NEW APPLICATION PROCESS - PROPOSAL

CONTEXT:

- WE ARE ALL BUSY! THIS IS UNDERSTANDABLE! HOWEVER, DUE TO THIS....

- DELAYS IN REC RESPONDING TO APPLICANTS

- ONCE REC RESPONDS, DELAYS IN PIs RESPONDING BACK TO REC

- DELAYS IN GETTING PROJECTS STARTED AS THERE IS NO DATA ENTRY SHEET OR DSA ALREADY SET UP

- DELAYS IN RECEIVING DSA AND DATA FROM PARTICIPATING CENTERS

- DELAYS IN ABSTRACT SUBMISSIONS AND MANUSCRIPT COMPLETION

NEW APPLICATION PROCESS - PROPOSAL

- EACH PI CAN ONLY HAVE A MAXIMUM OF 2 STUDIES THAT THEY ARE MANAGING AT ANY GIVEN TIME

- A MINIMUM OF 4 REC MEMBERS MUST REVIEW A PROPOSAL BEFORE A RESPONSE IS SENT TO THE PI

- THE REC HAS A MAXIMUM OF 4 WEEKS TO SEND THEIR RESPONSE TO THE PI

- THE PI THEN HAS A MAXIMUM OF 4 WEEKS TO SEND THEIR RESPONSE TO THE REC AND FOR REC TO APPROVE THE PROJECT

- ONCE THE PROJECT IS APPROVED, THE PI THEN HAS A MAXIMUM OF 4-6 WEEKS TO GET ALL NECESSARY DOCUMENTS TOGETHER TO LAUNCH A PROJECT (DISCUSSED IN NEXT SLIDE)

- PARTICIPATING CENTERS MUST SIGN DSA AND SEND DATA TO PI WITHIN A MAXIMUM OF 8 MONTHS

- ALL PROJECTS SHOULD HAVE AN ABSTRACT BY 12-18 MONTHS OF SUBMISSION AND A MANUSCRIPT DONE BY 18-24 MONTHS SINCE START OF THE PROJECT (THERE MAY BE SPECIAL CIRCUMSTANCES THAT AFFECT THIS TIMELINE BUT THIS IS THE AIM)

TO LAUNCH A PROPOSAL TO THE GROUP

THE PI MUST HAVE THE FOLLOWING DOCUMENTS COMPLETED AND SUBMITTED

TARPSWG

MUST SUMBIT APPLICATION – PROTOCOL AND DATA ENTRY SHEET TO REC FOR REVIEW

ONCE APPROVED BY REC – PI MUST PROVIDE IRB APPROVAL LETTER FROM PI INSTITUTE

PI MUST PROVIDE DATA SHARING AGREEMENT FROM PI INSTITUTE FOR OTHERS TO SIGN

DOCUMENTS REQUIRED TO LAUNCH A PROJECT

1. APPROVED STUDY PROTOCOL

2. APPROVED DATA ENTRY SHEET (EXCEL OR REDCAP OR WHATEVER PI WANTS TO USE)

3. IRB APPROVAL LETTER FROM PI INSITITUTE

4. DATA SHARING AGREEMENT FROM PI INSTITUTE

- WITHOUT ALL OF THESE DOCUMENTS IN PLACE A PROJECT WILL NOT BE LAUNCHED – THIS IS TO ENSURE EVERYTHING IS TRULY READY FOR A PROJECT TO REALISTICALLY BE COMPLETED IN 18-24 MONTHS OF THE START DATE

OPTIONS FOR DSA

- PI INSTITUTE CAN ORGANIZE THEIR OWN DSA THROUGH THEIR CONTRACTS OFFICE – THIS IS VERY ACCEPTABLE

- FOR THOSE THAT WOULD LIKE TO, AND HAVE DIFFICULTY WITH DSA IN THEIR OWN INSTITUTE, WE CAN CREATE AN APPENDIX FOR THEIR RETROSPECTIVE PROJECT VIA THE RESAR FRAMEWORK AGREEMENT WHICH HAS ALREADY BEEN CREATED
  - IN ORDER TO DO THIS,
    - THE PI OF THE STUDY MUST BE ALREADY ON THE FRAMEWORK AGREEMENT OR MUST SIGN IT AND BE ON IT
    - THE PARTICIPATING CENTERS THEN MUST ALSO SIGN THE FRAMEWORK AGREEMENT
    - THEN THEY CAN SIGN THE APPENDIX FOR THIS SPECIFIC RETROSPECTIVE PROJECT THAT CAN BE CREATED

ONCE PROJECT IS LAUNCHED

- THE REC CHAIR WILL LAUNCH THE PROJECT TO THE TARPSWG GROUP TO ASK FOR PARTICIPATION AND WILL ATTACH ALL OF THE DOCUMENTS

- THESE DOCUMENTS SHOULD BE USED BY PARTICIPATING CENTERS FOR THEIR RESPECTIVE IRB'S AND CONTRACT OFFICES

- THE PROJECT WILL REMAIN OPEN FOR 2-3 WEEKS TO ALLOW TO RESPOND ABOUT PARTICIPATION. AFTER THIS TIME, THE PROJECT WILL BE CLOSED TO PARTICIPATION

- PARTICIPANTS MUST GET THEIR OWN IRB, DSA SIGNED AND SEND THEIR DATA TO THE PI WITHIN 8 MONTHS.

- PI WILL SET DEADLINES TO PARTICIPATING CENTERS TO SUBMIT DATA AND CORRECTIONS WHEN NEEDED.

- A DEADLINE CAN BE EXTENDED ONCE. IF THE PARTICIPATING CENTER STILL CANNOT PROVIDE THE DATA/CORRECTIONS IN A TIMELY MANNER THEY MAY BE EXCLUDED FROM THE PROJECT (AT PI'S DISCRETION)

QUESTIONS/DISCUSSION

THANK YOU!