# IRB Member Training December 2016

- Objectives:
  - *Overview the IRB's approval timeframe for the current year*
  - *Discuss IRB case examples for ethical consideration*
  - *Solicit Feedback on the updated IRB member service recognition letters*

# PENN IRB:

## *A TALE OF EFFICIENCY*

# We as a staff process far more reviews than the average IRB at a far faster rate

- Brief recap of the many reviews the Penn IRB processes annually

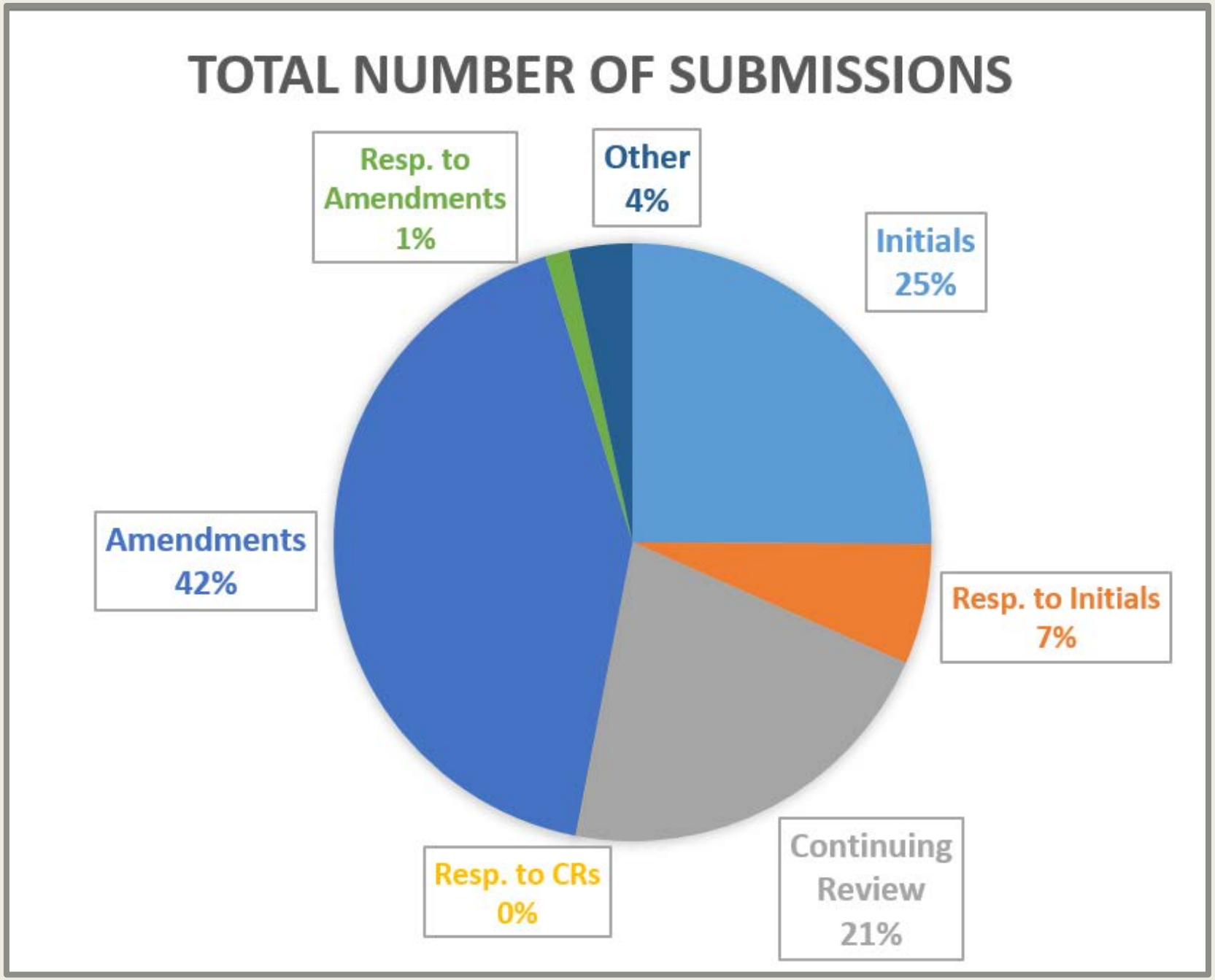
- Snapshot of the average days it takes to process each action by type, including days corresponding with study team

The Penn IRB annually sees almost

**34 TIMES**

the number of new studies as the median IRB.

| *Total Number of Annual[1] Submissions* | | | | |
|---|---|---|---|---|
| Type | Full | Expedited/ Other | Total | % Total |
| **Initials** | 530 | 2,897 | **3,427** | 25.1% |
| Resp. to Initials | 87 | 804 | 891 | 6.5% |
| **Continuing Review** | 671 | 2,254 | **2,925** | 21.4% |
| Resp. to CRs | 0 | 3 | 3 | 0.0% |
| **Amendments** | 463 | 5,304 | **5,767** | 42.2% |
| Resp. to Amendments | 39 | 137 | 176 | 1.3% |
| **Other** | 57 | 410 | 467 | 3.4% |
| **Total** | 1,847 | 11,809 | **13,656** | |




And that number is only **a quarter** of what we process every year…

# Yet, we as a staff manage to assess and review all these studies at an incredible pace

| *Average Days [2] to Process* | | | |
|---|---|---|---|
| Type | Full | Expedited/ Other | Overall[3] |
| **Initials** | 21.4 | 3.2 | 12 |
| Resp.[4] to Initials | 18.6 | 3.6 | 11 |
| **Continuing Review** | 22 | 0.8 | 11 |
| Resp. to CRs | -- | 1 | 1 |
| **Amendments** | 15.8 | 1.1 | 8 |
| Resp. to Amendments | 13.1 | 1.9 | 8 |
| **Other** | 8.8 | 5.5 | 7 |
| **Total** | 17 | 2 | **8** |

So thank you, everyone -

- For processing so many complex, varied reviews from all over the University
- For maintaining a balance of efficiency and efficacy to review so many studies at such a lightning-fast rate

# PENN IRB:

## *CASE EXAMPLES FOR ETHICAL CONSIDERATION*

# Case 1

- Study: To determine if the ethical concerns with incentives for research manifest; to assess their possible benefits; and to evaluate their cost-effectiveness to increase RCT enrollment.
- Propose Design: The study tests 3 incentives for participating in an RCT comparing conventional radiotherapy with proton-beam therapy for stage II-IIIB non-small-cell lung cancer. Participants will learn they are being offered either $0, $400, or $1,200, depending on randomization, to participate in the parent trial at this stage. Participants are not alerted to their assigned parent trial arm (conventional radiotherapy or proton-beam therapy) at this stage. This step will occur during or before the dry-run/set-up appointment.
- Concern: Why was deception needed to conduct the research? Would the deception component alter the decision making process for subjects undergoing cancer treatment? Was the study minimal risk (which is a criterion for deception)?

# Case 1 - Resolution:

- Criteria for deception determined to be met.  The IRB required confirmation of the sample size was of sufficient power to detect any early evidence undue influence.
- No subjects have been enrolled in the study. Any adverse events (incidents of perceived undue influence) require immediate reporting for consideration by IRB #8,

# Case 2

- Study Objective: To record respiratory function measurements during delivery room resuscitation of preterm infants to identify characteristics of delivered inflations that are associated with effective lung aeration.
- Proposed modification: The study currently sought parental permission from the mother to allow for use of observational data until she was stable and capable of making an informed decision. A full waiver of consent was requested for the study population for reasons relating to compassion and practicability. They argued that by approaching families of such critically ill newborns for consent to use the collected data would not be appropriate or compassionate as NICU admissions are extremely stressful for infants and their families.
- Concerns: What proportion of the population did the rationale for compassion apply to (e.g. a fraction)? An arm of this study operated under a prospective consent process and that the process has been carried out successfully, along with a number of other studies that utilize prospective informed consent among the same study population. How did the lack of a time limit for obtaining consent per the approved consent process justify the waiver request? Was there any evidence or publications available to support the argument that parents in this situation would be harmed psychologically from being approached for participation in the study?

# Case 2 - Resolution:

- The IRB determined that if/when eligible infants are critically ill or do not survive, and investigators feel it is not possible to approach or obtain consent from the infants' families, they may continue to submit exception requests to be assessed on a case-by-case basis. Because of this, the IRB recommended that an alternate consent form be created for the parents whose newborns have died as the current consent form alludes to the infant surviving. Additionally, the IRB recommended the study team revisit the consent form and revise to clearly address that they are asking for permission to use the infant's data that has been collected.

# Case 3

- Study Objective: To determine safety and efficacy of transplanting kidneys from HCV-positive donors into 20 HCV-negative patients on the kidney transplant waitlist.
- Proposed Modification: The study documents were amended to include blood testing for resistance to Hepatitis C therapy drugs. The Board raised a concern related to the timing of this test and the administration of the drug; while the FDA recommends waiting until after the test result comes back indicating that there is not a resistance to the drug before is the drugs are administered as these drugs often have strong side-effects, the study team proposed to begin treatment with the drug and cease treatment should this test indicate a resistance.
- Concerns: What are the risks of potentially exposing subjects to Hepatitis C drugs unnecessarily for a week [until the test result was available]? Was the risk greater than the risk of potentially delaying treatment for Hepatitis C for subjects who may need it until the test result was available?

# Case 3 - Resolution:

- Delaying treatment for all subjects may pose greater risk to these subjects than having a smaller group of subjects be exposed to a drug for this period that will not be effective for them. To assess whether the resistance rates are within the expected ranges and whether it is appropriate to initiate treatment without this test in the future, the Board stipulated that the study team track the number of subjects that present a resistance to the drug and include this information to the Board at the time of next continuing review. The informed consent document was revised to include information regarding the FDA recommendations regarding the timing of test in relationship to initiation of Hepatitis C drugs, how the timing will differ in this study and to include exposure of potentially unnecessary risks of Hepatitis C drugs.

# PENN IRB:
# IRB MEMBER SERVICE RECOGNITION LETTERS

# IRB Member Service Recognition Letters

- As of August 22nd, member recognition letters began to be sent to all members from the past year, as well as to any supervisors or additional designated individuals members marked in the Member Information Survey
- What do you think of the content of the letters?
  - *Should the number of meetings you attend be included?*
  - *Should the types of submissions you review be included?*
- Do you have any suggestions for how the letters are tailored in the future?
- Do you have a preference on who should receive these letters moving forward?
  - *E.g. Send to just designated individuals from survey, automatically send to department chairs, etc.*