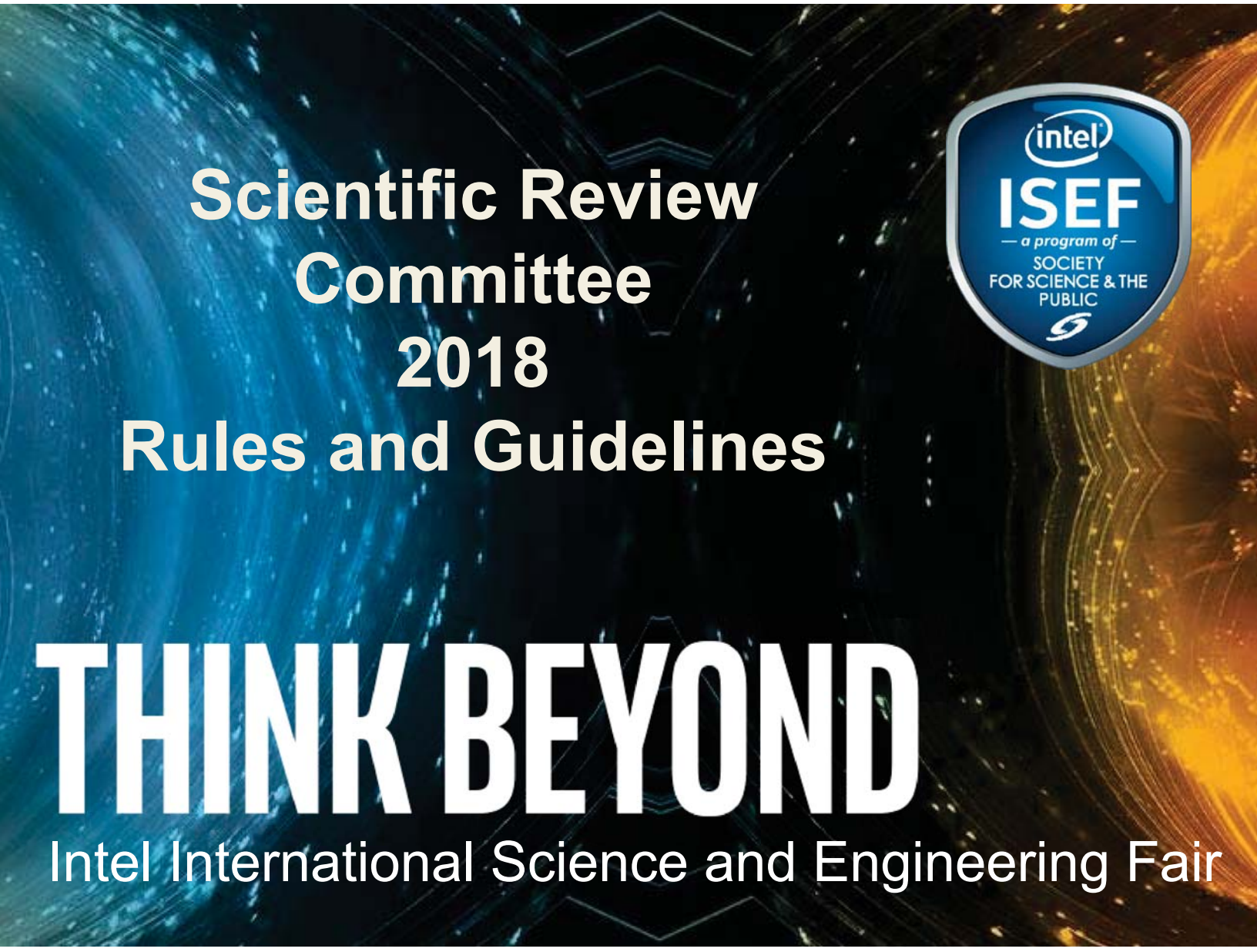
Scientific Review Committee 2018 Rules and Guidelines



2018
Rule Clarifications
&
Changes

Introductions
&
Acknowledgements

SRC Members

Mrs. Christine Miller, Chair
Ms. Susan Appel
Mr. Henry Disston
Dr. Jennifer Green
Dr. Paula Johnson
Dr. Timothy Martin
Mrs. Evelyn Montalvo
Dr. Jason Shuffitt
Mrs. Andrea Spencer

Summary of Changes

- Review Committees
  - Added PharmD to the list of medical professionals allowed on IRB (pgs1-8)

- Human Participants
  - Modified the rules related to the expedited review process (pgs 9-10)
  - All human projects are considered to have some level of risk (pg 11)

Summary of Changes

- Vertebrate Animals
  - Clarification of required IACUC documentation (pg12)
  - Clarification of toxic studies (pg13)

- PHBAs
  - Clarification about Genome editing (pg 16)
  - Clarification about non-native species (pg 16)

Summary of Changes

- Form 1 (pg 29)
  - –Formatting changes mostly to increase awareness of fact that testing inventions, etc. most likely will require a completed form 4 (Human Subjects).

Summary of Changes

- Research Plan (pg 31)
  - All projects must have a Research Plan and/or Project Summary
  - Clarifications of when Research Plan, Addendums, and/or Project Summary are required.

Summary of Changes

- Form 6A (Pg 40)
  - –Signature Sections
    - Dates required for QS and SRC signatures.

HUMAN PARTICIPANTS

Review Processes for Human Participant Projects

- Exempt Projects/Studies
  - No IRB Review, No Form 4
- Expedited Review Projects/Studies
  - IRB Review by one adult, Yes, Form 4
- Full IRB Review Projects/Studies
  - IRB Review by at least 3 adults, Yes, Form 4

Human Participant Involvement in Student-designed Invention, Prototype, Computer Application & Engineering/Design Projects

- Testing of the invention by any human participant require attention to the potential risks to the individual(s) testing or trying out the invention/prototype.

- To be considered for Exempt Status or Expedited Review, the data collected/feedback received must be a direct reference to the invention/prototype (i.e., personal data cannot be collected) and the testing may not pose a health or safety risk.

  – Exempt Status can be used when the student researcher is the only person testing the invention/prototype. It is recommended that a Risk Assessment Form (3) be completed.

  – Expedited Review process may only be used for projects that involve human participants to test a student designed intervention or prototype in which the feedback obtained is related to the invention.

Human Participant Involvement in Student-designed Invention, Prototype, Computer Application & Engineering/Design Projects

- Full IRB Review is necessary if the activities involved in testing of the invention or prototype **are more than minimal risk or involve collection of personal information from participants.**

- Full IRB Review is necessary if the testing of the invention, prototype or project **involves a medical intervention (as defined by the FDA or Medical Practices Act)** and must be conducted in a ***Registered Research Institution with IRB approval from the institution.***

Exempt Projects

(No IRB review or Form 4 Required)

1) Student-designed Invention, Prototype, Computer Applications or Engineering/Design **project when no health/safety hazard & the student researcher is the only human testing the invention.** → Form 3 is Recommended.
2) Data/record review studies (publically available data)
3) Behavioral Observations in public setting
4) Pre-existing, de-identified/anonymous data set

Expedited Review

- The IRB member reviewing the project will determine whether appropriate safety precautions will be employed and whether the project meets criteria for expedited review.

- If a project submitted for expedited review does not meet the specified criteria, the project must undergo full IRB review.

- The IRB member reviewing the project **must** have the **expertise necessary** to make such a decision and/or receive advisement from an appropriate expert.

Expedited Review Process

- One IRB member must review the project and certify that it meets criteria for expedited review.
  - Appropriate expertise
  - IRB member confirms that it does meet expedited review criteria before approving as expedited
  - If it does not meet criteria, the project must undergo Full IRB Review (3 adults).

Student Designed Inventions & Engineering Projects

- Student-designed Invention, Prototype, Computer Applications & Engineering/Design Projects
- Human involvement to test the invention requires Form 4 (Review & Pre-approval)
- **Expedited Review (one adult review)**

- Testing a student-designed project
  - **Does it work?**
  - Examples: Computer game, re-designed mouse, devices to improve lives
  - Data/information is in direct reference to the invention & no personal data collected
  - Testing does not pose a health or safety hazard

Expedited Review Cannot Be Used

- Project looking at a change in behavior or cognition over time
- Project comparing performance of different groups of participants
- Project collecting information about mental health or personal opinions
- Research study about the “invention” as an intervention to change behavior
- Testing the invention poses any health or safety hazard or involves collection of personal information
- **In these cases, Full IRB (3 members) Required**

BELOW - IRB USE ONLY

Must be completed by Institutional Review Board (IRB) after review of the research plan. All questions must be answered for the approval to be valid. (If not approved, return paperwork to the student with instructions for modifications.)

☐ Approved with Full Committee Review (3 signatures required) and the following conditions: (All 6 must be answered)

1. Risk Level (check one) : ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist (QS) Required: ☐ Yes ☐ No
3. Designated Supervisor (DS) Required: ☐ Yes ☐ No
4. Written Minor Assent required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
5. Written Parental Permission required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
6. Written Informed Consent required for participants 18 years or older:
   ☐ Yes ☐ No ☐ Not applicable (No participants 18 yrs or older in this study)

☐ Approved with Expedited Review (1 signature required). Study involves either of the following:

- ☐ Human participants will only provide feedback on project design/student-designed invention or prototype. etc., no personal data will be collected and there are no health or safety hazards.
- ☐ Student is the only subject of the research and no more than minimal risk is involved.

IRB SIGNATURES (All 3 signatures required unless expedited review checked above) None of these individuals may be the adult sponsor, designated supervisor, qualified scientist or related to (e.g., mother, father of) the student (conflict of interest).

I attest that I have reviewed the student's project, that the checkboxes above have been completed to indicate the IRB determination and that I agree with the decisions above.

Medical or Mental Health Professional (a psychologist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, or registered nurse) with expertise related to this project.

Full IRB Review

- 3 members with appropriate expertise
- Each member must review research plan
- Ideally, there is discussion with all members present who consider the safety of the participants and student researcher and make a decision about whether the project should be approved or not approved as written in current research plan.
  - Unapproved project
    - Student told he/she cannot undertake this project
    - Student can be asked to make revisions to address IRB concerns (e.g., privacy, safety, etc)

BELOW - IRB USE ONLY

Must be completed by Institutional Review Board (IRB) after review of the research plan. All questions must be answered for the approval to be valid. (If not approved, return paperwork to the student with instructions for modifications.)

☐ Approved with Full Committee Review (3 signatures required) and the following conditions: (All 6 must be answered)

1. Risk Level (check one) : ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist (QS) Required: ☐ Yes ☐ No
3. Designated Supervisor (DS) Required: ☐ Yes ☐ No
4. Written Minor Assent required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
5. Written Parental Permission required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
6. Written Informed Consent required for participants 18 years or older:
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Medical or Mental Health Professional (a psychologist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, or registered nurse) with expertise related to this project.

Rule of Thumb

If in doubt or confused about Expedited Review…….

Use FULL IRB (3 Member) REVIEW!

VERTEBRATE ANIMALS

Vertebrate Animals clarification

- 2017 Wording:

  Documentation is required of the IACUC approval for the original animal study from which tissue are obtained.

Vertebrate Animals clarification

- 2018 Wording

Use of tissues obtained from research conducted at a Regulated Research Institution requires a copy of an IACUC certification with the name of the research institution, the title of the study, the IACUC approval number, and the date of IACUC approval.

Vertebrate Animals clarification

- 2017 Wording 10.a.

  Induced toxicity studies with known toxic substances that could cause pain, distress or death, including but not limited to alcohol, acid rain, pesticides, or heavy metals.

Vertebrate Animals clarification

- 2018 Wording 10.a.

  Induced toxicity studies with known toxic substances that could cause pain, distress or death, including but not limited to alcohol, acid rain, pesticides, or heavy metals **or studies with the intent to study toxic effects of a substance on a vertebrate animal.**

Vertebrate Animals clarification

- 2017 Wording A.5. (pg. 13):

  The final disposition of the animals must be described on Vertebrate Animal Form 5A.

Vertebrate Animals clarification

- 2018 Wording A.5. (pg. 13):

  The final disposition of the animals must be **conducted in a responsible and ethical manner,** and must be described on Vertebrate Animal Form 5A.

PHBA'S

PHBA clarification

- 2017 Wording B.4. (pg 16)

  All rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in a Regulated Research Institution and approved by the IBC prior to experimentation.

PHBA clarification

- 2018 Wording B.5. (pg 16)

  Genome editing studies with possible biological impact including alteration of germline cells (insertion of gene drives, use rapid trait development systems (RTDS®) **should be categorized as a BSL-2 study** and **must be conducted at an RRI** and approved by the IBC from the institution.

PHBA clarification

- 2018 Wording B.6. (pg 16)

  Introduction or disposal of non-native, genetically-altered, and/or invasive species (e.g. insects, plants, invertebrates, vertebrates), **pathogens, toxic chemicals or foreign substances into the environment is prohibited.** Students and adult sponsors should reference their local, state and national regulations and quarantine lists.

FORM CHANGES

FORM 1: Checklist for Adult Sponsors

New Item 6: (pg 29)

Humans, including student designed invention/prototype.

- Human Participants Form (4) or appropriate Institutional IRB documentation
- Sample of Informed Consent Form (when applicable and/or required by the IRB)
  - Qualified Scientist Form (2) (when applicable and/or required by the IRB)

Research Plan

- Research Plan (pg 31)
  - All projects must have a Research Plan and/or Project Summary

    •Written prior to experimentation detailing research question(s), methodology, and risk assessment.

    •Addendums required if changes are made during the research. Any additional approvals must be obtained and documented. This document can serve as Project Summary.

    •If no changes are made from the original research plan, no project summary is required.

Form 6A
PHBA Risk Assessment Form

- Form 6A (Pg 40)
  - –Signature Sections
    - Dates required for QS and SRC signatures.

FREQUENT SRC ISSUES

Frequent SRC Issues

- Missing Information
  - Source of Cell Cultures
    - ATCC vs Fresh Tissue
  - Strain of Bacteria, esp. *E. coli*

Frequent SRC Issues

- Missing or Incomplete Forms
  - Research Plan/Project Summary
  - Form 3 - Risk Assessment
  - Form 4 – Human Participants
  - Forms 6A & 6B – PHBA
  - Form 7 – Continuation Projects Form
  - Form 1C – Regulated Research Institute/Industrial Setting
  - Form 1B -

Frequent SRC Issues

- Too Much Information
  - Previous Years Work described in Abstract
  - Description of Mentor's work versus Student's experiment
  - Signed Human Consent Forms
  - References to Patents or Copyrights
  - MSDS Sheets

2017
FTQ'S

2017 FTQ's

5 Failed to Qualify

3 Guests

Top Reasons for FTQ

- BSL2 work in BSL1 lab setting
- Toxicity or stressful studies involving vertebrate animals.
- Too Many Students
- Students too Old
- Human Participants with no prior or improper IRB approval

QUESTIONS
&
ANSWERS

SUGGESTIONS FOR RULE CHANGES/CLARIFICATIONS ARE ALWAYS APPRECIATED AND CAN BE EMAILED TO:

SRC@SOCIETYFORSCIENCE.ORG

COMPLAINTS CAN BE EMAILED TO:

SRC@SOCIETYFORSCIENCE.COM