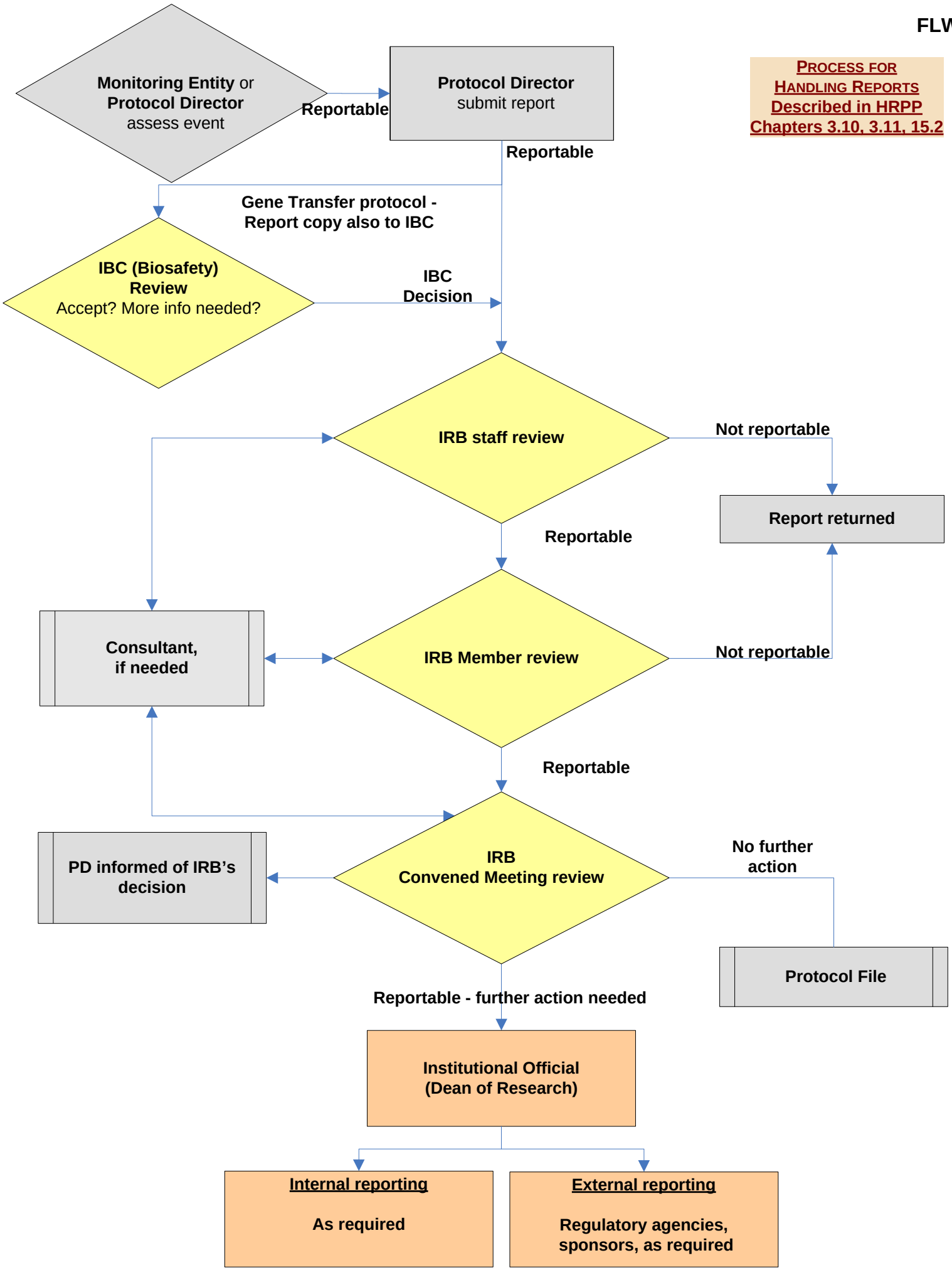
PROCESS FOR HANDLING REPORTS Described in HRPP Chapters 3.10, 3.11, 15.2
Monitoring Entity or Protocol Director assess event
Reportable
Protocol Director submit report
Reportable
Gene Transfer protocol - Report copy also to IBC
IBC (Biosafety) Review Accept? More info needed?
IBC Decision
IRB staff review
Not reportable
Report returned
Reportable
Consultant, if needed
IRB Member review
Not reportable
Reportable
PD informed of IRB's decision
IRB Convened Meeting review
No further action
Protocol File
Reportable - further action needed
Institutional Official (Dean of Research)
Internal reporting
As required
External reporting
Regulatory agencies, sponsors, as required