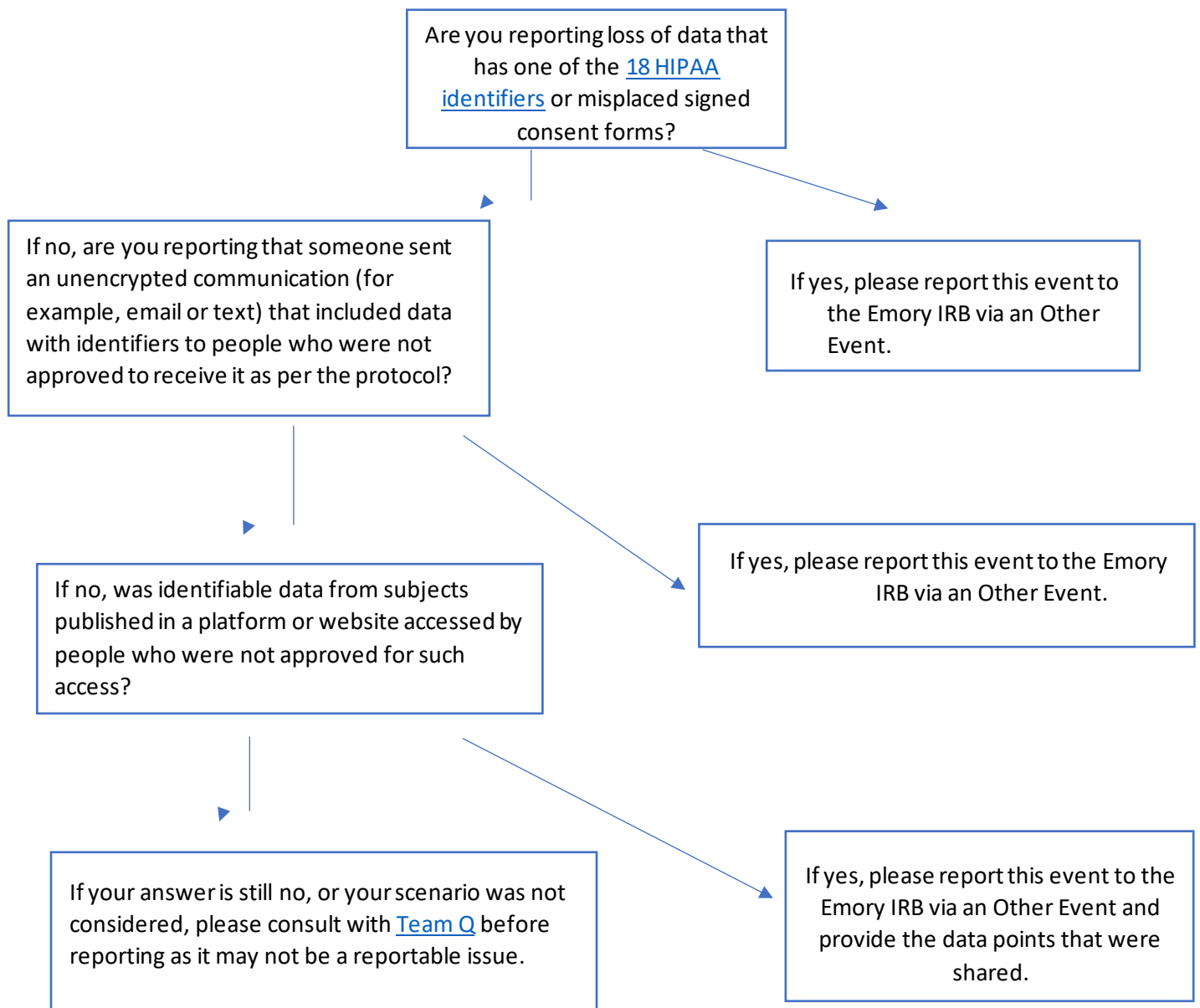
- Internal (at this site) death related or possibly related to the research
- Surgery on the wrong side
- Drug provided to the wrong patient or a patient received the wrong drug
- Fabrication, plagiarism, or falsification of data
- HIPAA privacy matter (report any inadvertent data disclosure and we will help determine further actions)
- Study Suspension (related to compliance concerns)

Create an **Other Event submission** from within your Emory CEDE submission in Insight. **Upload** a copy of the report(s) made to the external reviewing IRB, and any correspondence you have already received from the reviewing IRB (but do not delay waiting for their determination).

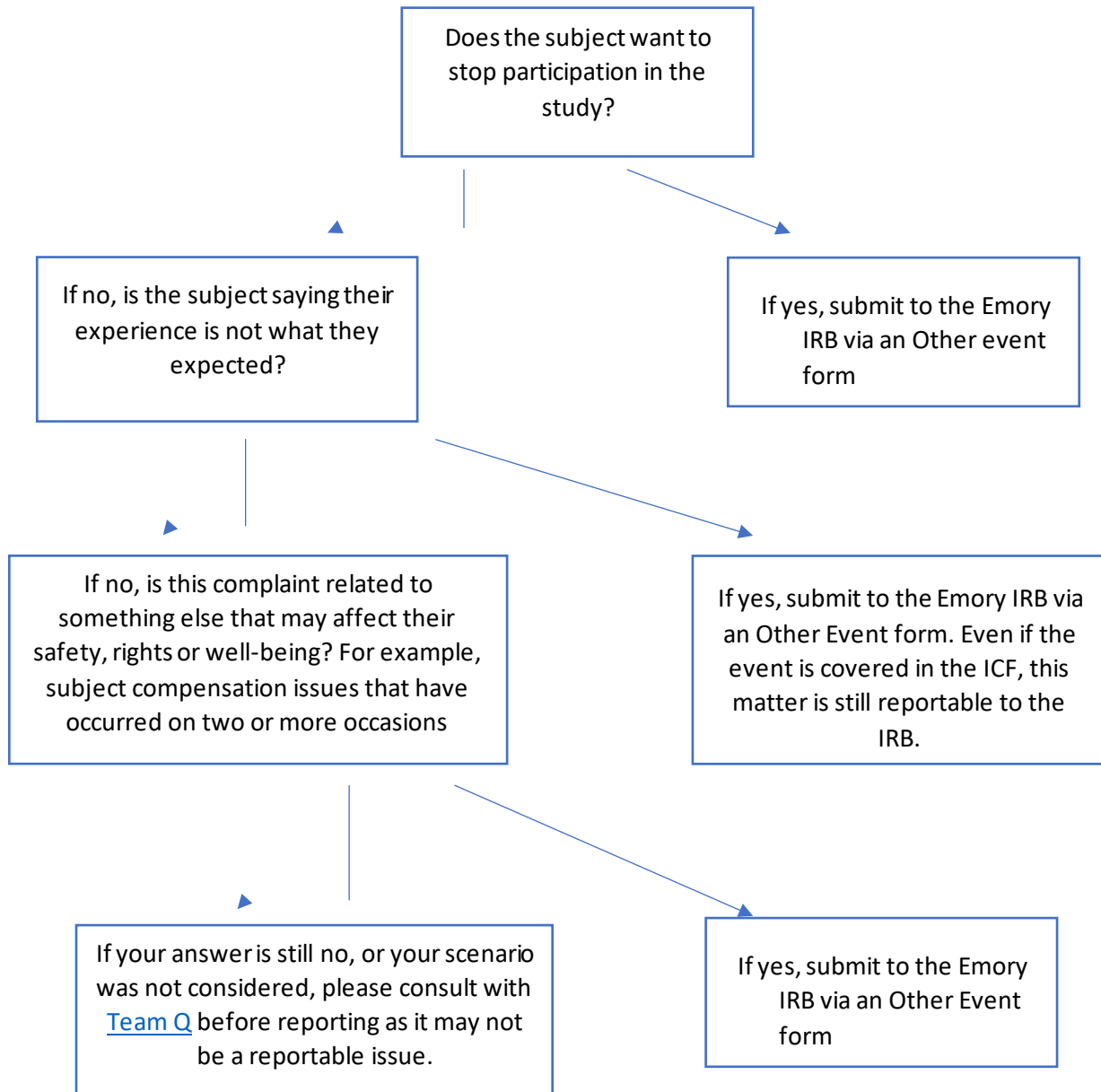
# Safety event



# Loss or mismanagement of identifiable information

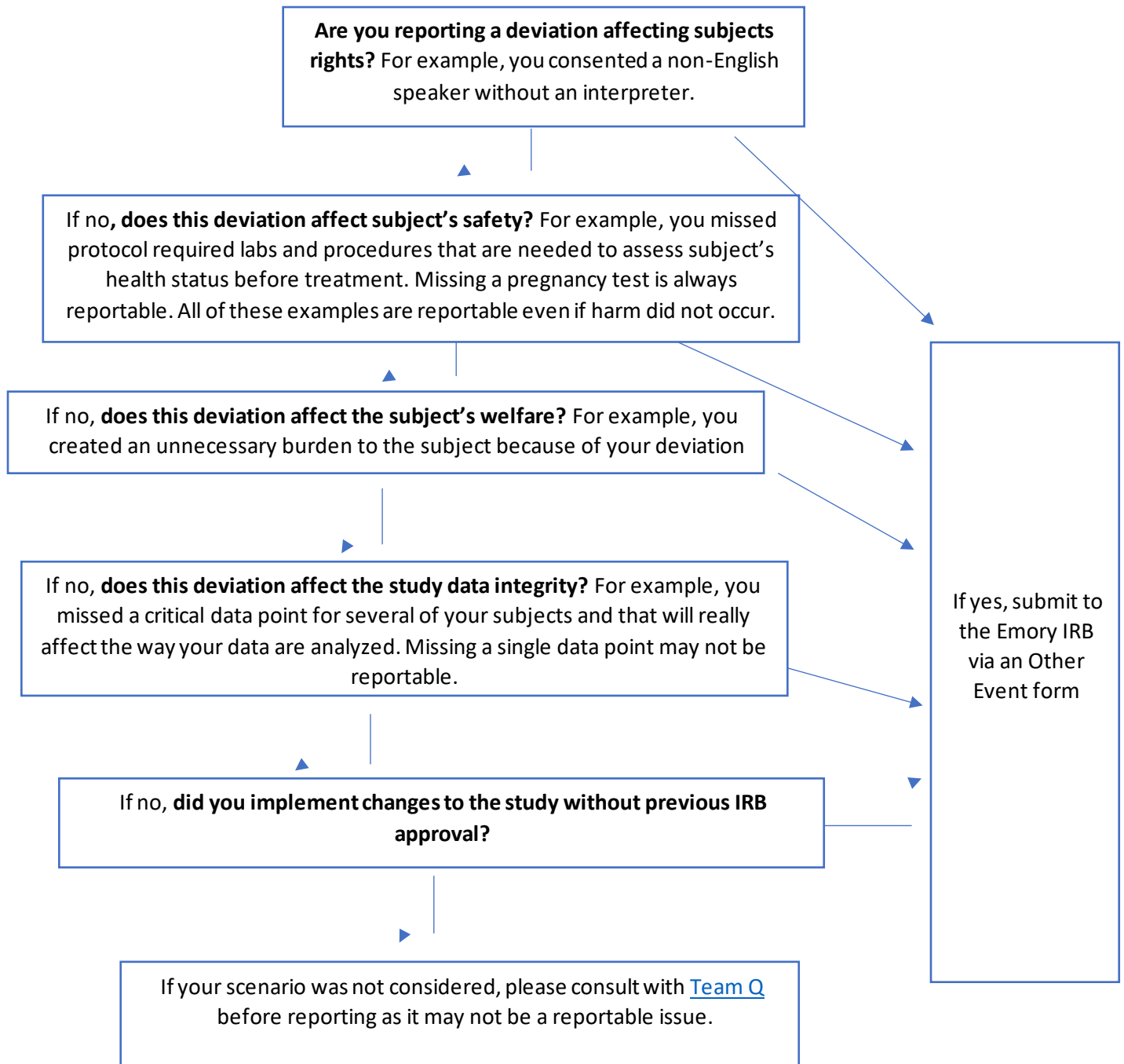


# Complaints



# Deviation from IRB approved protocol

**Note: All eligibility deviations and failures to maintain or submit FDA regulatory information are reportable (for example, DOA, 1572, IND or IDE annual reports, etc.)**



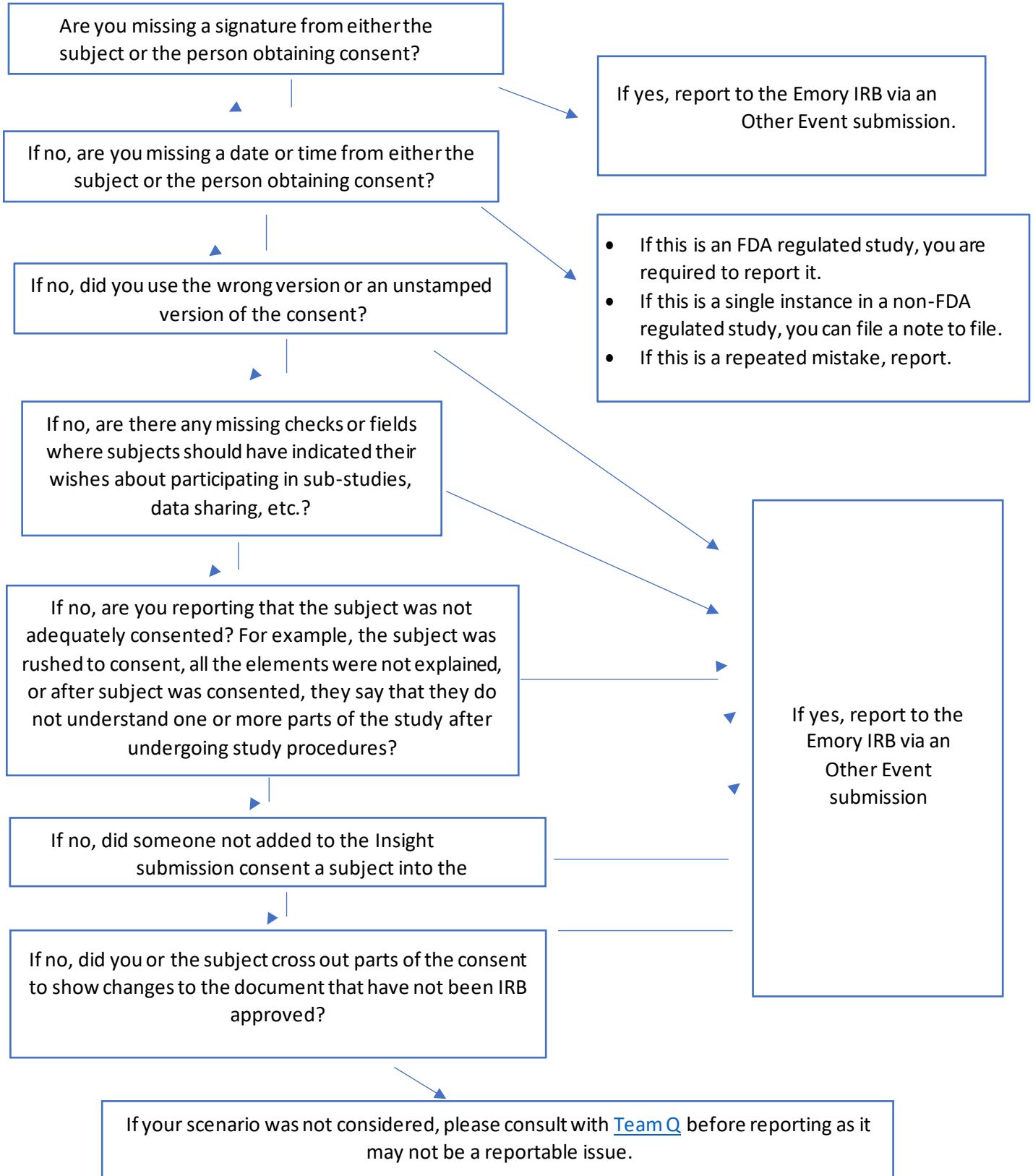
## Submission requested by the sponsor that does not meet our reporting criteria

Review your protocol and grant/contract to push back if you do not have the requirement to submit to the Emory IRB. If your sponsor is not aware of our reporting requirements, please review this document or **this guidance**.

If your sponsor is still adamant about reporting, please submit an Other Event. Please explain why this matter does not meet reporting criteria and why you are reporting this event.

As a reminder, the Emory IRB does not issue letters for events that are acknowledged. Please review **this memo** for more information.

## Consent process errors





## Errors involving drug/device administration or REMS requirements deviations

