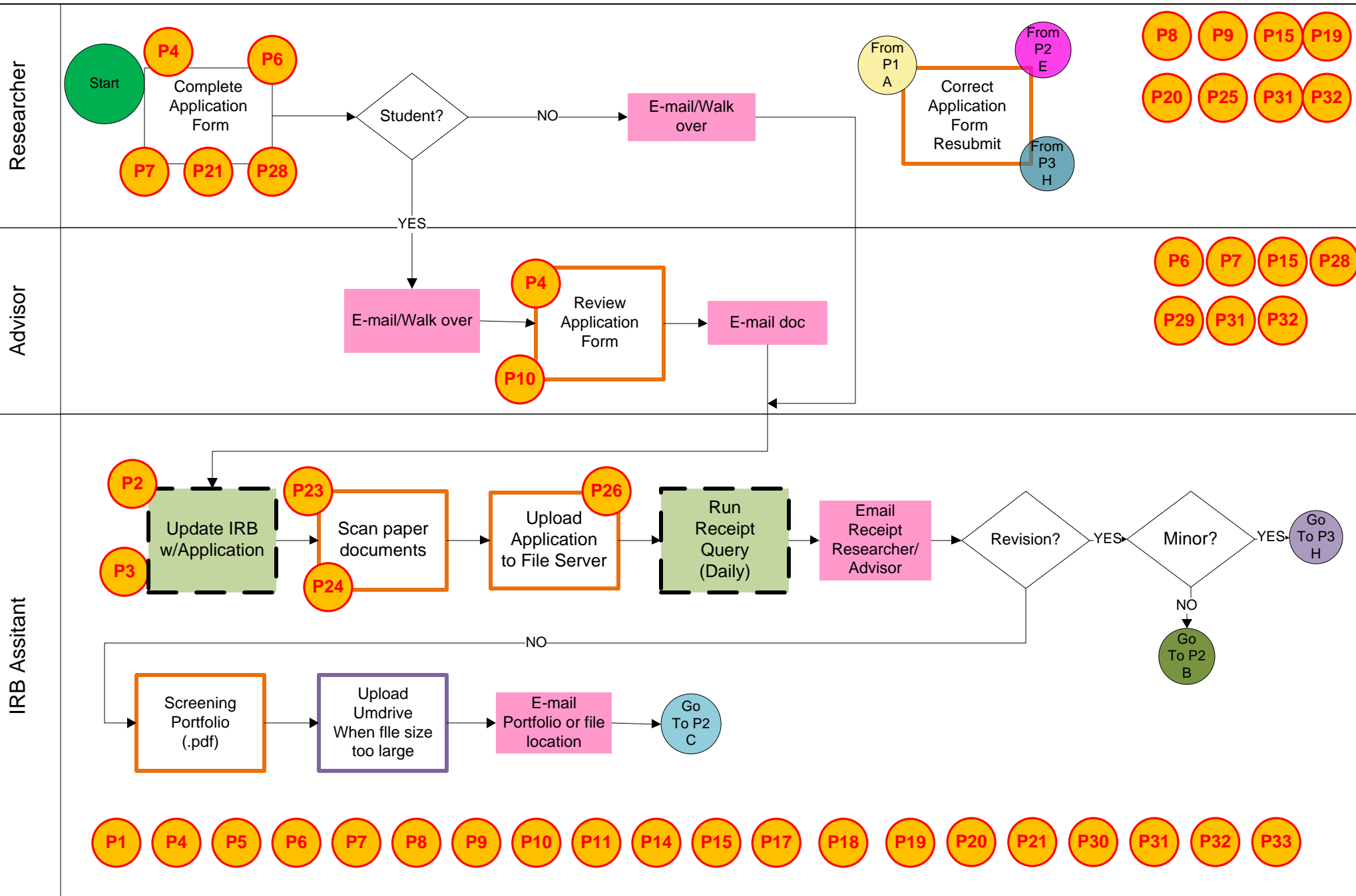
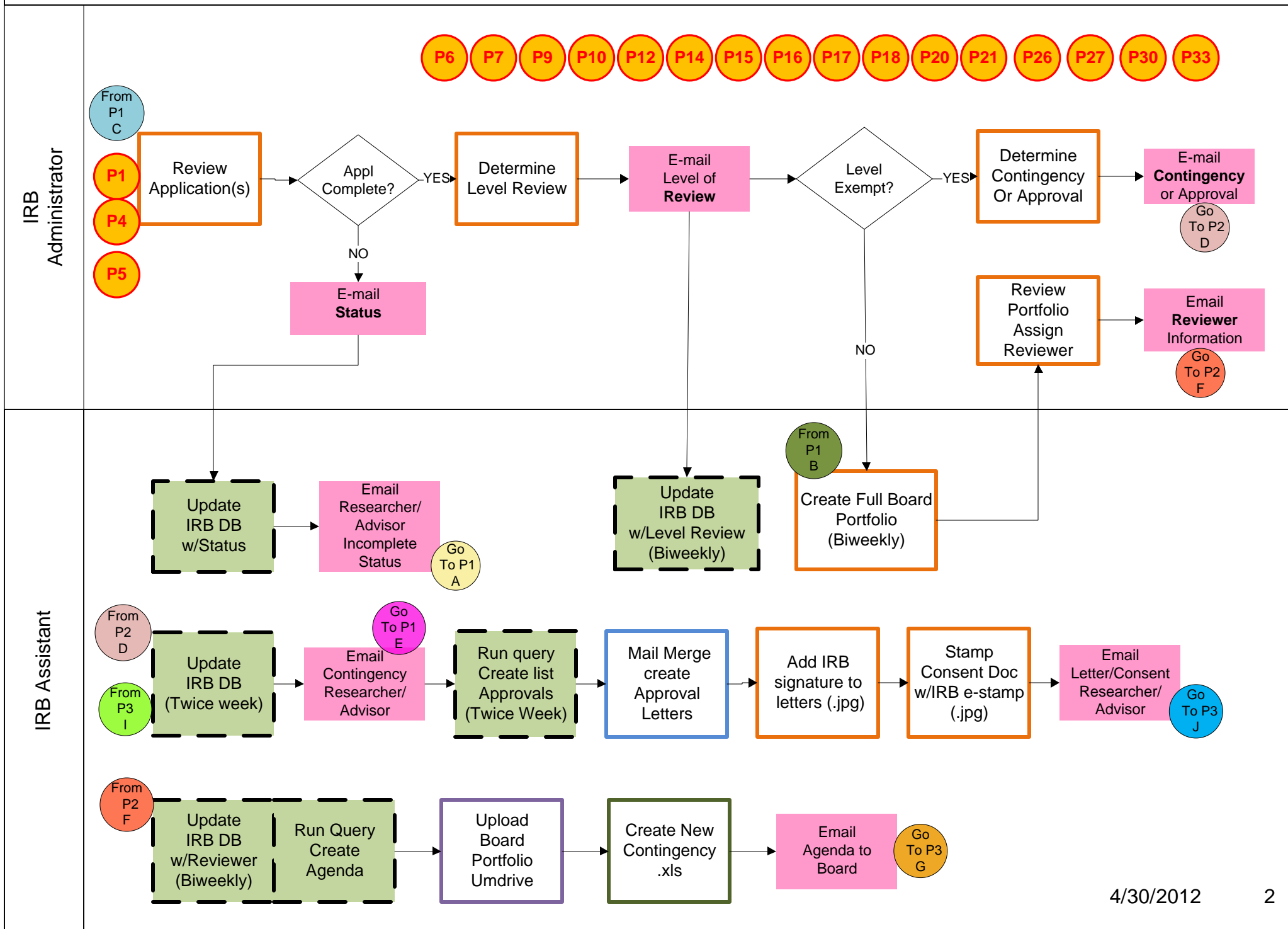


# Institutional Review Board (IRB) – “AS IS”

Portfolio defined: Multiple Application forms

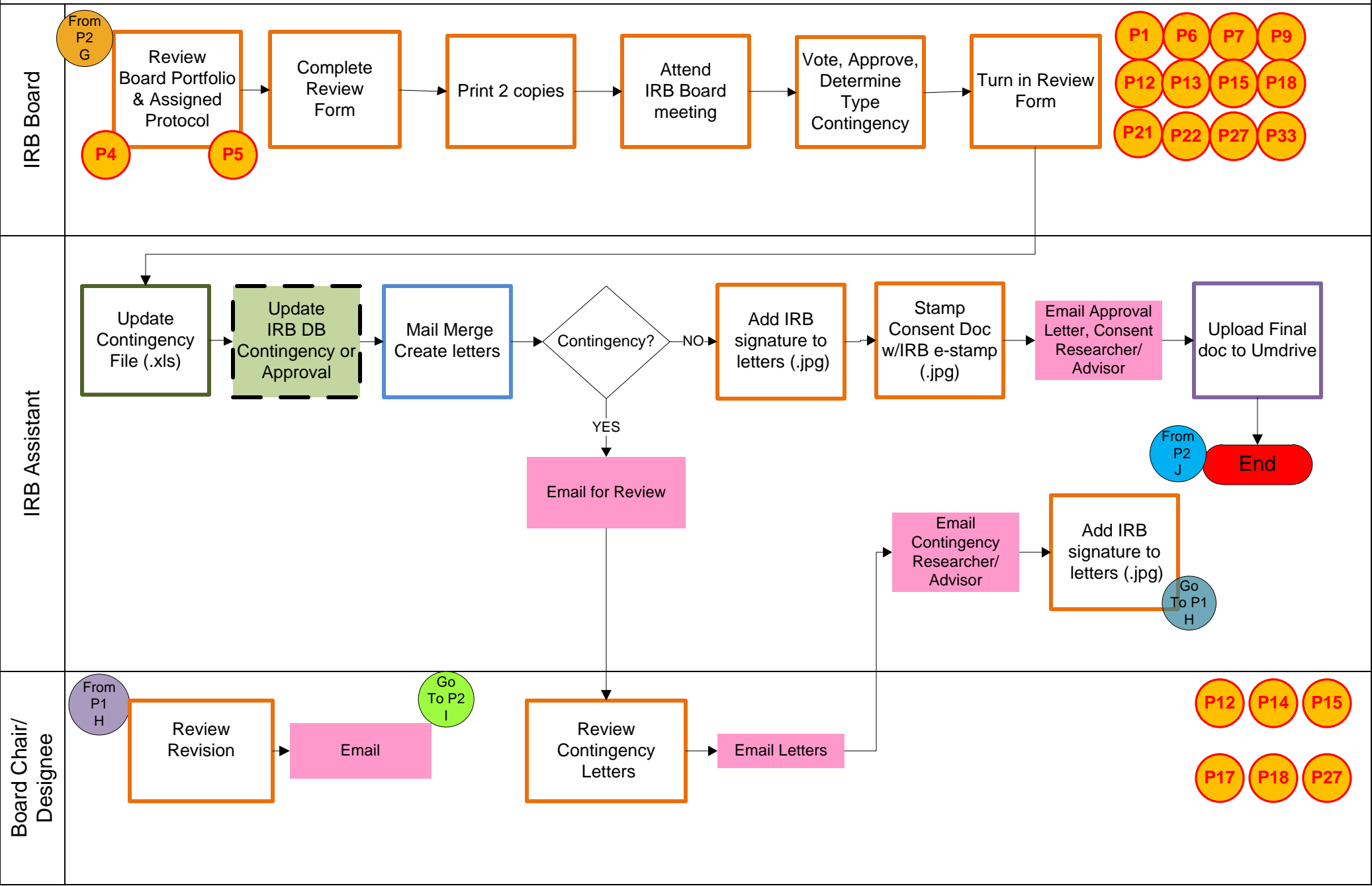


# Institutional Review Board (IRB) – “AS IS”



Institutional Review Board (IRB) - "AS IS"

Phase



## Pains & Issues:

### Please Read First:

The issues and pain points identified during the As Is Process Mapping workshop and the Analysis workshop are noted below. The Issue is numbered and its Root Cause Analysis is in red text, preceded by **RCA** prefix.

1. Faculty advisors and graduate students are not trained IRB process

RCA: Faculty are not aware there is a training, do not attend IRB Administrator's training when made available. Training only available on campus, no online training available

2. New - Old Database

RCA: Records prior to 2012 are not in the new database

3. Lots of manual data entry

RCA: Multiple handoffs for updating the database, inability for IRB database to read Banner and pull in faculty/staff/student data

4. Inaccurate submissions

RCA: Not all faculty advisors & program coordinators are trained in the IRB process. Learning curve for graduate students. IRB process and human subject concerns continue evolving

5. Repeated common errors

RCA: Written instructions are not clear

6. Limited IRB staff to help educate within RSS

RCA: Staffing issue within IRB office. Training is not available online

7. CITI training not completed before submission of RPA (Request Protocol Approval)

RCA: Researchers are not required to complete training before submission

8. Faculty advisor do not complete review in a timely manner student's RPA

RCA: Workload

9. Faculty advisors don't always review the students RPA

RCA: Workload

10. RPA is a paper form to be downloaded and completed

RCA: There isn't a web base form or database

11. Look up Banner Identification number (U#)

RCA: Inability to read Banner and pull data into Access database

12. Not all Board members complete review form before Board meeting

RCA: Workload

13. Huge Learning Curve for new board members

RCA: pull from page 1 abt training

14. Multiple Handoffs by e-mail

RCA: Used to communicate to IRB assistant action is needed to update IRB database

15. Federal documentation requirements; internal complex process to meet this requirements

RCA: Federal mandated

16. Not all board members prepare contingencies

RCA: Workload, learning curve and not enough training

17. Manual e-mails are created for communication

RCA: There isn't a systematic process in place

18. New Board members tend to have lots of errors

RCA: Learning curve and not enough training

19. Researchers cannot identify the application status without contacting IRB staff

RCA: No access to the database, status is not available for view

20. Researchers do not apply early enough (students)

RCA: They don't know to apply, no type of notification to apply. Lack of understanding of turn around time

21. Researchers use outdated forms

RCA: Forms are downloadable, use previous form they have used, make changes and submit

22. Not easily identifiable which Board portfolio file members are to review on UMdrive

RCA: Retain old portfolios in same folder

23. Manual creation of .pdf documents to store on UMDrive and in the database

RCA: Documents aren't created in a database system, no electronic approvals can be captured

24. RPA sometimes delivered in paper form

RCA: No online submission form and electronic signature, mistrust of the process and want paper

25. Turn around time

RCA: Unclear expectations, incomplete and inaccurate submissions, currently 90% board is new, IRB staff backup

26. File server names or inconsistent

RCA: File name standard has not been implemented

27. Board turnover, replacement

RCA: Policy and procedures, terms are not defined, not staggered

28. RPA form is cumbersome and misinterpreted

RCA: Design issue from IRB staff, use of jargon

29. Faculty advisors are not always notified by IRB

RCA: Mail merge cannot add multiple e-mail addresses

30. IRB office procedures not documented

RCA: Workload handled by temp employee

31. Annual renewal reviews

RCA: Knowing when renewals are due

32. Completion Reports

RCA: Researchers do not submit closure documentation

33. Modifications to approved protocol are not clear upon resubmission

RCA: Not clearly explained

# Legends

