Reportable New Information 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 RNIs 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 RNIs in studies reviewed by an External IRB

What and How to Report to the External IRB

When assessing the need to report an RNI, 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 RNI 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 **RNI submission** from within your Emory XIRB submission in eIRB. **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

Is this event (possibly or probably) related to the subject's participation in the study?

If no, this event is not reportable to the IRB. Log this event in your records to assess if the relationship to study participation may change in the future.

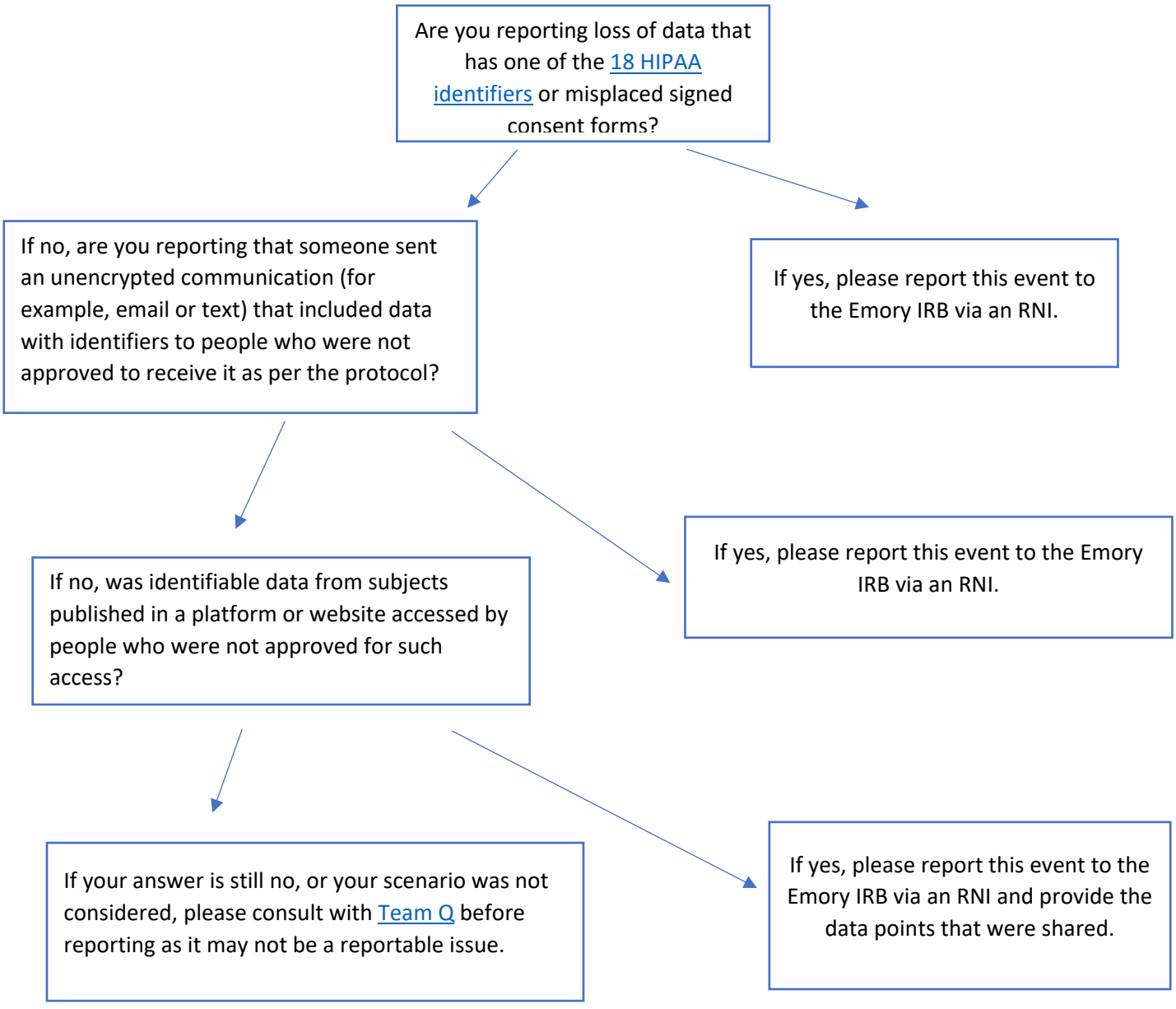
If yes, was this event anticipated regarding the known risks of the study drug, device, or procedure and occurring at an expected frequency and severity?

If this event is anticipated, it is not promptly reportable. Please submit it at continuing review using our summary at CR document.

If no, is this unanticipated event serious and suggesting an increased risk for participants or others? This could be an adverse event that impacted subject's health. For example, a subject experienced uncontrolled vomiting that required medical treatment. It could also be a serious adverse event as defined in our P&Ps.

If yes (unanticipated, related, severe), submit to the Emory IRB using our RNI form. If unsure, submit an RNI.

Loss or mismanagement of identifiable information



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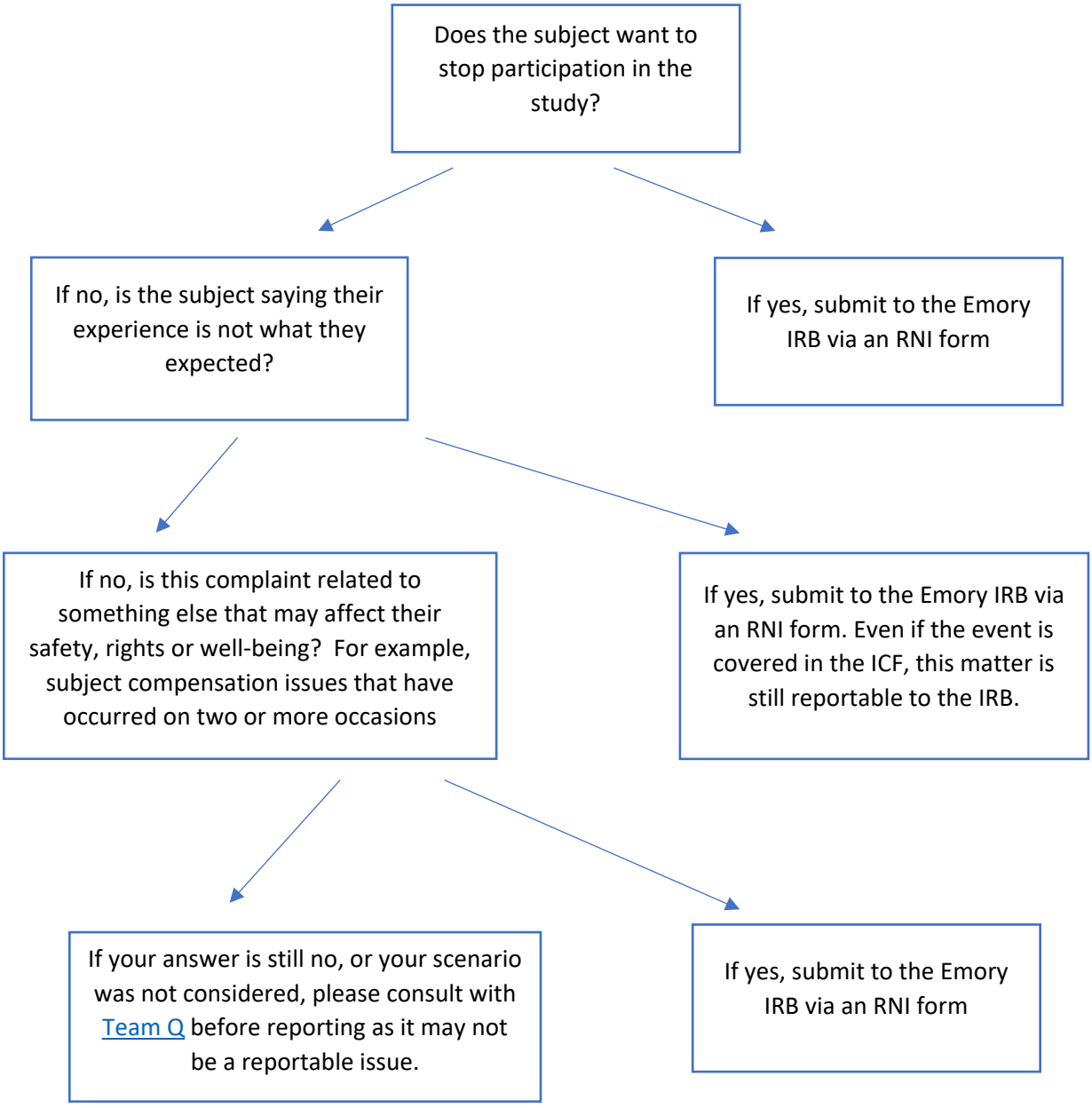
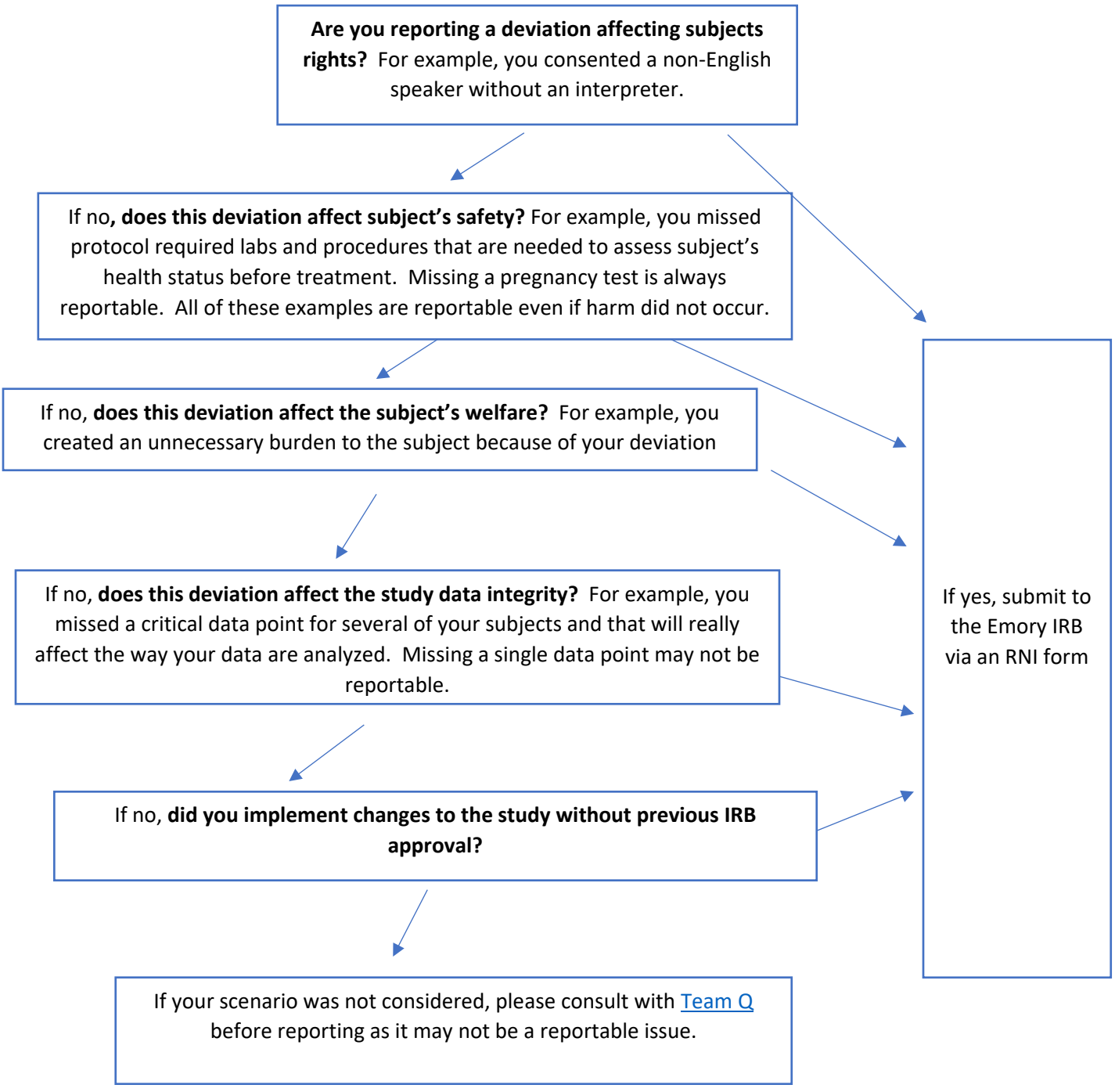
Complaints


Does the subject want to stop participation in the study?
If no, is the subject saying their experience is not what they expected?
If yes, submit to the Emory IRB via an RNI form
If no, is this complaint related to something else that may affect their safety, rights or well-being? For example, subject compensation issues that have occurred on two or more occasions
If yes, submit to the Emory IRB via an RNI form. Even if the event is covered in the ICF, this matter is still reportable to the IRB.
If your answer is still no, or your scenario was not considered, please consult with Team Q before reporting as it may not be a reportable issue.
If yes, submit to the Emory IRB via an RNI form

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.)



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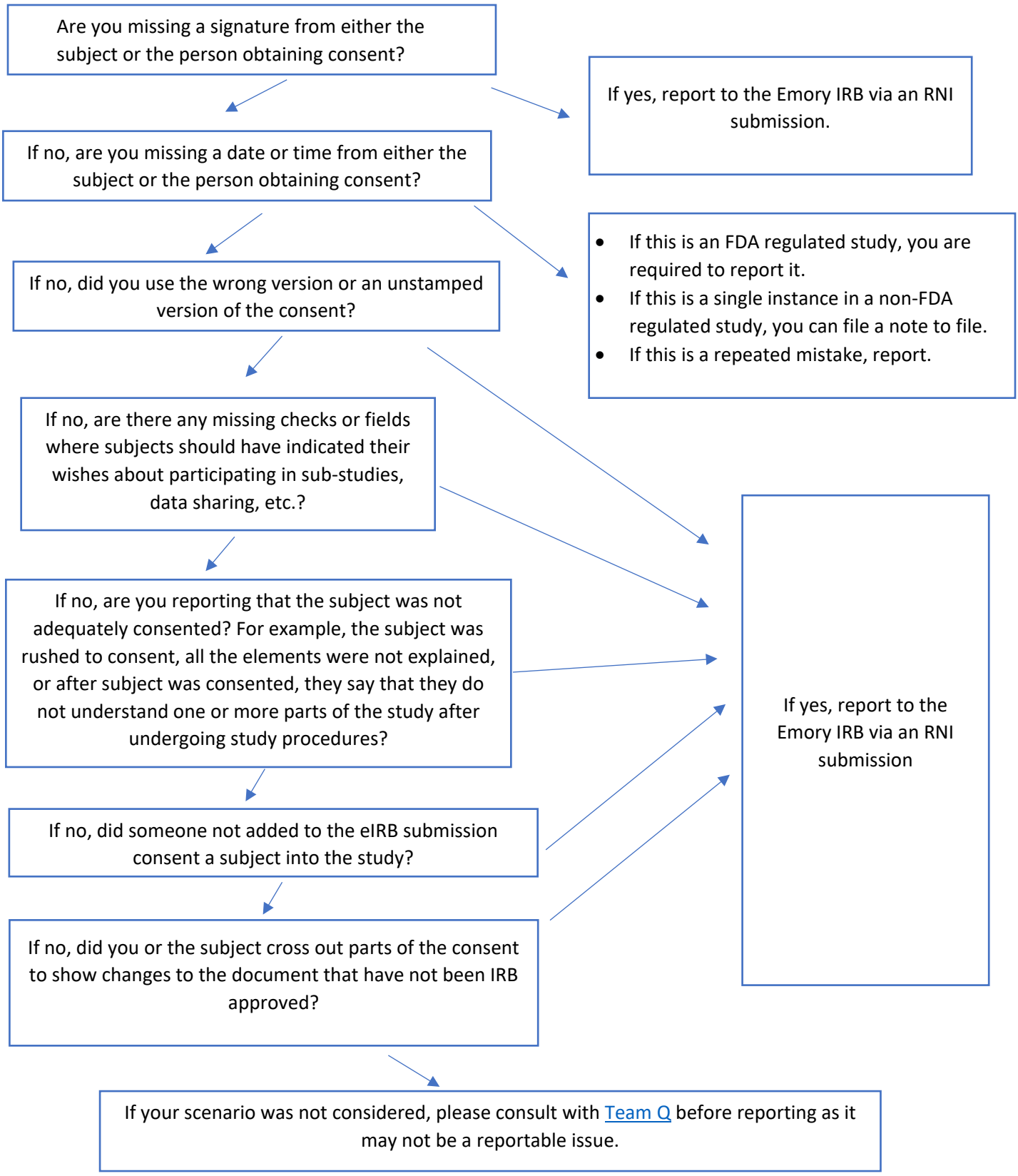
Submission requested by the sponsor that does not meet our reporting criteria

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 RNI. 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



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Errors involving drug/device administration or REMS requirements deviations