RESEARCH ETHICS COMMITTEE (REC) INVESTIGATOR TRAINING

Dr. Lisa Potts, REC Chair

Nicole Hagan, REC Graduate Assistant

Contact: rec@spalding.edu

REC MEMBERS - THANK YOU!!

Chair: Lisa Potts, ASOT
Graduate Assistant: Nicole Hagan

- Regina Martin – Business (Non-Scientist Member)
- Kristen Harris – Education (Non-Scientist Member)
- Norah Chapman – Psychology
- Jyoti Heiple – ASOT
- Leslie Cairo – Social Work
- Goutam Singh – Physical Therapy
- Mike Starling – Psychology
- Kelly Noble – Nursing
- Cindee Quake-Rapp – Non-Affiliated Community Member
- Rebecca DiCrosta – Non-Affiliated Community Member
- Tom Malewitz – Alternate Member
- Jeremy White – Alternate Member
- Brenda Nash – Prisoner Representative

Contact: rec@spalding.edu

OVERVIEW

- Purpose
- Define human subjects research
- Exemptions
- Types of Reviews
  - Expedited
- Review Process
- Preparing your proposal
- Additional Considerations

REC PURPOSE

- To protect the safety and privacy of human subjects research participants.
  - Charged with reviewing all research projects involving human subjects
    - *Assure research is conducted in accordance with the Department of Health and Human Services policy for protection of human research subjects as written in the code of federal regulations (CFR)Title 45 Part 46.*
  - Belmont Report / Common Rule (2018)
  - OHRP https://www.hhs.gov/ohrp/index.html

WHAT IS HUMAN SUBJECTS RESEARCH?

HUMAN SUBJECTS? [45 CFR 46.102 E (1-3)]

HUMAN SUBJECT:

- Obtain data through INTERVENTION or INTERACTION with a LIVING individual
  - Environmental modification = intervention
  - Email and survey communications = interaction

AND / OR

- Generation or use of IDENTIFIABLE and / or PRIVATE information

Ask yourself: Am I gathering information strictly by observation in a public setting?

NO = HUMAN SUBJECTS RESEARCH

WHAT IS RESEARCH? [45 CFR 46.102 l]

RESEARCH:

"….*a* ***systematic investigation****…designed to develop or* ***contribute to generalizable knowledge****."* It continues to note that, "*some demonstration and service programs may include research activities."*

- Four specific types of activities are NOT considered to be research
  1. Biographical work
  2. Public health information
  3. Criminal justice casework
  4. National defense, homeland security, etc.

ASK YOURSELF: AM I…

1) WRITING A BIOGRAPHY OR ARTICLE ABOUT A SPECIFIC PERSON?
2) COLLECTING PUBLIC HEALTH INFORMATION TO BE USED BY PUBLIC HEALTH OFFICIALS TO INFORM PUBLIC HEALTH BASED DECISIONS?
3) COLLECTING INFORMATION FOR A COURT CASE?
4) COLLECTING INFORMATION FOR THE FBI, CIA, OR OTHER FEDERAL AGENCY IN SUPPORT OF A NATIONAL SECURITY MISSION?

NO TO ALL = RESEARCH

OTHER CONSIDERATIONS

Research generally does **NOT** include operational activities such as practice in medicine, psychology, social work, and public health

- Ex: routine outbreak investigations and disease monitoring

Research is also **NOT** studies for internal management purposes

- It generally does not include journalism or political polls, unless there is a clear intent to contribute to generalizable knowledge

WHAT IS YOUR INTENT?

**note, intent to publish does not automatically = research*

MORE ABOUT PROGRAM EVALUATION RESEARCH

- Collecting data for process improvement may not be considered human subjects research.
  - PROGRAM EVALUATION / IMPROVEMENT
  - QUALITY ASSURANCE / IMPROVEMENT

- **Systematic investigation** of programs designed to contribute to **generalizable knowledge** of "best practices" IS considered human subjects research

- TO CONSIDER: Are you collecting information solely for the purpose of improving a process internally?
  - NO → human subjects research

DO YOU NEED SUBMIT A PROPOSAL TO THE REC?

- Are you **systematically** collecting or analyzing private, identifiable data to **answer a specific question?**

AND / OR

- Will you be generating information from a **living** individual through **intervention or interaction** with them?

YES = MUST SUBMIT AND OBTAIN REC APPROVAL **BEFORE** INIATING YOUR RESEARCH

PROPOSAL SUBMISSION & REVIEW

https://rec.spalding.edu/

Complete CITI training

- Everyone involved
- Once / 3 years
- http://www.citiprogam.org

Determine level of review

- Exempt
- Expedited
- Full

TYPES OF REC REVIEW

https://rec.spalding.edu/

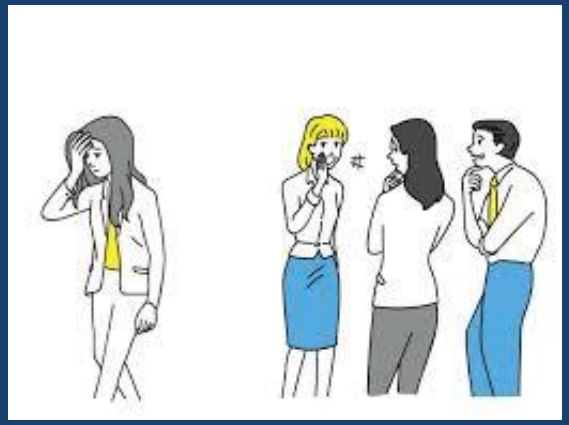
DETERMINE THE TYPE OF REVIEW

Research projects are reviewed at three different levels: *full committee review, expedited review and exempt review.*

- **FULL COMMITTEE**: Studies that involve more than minimal risk
- **EXPEDITED**: No more than minimal risk
- **EXEMPT**: Risk is minimal / no more than every day life.
  - Not bound by the OHRP regulations, though it may still be best practice to follow their guidance

RISKS TO CONSIDER

- Physical
- Emotional
- Criminal or civil liability
- Damaging to:
  - Financial standing
  - Employability
  - Insurability
  - Reputation
- Stigmatizing



CONFIDENTIALITY OF DATA

- Respecting a participant's right to be free from unauthorized release of information
  - relationship of trust
  - expectation that data will not be given to others without permission

- Agreement established between investigator and participant, and maintained by handling, management, and dissemination of research data

EXEMPT REVIEW

- Research involves no more than minimal risk / every day life
- Exempt research does not require ongoing (annual) review
- However, REC application for human subjects research must be submitted and approved in advance

REC determines and approves exempt status

CATEGORIES OF EXEMPTION
45 CFR 46.104(d)

1) Established **educational setting involving normal education practices**
   - **W**ill not impact student learning opportunities
   - Assessment of educators

   **applies to children*

2) Only includes **educational tests, surveys, interviews or observation AND:**
   - Identity cannot be ascertained or linked to subject **OR**
   - Disclosure of information would not put subject at any kind of risk **OR**
   - Confidentiality of identifiable information is maintained

   ***does NOT apply to children*

CATEGORIES OF EXEMPTION
45 CFR 46.104(d)

3) Research involving **benign behavioral interventions*** and collection of information from adults with their agreement **AND:**
   - Identity cannot be ascertained or linked to subject **OR**
   - Disclosure of information would not put subject at any kind of risk **OR**
   - Confidentiality of identifiable information is maintained

**benign behavioral interventions are brief, harmless, painless, non-invasive, will not have significant adverse lasting impact, and no reason to believe they would be offensive or embarrassing*

***does NOT apply to children*

CATEGORIES OF EXEMPTION
45 CFR 46.104(d)

4) Secondary research for which consent is not required if one of the following criteria is met:
   - Identifiable info or specimens are publicly available
   - Identity of info or specimens cannot be ascertained or linked to subject
   - Research is for health care operations or public health activities per 45 CFR 164.512(b)
   - Research is conducted on behalf of a federal department or agency using government generated or collected information
     - Must be in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501

**applies to children*

CATEGORIES OF EXEMPTION
45 CFR 46.104(d)

5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads….
   - The research or demonstration project must be published on the supporting department /agencies website list prior to commencing the research involving human subjects.

   **applies to children*

6) Taste and food quality evaluation if using wholesome foods without additives or with additives at the level approved by the FDA

   **applies to children*

7-8) Secondary research on information or specimens utilizing broad consent that meets additional requirements per CFR 46.111, .116 or .117

   *apply to children

RESEARCH THAT IS NOT ELIGIBLE FOR EXEMPTION:

- Research involving prisoners
- Surveying or interviewing of children
- Observation of children when researcher is participating in the activities being observed

EXPEDITED REVIEW

- Research with no more than minimal risk
  - Identifiers linked to personal / sensitive responses
  - Personal or sensitive information
  - Risk minimal, but beyond everyday life
  - Approval can be given by REC reviewers without convened meeting
  - No continuing review is required
  - Submit project completion notification to REC

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

EXPEDITED REVIEW CATEGORIES

1-3. Certain drug, device and blood samples studies

4. Collection of data (or biological specimens) through noninvasive procedures routinely employed in clinical practice
   - EEG, MRI, sensors, etc.
5. Materials / data collected solely for non-research purposes
   - secondary use, records review
6. Voice, video, digital, or image recordings made for research purposes
7. Research on individual or group characteristics or behavior
   - Surveys, interview, focus group
   - Program eval, QA
   - Some psychological research

8-9. Certain continuing reviews

FULL COMMITTEE REVIEW

- Research that involves more than minimal risk
  - Minors if data are sensitive
  - Vulnerable populations (prisoners, individuals with impaired decision making abilities, pregnant women, fetuses, newborns)
  - Increased physical discomfort, risk of injury or invasion of privacy

  - Requires a quorum of REC members present at convened meeting with a majority voting to approve

FULL REVIEW EXAMPLES

- Drug or device study
- Research involving sensitive questions and/or invasive procedures
- Studies where information may be disclosed that could require mandatory legal reporting (e.g., child/elder abuse)
- Studies involving deception which raises subject risk level
- Research with protected populations
  - Children, inmates, handicapped or disabled persons, pregnant women and fetuses
  - *Anyone* REC feels is vulnerable because of their circumstances (e.g. students)

SPECIFIC TYPES OF RESEARCH

SURVEY RESEARCH: DECISION CHART 4

See the America Association for Public opinion research website for a list of FAQ regarding survey research.

- May be asked to use "information sheet" as consent (i.e. name / signature not included)
- Online survey research must be conducted through the University's QuestionPro account.
  - Disable collection of IP addresses when possible
- Survey research may be exempt if:
  - The information cannot be linked to or used to ascertain the identity of the subject.*

OR

  - The subjects' responses were disclosed it would not place them at risk of criminal or civil liability or affect their financial, educational, occupational or social status.*

OR

  - It has been determined that confidentiality of identifiable information will be maintained.

**If your research involves children, these criteria only apply if the research involves educational tests or is strictly observational.*

RECORDS REVIEW / ARCHIVAL DATA

- No direct interaction with human subjects
- Review data from existing records
- Ongoing collection of data from records obtained for other purposes
- Submit records review request form on REC website
- Consider if obtaining consent is feasible and how it will impact the level of risk involved
  - Obtain consent (or documentation of broad consent)

    OR
  - Request waiver of consent

RECORDS REVIEW / ARCHIVAL DATA-HIPAA

The following **three criteria must be satisfied** for an IRB or Privacy Board to approve a waiver of authorization (for consent) under the HIPAA Privacy Rule:

1. **No more than minimal risk** to the privacy of individuals, based on, at least, the presence of the following elements:
   - an adequate confidentiality plan
   - plan to destroy the identifiers at the earliest opportunity
   - adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for oversight of the research, or for other research that would be permitted by this subpart;
2. The research **could not practicably be conducted without the waiver** or alteration; AND
3. The research **could not practicably be conducted without access to and use of the PHI**

https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

RECORDS REVIEW EXAMPLE

- An investigator obtains only coded information on the treatment outcomes of patients treated for arthritis with Drug A versus Drug B from the patients' treating physician.
- The only involvement of the treating physician is to provide coded information to the investigator.
- The investigator and the treating physician enter into an agreement prohibiting the release of the key to decipher the code to the investigator under any circumstances.

RECORDS REVIEW EXAMPLE

- An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients' existing individually identifiable medical records at the clinics where the patients were treated.
- The investigator records the patients' treatment outcomes in a coded manner that could permit the identification of the patients

RECORDS REVIEW EXAMPLE

- An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients' existing individually identifiable medical records at the clinics where the patients were treated.
- The investigator records only patient age, sex, diagnosis, treatment, and health status at the end of 6 months of treatment so that the investigator cannot link the recorded information back to the patients

RECORDS REVIEW / ARCHIVAL DATA-FERPA

- **May an educational agency or institution disclose personally identifiable information from students education records to third parties for the purpose of conducting a study on its behalf?**
- FERPA contains an exception to its general consent rule under which an educational agency or institution may disclose personally identifiable information from education records without consent to organizations conducting studies for, or on its behalf.
- **Studies must be only for the purpose of: developing, validating, or administering predictive tests; administering student aid programs; or improving instruction.**
- A written agreement with the organization is required, specifying the purposes of the study and the use and destruction of the information. 34 CFR § 99.31(a)(6)
- https://studentprivacy.ed.gov/frequently-asked-questions

VULNERABLE POPULATIONS

RESEARCH WITH PRISONERS (SUBPART C)

- Exemptions do not apply unless the research only incidentally includes prisoners
- Un-incarcerated persons are the reference for risk

Four categories of research involving prisoners:

1. Cause, effects, processes of incarceration and criminal behavior
   - No more than minimal risk and inconvenience
2. Prison institutions or prisoners as incarcerated persons
   - No more than minimal risk and inconvenience
3. Conditions specifically affecting prisoners*
4. Practices that may improve the health or well-being of the subject*

**require HHS secretary approval*

CERTIFICATE OF CONFIDENTIALITY (CoC)

- May be obtained from NIH for certain types of identifiable, sensitive information
  - Individual identified

OR

  - At least small risk for data could be used to reveal the identity of the individual

- Commonly used in prisoner research
- Provides assurance that researcher will maintain confidentiality

https://grants.nih.gov/policy/humansubjects/coc/information-institutional-responsibilities.htm

https://grants.nih.gov/policy/humansubjects/coc/suggested-consent.htm

RESEARCH WITH CHILDREN: 45 CFR 46 SUBPART D

- Only certain exemptions apply to children
  - Observation with no researcher participation
  - Educational tests
  - Identity can not be ascertained
  - Disclosure of information would not put at criminal or civil risk or be damaging
- Must be no more than minimal risk to be considered for expedited review

RESEARCH WITH CHILDREN: ASSENT
45 CFR 46 SUBPART D

- Assent (failure to object is NOT assent)
  - Should be solicited when appropriate
  - Verbal or written at appropriate grade level
  - Assent not necessary if:
    - Limited capability of some or all children involved; OR
    - Intervention may provide direct benefit and is not available outside of the research

RESEARCH WITH CHILDREN: PARENTAL PERMISSION 45 CFR 46 SUBPART D

- Parental permission
  - At least one parent:
    - No more than minimal risk; OR
    - More than minimal risk but may provide direct benefit to child AND favorable risk:benefit
  - Both parents:
    - More than minimal risk and no direct benefit
      - Minor increase in risk (no significant threat to well-being)
      - Likely to yield important information regarding disease or condition
    - Otherwise not approvable but opportunity to understand, prevent or alleviate serious problem affecting children
      - Must be reviewed by HHS Secretary appointed pane of experts
    - Wards may not participate in these types unless:
      - it is related to status as wards; or
      - In schools, camps, etc. where most children are not wards; AND
      - REC must appoint an advocate for the ward

RESEARCH WITH CHILDREN: PARENTAL PERMISSION 45 CFR 46 SUBPART D

- Waiver or alteration of permission allowed only if:
  - All general waiver conditions (45 CFR 46.116(f)) are met; and
  - There is no more than minimal risk; and
  - Both assent and parental permission are sought
- For research requiring permission from both parents:
  - If one parent is deceased, unknown, incompetent;
  - or not reasonably available;
  - or one parent has legal custody

→ permission from both parents is not required

PROPOSAL SUBMISSION & REVIEW

https://rec.spalding.edu/

Complete CITI training

- Everyone involved
- Once / 3 years
- http://www.citiprogam.org

Determine level of review

- Exempt
- Expedited
- Full

Prepare materials

- Cover page info
- Proposal
- Recruitment script
- Consent form(s)
- Other

PROPOSAL COMPONENTS

- COVER PAGE
  - Investigator info
  - CITI certificate(s)
  - Site(s) of research
  - Target population
  - Duration
  - Funding
  - Review category
- PROPOSAL DETAILING:
  - Background / purpose of research
  - Recruitment process
  - Consent process
  - Data collection / research procedures and methodology
  - Risks and benefits of research
  - Data storage and confidentiality
  - Appendices and attachments

PROPOSAL COMPONENTS CONTINUED

- Consider timeline of project events and describe accordingly
- Include all materials that will be used as attached appendices
  - Recruitment scripts (emails, social media posts, fliers, etc.)
  - Consent / assent / permission forms (or waiver request if applicable)
  - Video / photo release forms
  - Questionnaires / surveys (in full) / interview prompts, etc.
  - Debriefing script / form
  - Site permission letter
  - Any other documentation that will be used in the study
    - Intervention protocols

INFORMED CONSENT

Must Include the Following Information:

- Statement of research
- Purpose of the research
- Procedures involved in the research
  - Who, what, when, where, how long
- Alternatives available should a subject decide not to participate in the research
- All foreseeable risks and discomforts to the subject, including physical injury, psychological, social, or economic harm, discomfort, or inconvenience
- Benefits of the research to society and possibly to the individual subject (if any)

INFORMED CONSENT CONTINUED

Must Also Include the Following Information:

- Length of time the subject is expected to participate
- Payment for participation (if applicable)
- Statement that participation is voluntary and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive
- Subjects' right to confidentiality and right to withdraw from the study at any time without any consequences
- Explanation of how privacy / confidentiality will be maintained
- Investigator contact information
- REC Statement and contact information, including current chair

CONSIDERATIONS FOR WAIVER OF CONSENT

- No more than minimal risk
- Research could not practicably be carried out without the waiver
- Research could not practicably be carried out without using private information or identifiable biospecimens
- The waiver will not adversely affect the subjects
- When appropriate, subjects will be provided with additional pertinent information after participation

ANONYMITY & CONFIDENTIALITY

Anonymity

- Protects subjects' privacy by maintaining no record of their identity
- Consent forms constitute a record, which is why they are sometimes waived to protect anonymity of subjects

Confidentiality

- Protects subjects' privacy by:
    1. Keeping identifying information separate from the data gathered;
    2. Coding any identifying categories in the data set;
    3. AND locking up the list of subjects by code until the list is destroyed

About Research Participation

A Library of Resources About Research and Research Participation

ARP
ABOUT RESEARCH PARTICIPATION

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

OHRP has developed the *About Research Participation (ARP)* online collection of resources for you. These materials will help you understand what research is and what is involved in research participation. They will empower you to make your own informed decisions regarding potential participation.

Interested in learning more?

Access using the link *www.hhs.gov/About-Research-Participation* or scan this QR code and have access to our library of resources at your fingertips!

- Watch short informational videos
- Read infographics on the history of human research protections
- Print a list of questions to ask about research participation

All of our ARP materials are available in Spanish!

Additional questions? Email us at *OHRP-EDU@hhs.gov*
or call toll-free *(866) 447-4777*

OASH | Office for Human Research Protections

Prepare Materials

- Check for completeness & clarity
- Check readability

Submit Proposal

- Check REC website before submitting

COMMON MISTAKES

- Recruitment and consent process are not clearly explained
- Methods / intervention / data collection processes not clearly explained
- Unclear timeline of events
- Discrepancies between proposal and consent or other documents
- Readability too high
- Templates not followed
- Missing appendices
- Missing signatures

CRITERIA FOR APPROVAL

- All necessary components / appendices have been submitted
- Risks are minimized
- Risks are reasonable in relation to proposed benefit
- Equitable selection of subjects
- Informed consent sought and documented
- Data monitoring plan (if needed)
- Adequate plans to protect privacy and maintain confidentiality
- Additional safeguards to protect vulnerable populations

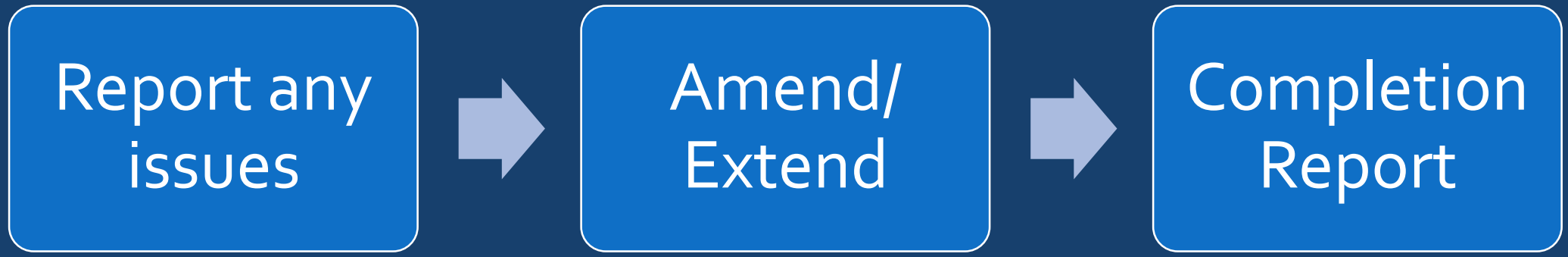
OTHER CONSIDERATIONS

- READING LEVEL
  - Ensure understanding of material
  - 8th grade level or lower, unless specific justification is provided for otherwise
  - Applies to consent form AND any other written information provided to the participant
- SNOWBALL SAMPLING
  - Using current participants to recruit others
  - May be acceptable in certain circumstances-must use caution not to incidentally disclose private information of participants / potential participants
  - Cannot provide compensation for referrals
  - Good alternative: give participants flyers, etc to pass along rather than asking for names.

- Deferred
- Approved
- Conditionally approved
- Denied

WHEN CAN I START COLLECTING DATA?

- After all requirements of the REC have been fulfilled; and
- An approval letter from the Chair of the REC has been received
  - Any data collected prior to that date is not valid.
  - If the study involves a sponsored project, no funds can be expended until study is approved by REC



- Must be submitted 30 days prior to approval expiration

WHAT ABOUT COLLABORATIONS WITH OTHER INSTITUTIONS?

- Studies with approval from another IRB may not need REC approval.
- You must still notify the REC
- Must submit an IRB Authorization Agreement (IAA) for approval.

QUESTIONS?

PLEASE VISIT THE REC PAGE ON YOUR SPALDING PORTAL. THERE YOU CAN FIND…

- Links to forms and templates required for your proposal submission
- Submission form (coming soon)
- Links to OHRP and other helpful websites
- Examples of completed forms
- Other information to help with your proposal preparation and submission

REC CONTACT INFO

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