

SCIENCE TALENT SEARCH

A program of SOCIETY FOR SCIENCE Since 1942

REGENERON SCIENCE TALENT SEARCH 2024 RULES AND ENTRY INSTRUCTIONS

APPLICATIONS DUE ON WEDNESDAY, NOVEMBER 8, 2023 AT 8:00 PM EASTERN TIME! All entrants should review this document prior to applying.

CHECKLIST FOR REGENERON STS ENTRANTS

Applying to Regeneron STS? Review this book carefully, and complete this checklist! The checklist below is provided to help you navigate the Rules Book so that you do not miss information pertinent to your project.

- 1.
 □ Review the basic eligibility requirements on page 6.
- 2. 🗌 Read the Entry Rules and Ethics Information on pages 9 and 10.
- - a. If you worked with vertebrate animals or vertebrate animal cell lines or tissue cultures, review page 20.
 - b. If you worked with humans or human tissue samples, or sets of human data, review page 14. This includes all surveys.
 - c. \Box If your engineering project or invention was tested on humans, review page 14.
 - d. 🗌 If you worked with Potentially Hazardous Biological Agents, review page 22.
- 4. 🗌 Mark the application deadline on your calendar.
- 5. Open your online application at <u>sciencetalentsearch.smapply.org</u>.
- 6. 🗆 Request your recommendations right away! See page 28.
- 7. 🗆 Work on your research report. See page 26.
- 8. C Review common reasons projects fail to quality on page 43 make sure these reasons do not apply to you!
- 9. 🛛 Submit by the deadline on Wednesday, November 8, 2023 at 8:00 pm Eastern Time!

Questions about your eligibility, your project or the application? Email **sts@societyforscience.org**.

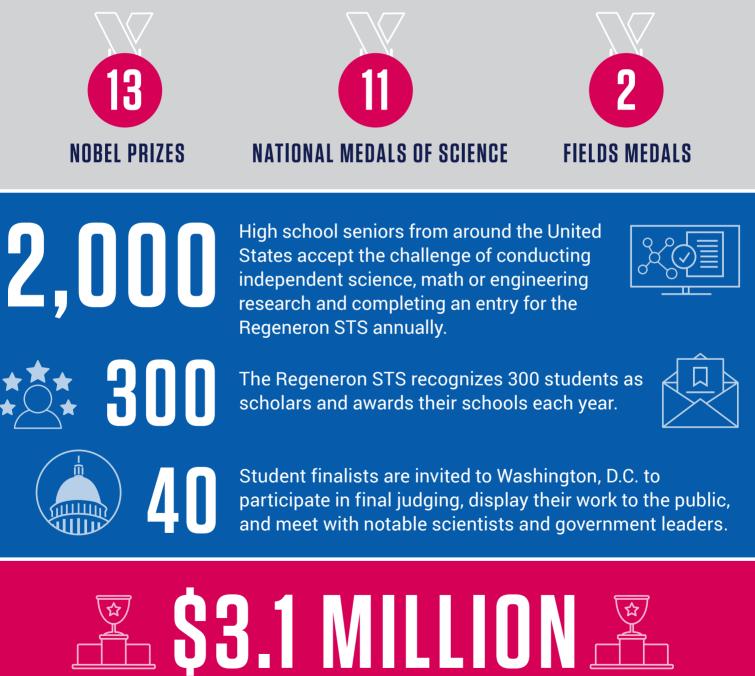
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REGENERON SCIENCE TALENT SEARCH

Regeneron STS is the oldest and most prestigious science and mathematics competition for high school seniors, providing an important forum for original research that is recognized and reviewed by a national jury of professional scientists since 1942.

Alumni have made extraordinary contributions to science and have earned many of the world's most distinguished science and math honors including:



Each year, Regeneron STS scholars and finalists compete for \$3.1 million in awards.

IMPORTANT DATES

Application Opens

June 1, 2023

Vist: sciencetalentsearch.smapply.org

Technical Support Deadline November 7, 2023 at 8:00 pm Eastern Time

Students submitting a technical support request by this date and time are guaranteed that the problem reported will be resolved before the Application Deadline. The Society cannot guarantee that requests for technical assistance will be resolved if submitted after this date and time.

Application Deadline

November 8, 2023 at 8:00 pm Eastern Time

All parts of the application must be received by the Society by this date and time, including recommendations. Recommendations must be submitted by the recommendation provider by this date and time. No portions of the application will be accepted after the deadline for any reason. Materials are only accepted through the online application portal.

Top 300 Scholars Announced	January 10, 2024
Top 40 Finalists Announced	January 24, 2024
Regeneron Science Talent Search Finals Week	March 7-13, 2024
Top 10 Winners Announced	March 12, 2024

Visit the Regeneron STS website for updates societyforscience.org/regeneron-sts



"Applying for Regeneron STS is a chance to have your hard work recognized and join a community of thousands of other student scientists. Make sure you have a well-written paper, but also let your personality shine through in the short responses. STS is not just about your research – it's about who you are as a scientist and a person."

CINDY DEDIANOUS, REGENERON STS FINALIST 2023

AM I ELIGIBLE?

Entrants must meet all of the eligibility requirements listed below.

1. AGE

Applicants must:

- a. be over 13 years of age and have legal parental or guardian consent to submit the application and participate, OR
- b. be 18 years of age or older, OR
- c. be an emancipated minor.

2. CITIZENSHIP

On the application deadline, applicants must be:

- a. A student (of any citizenship) who is enrolled in and attending secondary school AND who maintains full-time residence in the United States, Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, Wake and Midway Islands or the Marianas OR
- b. A United States citizen enrolled in their final year of secondary school on the application deadline date attending a:
 - i. Department of Defense Dependents School or an accredited overseas American or International School, OR
 - ii. foreign school as an exchange student, OR
 - iii. foreign school because their parent(s)/guardian(s) are temporarily working and living abroad.
- c. Proof of citizenship and school accreditation is required for 2b (above).

3. SCHOOL STATUS

Applicants must be in their final year of their secondary school (public, private, parochial, charter or home school), completing high school courses required for college applications, must not have graduated from high school before the Regeneron STS application deadline, and must not have entered any previous STS.

a. Students who are uncertain of their graduation year at the time of entry must notify the Society by December 15, 2023 to either withdraw their application due to continued uncertainty, or confirm that they will graduate in the 2023/2024 academic year.

4. TYPE OF RESEARCH

- a. Applicants must complete **individual research projects** to enter Regeneron STS. Research conducted as part of a pre-collegiate student team project is not eligible for Regeneron STS. This includes any research or portion of research regardless of whether it has or will be submitted to any competition. To remain eligible and collect Regeneron STS awards, the following statements must remain true about the submitted research project until June 1, 2024:
 - i. Students may not "split" a team project and enter it in Regeneron STS as individuals. Students also may not within the time between submission to Regeneron STS in November 2023 and June 2024 combine individual research submitted to Regeneron STS and present it as a team in competition, publications or any forum.
 - ii. Students who have been part of a team project wishing to continue as an individual may only submit the work completed independently and may not submit any work completed with the teammates.
 - iii. Research conducted alongside adult researchers in a research institution is permitted, but clarity and adequate knowledge of an individual's role and independence vs. work being done by the collective laboratory throughout the application is vital. Consideration should be given to the extent to which the research qualifies as independent research, given the student and adult responsibilities.

b. Continuation research projects and research completed over any length of time in any year of school is eligible for Regeneron STS.

5. CONFLICTS OF INTEREST

- a. Entrants may be mentored by any individual, including relatives or those with personal or professional relationships to the student entrant or members of the entrant's family. However, both students and recommenders must disclose any familial or personal relationship, real or perceived, within the application. This includes (but is not limited to) the following scenarios: mentors are, or have been, colleagues in the same department as the entrant's parents/guardians/other relative; mentor is supervised by the entrant's relative; mentor is a relative/neighbor/family friend of the entrant; etc.
- b. Children of Society for Science employees, Trustees, Regeneron Science Talent Search evaluators or judges are not eligible to enter the Regeneron Science Talent Search.
- c. Individuals who have mentored current year student applicants are not eligible to serve as evaluators or judges.

6. RESEARCH PROGRAMS

Entrants may conduct research within multiple environments, including those in which fees or tuition are paid as long as students meet all of the other criteria of independence per the eligibility requirements above. Entrants AND mentors must fully disclose the payment structure for mentorship, counseling, editing, publishing, etc. as applicable. This is a safeguard for the protection of students. No research program should guarantee placement in the Regeneron Science Talent Search.

7. LEGALITY

Compliance with all federal, state and local laws and regulations is essential. In addition, projects conducted outside the U.S. must also adhere to the laws of the country and jurisdiction in which the project was performed.

8. RULES FOR SCIENTIFIC RESEARCH

Research projects must adhere to all human, vertebrate animal, PHBA and hazardous material rules as outlined by the Regeneron Science Talent Search program. Other competition or research program rules do not override STS rules.



"During the application process, I was concerned I wouldn't be a 'good applicant' because I don't wish to pursue a career in STEM research. This wasn't true. It doesn't matter if you want to go into international relations, business, linguistics, or any other field, because there are always opportunities to apply a research mindset to your life. Applying will help you no matter what life path you follow."

LINDEN JAMES, REGENERON STS FINALIST 2023

APPLICATION REQUIREMENTS

All components of the application are collected through the online system, including school transcripts and test scores. Core components of the application include:

- · Essays, short answer responses, activity and basic information
- Scientific Research Report (maximum 20 page research paper about entrant's original research project) and any corresponding paperwork (see Appendices 7-11, pages 37–42)
- · Recommendations and Transcripts submitted by adults
- Test Scores (optional)

An entry will be considered for review and awards if the following tasks are complete in the online system:

- 1. Task 1: Basic Information
- 2. Task 2: Recommendation Requests

(Applicants must request recommendations from adults via the online application system. See Appendix 3 for more information and requirements.)

- 3. Task 3: Rules Wizard
 - a. Students will answer questions to determine if IRB/IACUC approvals, blank surveys, informed consent, wildlife permits, etc. are needed. See Appendices 7-11 for more information.
 - b. Carefully answer all questions and upload all required documentation. Failure to do so could result in disqualification.
- 4. Task 4: Science Research Description
- 5. Task 5: Research Report Upload (see Appendix 2 for paper requirements)
- 6. Task 6: Previous Research
- 7. Task 7: Essay Questions
- 8. Task 8: Activities, Interests and Awards
- 9. Task 9: Test Scores (OPTIONAL)
- 10. Task 10: Beyond Judging

"Submitted" status: Applications that are not fully submitted will not be accepted. Entrants must hit a submit button and will know their applications have been accepted when they receive a confirmation email. Entrants are required to attest to an Ethics Statement upon submitting their applications (see Ethics Statement on page 10).

ALL COMPONENTS OF THE REGENERON SCIENCE TALENT SEARCH APPLICATION ARE DUE ON **WEDNESDAY, NOVEMBER 8, 2023 AT 8:00 PM EASTERN TIME**, INCLUDING RECOMMENDATIONS FROM ADULTS. NO EXCEPTIONS WILL BE MADE.

ENTRY RULES

ENTRY RULES

- 1. Student must submit all required components of the Regeneron STS online application in order to be considered for awards. Application requirements are listed on page 8.
- 2. Both student and mentor(s) must attest to the Regeneron STS Ethics Statement, available on the next page.
- 3. The practice of mentor/adult compensation based on a student's results (placement) in the Regeneron STS is prohibited. Any such compensation will render the student entry ineligible for consideration and will be grounds for the revocation of any award already made.
- 4. Only one entry per student is allowed. Student must choose one project.
- 5. Student must obtain permission from their project mentor to enter research into Regeneron STS, and both will be asked to attest to this in the application.
- 6. The Society uses plagiarism detecting software to authenticate the Regeneron Science Talent Search entries including essays, research reports and recommendation letters. Every report is individually reviewed by the software and manually reviewed by a Regeneron STS Rules Advisor to determine whether the entry is in violation of Regeneron STS rules and guidelines. Submissions found to be in violation of the originality rules will not be considered for awards. Students who submit applications to Regeneron STS agree to the plagiarism screening. The Societyunderstands that entrant papers often resemble their mentors' research paper. This is one reason students are provided the opportunity to mention similar work and the level of their participation in published work of the lab.
- 7. Students may not provide links to external websites in their research report. Note that evaluators and judges are not permitted to click on additional links.
- 8. Students may not use ChatGPT or other AI tools to answer Regeneron STS application questions or draft the Research Report. Use of such tools for student research projects is permitted, and should be disclosed.
- Student is responsible for drafting all responses to application questions. Any outside support received from teachers, mentors, counselors, etc. in reviewing or editing responses must be reported in the application.



"Regeneron STS has introduced me to a truly inspiring cohort of scholars, scientists, and change-makers. After such an extraordinary week full of unforgettable experiences, I feel incredibly motivated to continue pursuing science with persistence, excitement, and – perhaps most of all – an enduring sense of hope."

ELANE KIM, REGENERON STS FINALIST 2023

ETHICS STATEMENT

The Ethics Statement below speaks to your personal conduct as a young adult within your peer community as well as your conduct as a research scientist, mathematician or engineer.

SCIENTIFIC RESEARCH & ACADEMIC INTEGRITY

- I certify that all the information provided is correct and complete without omission to the best of my knowledge and I certify that the Research Report I am submitting is my own individual work, not that of a student team, nor does it represent the work of others.
- I understand that I am responsible for all aspects of my submission's authenticity: the research, the Application, and all other documentation in the application process, as well as the display board and oral presentation if I am selected as a finalist.
- I attest all content in this submission is exclusively my work in substance and in presentation. I further understand that scientific fraud, misconduct, misrepresentation of work or attribution thereof, or violation of the rules and/or eligibility requirements may result in disqualification and forfeiture of any monetary awards and that the Society reserves the right in such cases to bar future participation in Society programs.
- I have acknowledged all potential conflicts of interest, payment for research programs and parental/familial involvement and outside support related to my STS project.

JUDGING AND INTELLECTUAL PROPERTY

- I understand and accept that the judging and evaluation process used by Regeneron STS/ the Society is confidential and proprietary and that by submitting a Regeneron STS entry, I expressly agree to Regeneron STS/the Society's right to maintain the confidentiality of such process.
- I agree to unconditionally accept the decision of the judges as final and binding in all matters related to the Regeneron STS program and understand that my application and Research Report will not be returned to me but shall become the sole property of Regeneron STS/the Society. I understand that Regeneron STS/the Society makes no warranties, representations or guarantees, express or implied, in fact or in law, with respect to the Regeneron STS program.
- I expressly waive any rights to challenge, inspect, observe or otherwise obtain any information that constitutes the confidential and proprietary information of the Regeneron STS/the Society judging and evaluation process. I also agree to permit Regeneron STS/the Society to use all information contained in my application in any way it deems appropriate for publicity purposes.
- I certify that I have not used AI tools, like ChatGPT, to construct the research report or responses to questions in the application.

ELIGIBILITY

- I certify that I am at least 18 years of age, or that I am an emancipated minor, or that I possess legal parental or guardian consent to submit the Application and participate in the Regeneron STS, and that I am fully able and competent to submit the Application and to abide by and comply with the Regeneron STS Rules and Entry Instructions. In any case, I certify that I am over the age of 13.
- I certify that I have read and fully understood all rules and eligibility requirements found in the Regeneron STS Rules & Entry Instructions and that I have complied with all rules and meet the eligibility for submitting this Regeneron STS entry.
- I understand that if selected as a top 40 finalist I am obligated to complete all necessary forms and megaform tasks as assigned by the Society for Science throughout the spring to prepare for my participation in Finals Week.
- I understand that the Society reserves the right to remove me from the program and forfeit any awards and/or bar future participation in Society programs for scientific fraud; personal or scientific misconduct; misrepresentation of work or attribution thereof; violation of the Regeneron STS rules, eligibility requirements, or the Regeneron STS Ethics Statement; and/or conviction of a criminal offense.

WHAT COULD I WIN? SELECTION PROCESS, AWARDS, FINALS WEEK EXPERIENCE

SELECTION PROCESS

Regeneron STS utilizes a holistic selection process to identify future leaders in science, technology, engineering and mathematics. All components of the entrant's application are reviewed and considered; the research project, while important, is not the only factor for award decisions.

After reviewing entries for completeness, accuracy, eligibility and rules adherence, student age, citizenship and residence, all portions of every eligible submission are evaluated by three or more doctoral scientists, mathematicians, and/or engineers in the appropriate scientific discipline. The originality of each entry is checked using plagiarism monitoring software. A rules committee reviews each project for compliance with the vertebrate animal and human participant rules. Entries are evaluated in four areas:

- · Research Report and Scientific Merit
- Student Contribution to the Research
- Academic Aptitude and Achievement
- · Overall Potential as a Future Leader of the Scientific Community

Regeneron STS only considers the content shared in each entrant's application package; Regeneron STS does not consider updates or materials sent after the submission deadline. Demonstrated student interest, outside letters of recommendation and quotas of any sort (category, region) are not factors in the selection process. Evaluators consider student circumstances and access to labs, activities and other personal context in relation to student achievement.

Three hundred scholars are selected. These top entries are further reviewed by an additional judging panel of doctoral scientists, mathematicians and engineers, who select 40 finalists. The 40 finalists travel to Washington, DC to compete for top 10 awards. During this time, finalists undergo two types of judging – project judging, relating to their research, and panel judging, designed to evaluate the depth and breadth of their general scientific knowledge.

ENTRANT RECOGNITION

All eligible and valid entrants will receive a t-shirt, laptop stickers, and a free one-year subscription to Science News magazine.

SCHOLAR AWARDS

Each of the 300 Scholars will receive a \$2,000 award. These awards will be mailed to Regeneron STS scholars in late spring upon completion and upload of a W9 Request for Taxpayer Identification Number to the Society's online payment portal.

SCHOOL AWARDS

The Regeneron Science Talent Search School Award recognizes excellence in teaching and school support of individual student research. The schools of each Scholar will receive \$2,000 per Scholar. The award is intended to contribute to excellence in science, math and/ or engineering education at the recipient school. In the case of home schooling, the award will be given to a public school district in the home state of the student, or to a 501(c)3 non-profit science organization of the student's choosing and at the approval of the Regeneron STS Director. The award will be mailed to the recipient in the spring after submission of the School Award Program application and a W9 Request for Taxpayer Identification Number to the Society.

REGENERON SCIENCE TALENT SEARCH FINALS WEEK & TOP 10 AWARDS

The 40 Regeneron Science Talent Search finalists will participate in an in-person competition March 2024. The program will include final in-depth judging, visits to historic sites and cultural institutions, and meetings with national leaders and prominent scientists and engineers. Finalists will exhibit their research to the public and will have the opportunity to exchange ideas and insights with each other, as well as with illustrious members of the scientific research community. Full participation in the Regeneron Science Talent Finals Week and completion of preparatory tasks are requirements of maintaining finalist status and receiving finalist award monies. Finalists must agree to the Society's Finalist Agreement, Media Agreement, Ethics Statement and other programmatic rules. The Regeneron Science Talent Institute culminates in a black-tie gala honoring the forty finalists, to be held mid-March 2024. The evening will conclude with the announcement of the top ten award winners.

FINALIST AWARDS

A panel of judges representing expertise across the disciplines of entry convenes and selects 40 finalists from among the scholars. In addition to an all-expense-paid trip to Washington, DC, finalists receive a minimum award of \$25,000. Award amounts are as follows:

FIRST PLACE AWARD \$250,000 SECOND PLACE AWARD \$175,000 THIRD PLACE AWARD \$150,000

FOURTH PLACE AWARD \$100,000 FIFTH PLACE AWARD \$90,000 SIXTH PLACE AWARD \$80,000 SEVENTH PLACE AWARD \$70,000 EIGHTH PLACE AWARD \$60,000 NINTH PLACE AWARD \$50,000 TENTH PLACE AWARD \$40,000 REMAINING THIRTY FINALISTS \$25,000

CONDITIONS OF AWARDS

All awards will be paid in the year they are awarded, if the student has provided the necessary documentation to process payment. Awards below \$20,000 not disbursed within two years of the award date will be subject to forfeiture (this primarily is applied to the \$2,000 Scholar and School Awards). Finalists must participate in the finals week program and complete required documents and tasks in order to remain in good standing and claim their award funds. For individual awards greater than or equal to \$20,000, annual payments will be made either to the student winner to use for educational purposes, or directly to their college or university of choice. The awardee must be an undergraduate or graduate student in good standing to receive payment. Payments must begin no later than six years after the award is made and must conclude within eight years of matriculation from high school. Initial payments will commence once the student has provided the necessary documentation to provide payment. Awards not disbursed within the dates noted above will be subject to forfeiture. The Society may approve, at its discretion, the extension of the payment schedules noted above if the student provides a request in writing detailing his or her individual circumstances. The Society reserves the right to deny any such request. Internal Revenue Service (IRS) regulations require that the Society file IRS Form 1099 for Miscellaneous Income for recipients of award monies which total \$600 or more during a calendar year; similarly, colleges and universities who receive direct payment from the Society on a student winner's behalf will file IRS Form 1098-T. Award recipients will receive their copy of Form 1099 from the Society, or Form 1098-T from their college or university, in January of the year following the year award payments are made. A full policy is provided to top 40 finalists.

ACADEMIC INTEGRITY

Regeneron STS, like colleges and universities across the nation, expects that students hold themselves to rigorous ethical standards, both academic and personal. Responsibility for integrity in scholarship is inherently the entrant's. Students must be responsible for all aspects of their work's authenticity as outlined in the eligibility rules above. Students must disclose parental involvement and other personal conflicts of interest.

The required signature box in the Ethics Statement stage of the application asks the entrant to attest to every statement, and by their signature, claim each one to be true and understood. It also attests that material submitted is exclusively the work of the applicant in substance and in presentation. If a determination is made at any point that an entrant has violated rules as outlined in this document or at the discretion of the Society, and/or misrepresented work or attribution thereof, the Society reserves the right to disqualify the entry, withhold and/or withdraw monetary awards and/or exclude the entrant from participating in Society programs.

INTELLECTUAL PROPERTY

Independent research for the Regeneron STS may produce findings that are the Intellectual Property (IP) of the entrant. Participation in the Regeneron STS requires disclosure of methods and results; they will be made available to our evaluators and judges, who sign nondisclosure agreements. Research reports are not shared with anyone besides Society staff, the judges, evaluators and science writers who draft the top 40 finalist biographies; all of these audiences sign confidentiality agreements. The public relations teams at Regeneron and the Society's PR firm receive essays from the applications for story mining and pitching, but do not receive copies of the research papers. Regeneron is not involved in the project review or student selection process. Results and methods may be made available to the public in summary format in the promotion of the project. If entrants are concerned about the protection of IP, they are urged to consider these issues with their supervising scientist and qualified adult advisors to make an informed decision before entering the Regeneron STS. The exhibition, posting, and judging process will not be modified in deference to journal embargoes or other considerations.

If an entrant is asked to waive copyright for the paper for publication in a peer-reviewed scientific journal, the entry is still considered eligible for Regeneron STS. The Society does not publish entrant, scholar or finalist research papers in full, or share with members of the media.

GRIEVANCES

If an adult or student entrant wishes to share a grievance or a suspected violation of STS entry rules, eligibility or research related rules, or suspicious research programs, they should email their concern to **sts@societyforscience.org**. The Society cannot investigate anonymous complaints, but will attempt to maintain confidentiality whenever possible.



"Regeneron STS gave me a goal to work towards, and I thought that it would also be a great way to connect with other likeminded people of my age. Browsing through past project winners, I was awed by the variety of projects and ideas that people had. It inspired me to submit to STS and become a part of that diversity of thoughts and ideas that are being recognized by this competition. As for advice, I think that anyone who is passionate about a project that qualifies for the competition to submit should submit! And definitely try to plan ahead if you can – the application is long!"

RYAN LEE, REGENERON STS FINALIST 2023

RULES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, HUMAN DATA & HUMAN TISSUE

HUMAN PARTICIPANT: Did you ask humans to take any sort of action (jump around, fill out a survey, test your invention, take a photo, donate blood, etc.)?

HUMAN TISSUE: Did you use human tissue (from a public database or catalog, from a mentor's study or anywhere)?

HUMAN DATA: Did you work with any data relating to humans, whether you collected it yourself, received it from a mentor or a hospital, or took from a public source?

If yes to any of the questions above, then you need to read this section carefully. Many of these types of projects require pre-approval from an Institutional Review Board (IRB) and you will need to share proof of this pre-approval. DO NOT START YOUR RESEARCH until you have obtained proper permissions.

In almost all cases mentioned above you will be asked to share the source of your data; in some cases, your mentor will need to certify this information. Be sure to save all paperwork, pay attention to research start and end dates, and make sure all paperwork is properly signed. Without this important documentation, your project might fail to qualify. Read more below.

HUMAN PARTICIPANT RESEARCH

Based upon the Code of Federal Regulations (45-CFR46), the definition of a human participant is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), or (2) identifiable private information.

Applies to all student researchers who collected human-related data (via surveys or other methods) or tested a device or program on humans. **IRB approvals, when needed, must be obtained before experimentation on human participants**.

- 1. Prior to starting experimentation, student researchers must write a research plan that includes a description of research participants, recruitment procedures, research methodology, assessment of risks and benefits of the research, procedures for minimizing physical, psychological and privacy risks to participants and procedures for obtaining informed consent/parental permission/assent.
- 2. The research plan must be reviewed and approved by a properly constituted Institutional Review Board (IRB) BEFORE the student may begin recruiting and/or interacting with human participants (see IRB guidelines on page 17). After initial IRB approval, a student with any proposed changes to the research plan must repeat the approval process before experimentation/data collection resumes.
 - a. If research is conducted in a high school, it is the responsibility of the student researcher to receive properly documented IRB approval before beginning the study. See Appendix 8 for a guide for high schools to create their own IRB process to approve student projects.
 - b. If research is conducted at a federally regulated research institution (e.g., university, medical center, NIH, correctional institution, etc.), the research plan must be reviewed and approved by that institution's IRB and properly signed documentation must be provided.
- 3. The research study must be in compliance with all privacy and HIPAA laws when they apply to the project. The IRB must confirm that the student is not violating the Medical Practice Act of the particular state or territory in which they are conducting the research. Students

What is a properly

constituted IRB? IRBs must be composed of minimally three adults, none of whom are related or have advised the student researcher. There are different requirements for school-level IRBs. See page 16 for more requirements. are prohibited from independently diagnosing disease, administering medication, and/or performing medical procedures on human participants.

- 4. Research participants must voluntarily give informed consent/assent, and in cases where the research participant is a minor, parental permission may be required. The IRB determines whether written documentation of informed consent/parental permission/ assent is necessary, not the student researcher. When informed consent is required by an IRB, student researcher must upload a blank copy, along with any blank copies of any surveys used, in the STS application in Task 3.
- 5. Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs), without written consent (Public Health Service Act, 42, USC 241 (d)).
- 6. If a student-designed invention program, software, concept, etc. is product tested by human participants, other than the student researcher, the project must be reviewed and approved by an IRB as described above before the product testing takes place. Student designed inventions should have documentation of risk assessment.
- 7. All standardized tests that are <u>not</u> in the public domain must be administered, scored and interpreted by a qualified professional as required by the instrument publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument. In these cases, the student must provide documented evidence of usage permissions and adherence to publisher requirements. Standardized tests in the public domain do not require documentation in the Regeneron STS application.
- 8. Studies that collect original photographs/videos of humans other than the student researcher require IRB pre-approval and photo consent forms.

HUMAN DATA, HUMAN PARTICIPANTS AND HUMAN TISSUE EXEMPTIONS

Some studies involving human data from surveys or human tissue samples or human observations are **not** considered human participant projects and are **exempt** from IRB review and approval, though the student researcher could be asked for documentation that demonstrates the origin of the data or tissue. Exempt studies include:

- Studies in which the data or tissue samples are preexisting and publicly available through public databases or published peer-reviewed research. In these circumstances, the student researcher will be asked to provide the source of the original study or reference to the publicly available database in the case of data, or documentation from a commercial supplier in the case of tissue samples. Data pulled from public Twitter or other social media accounts is considered exempt.
- 2. Behavioral observations of unrestricted public settings in which
 - a. the researcher has no interaction with the individuals being observed and
 - b. the researcher does not manipulate the environment or introduce stimuli or force reactions and
 - c. the researcher does not record any personally identifiable data.
- 3. Research in which the student receives preexisting or retrospective data, images or tissue samples in a de-identified/anonymous format from a mentor/supervising scientist/ PI, or supplier if not a mentor (for example, from a hospital), or more simply, data that is not publicly available. This adult must certify in the recommendation form, or through a letter provided to the student, that the data or tissue samples were NOT collected for the purpose of the student's project and have been properly deidentified before being given to the student, and are in compliance with all HIPAA laws. However, if the data provided to the student has not been published, the provider will be asked to share IRB approval information from their original study or a letter from the mentor describing how data was collected, dates of data collection, description of deidentification process, and date that data was provided to student researcher.

- a. Student researchers are sometimes involved in collecting human data for a mentor's study or participating in basic medical support with mentor permission (i.e. blood draws, saliva sample collection, etc.). If a student then only receives deidenitified data from mentor or source, this is permitted without need for pre-approval. However, both student and mentor must attest to the student's role in data collection and the deidentification of data before provided to a student.
- 4. Studies in which the primary cells/human tissue samples and/or data obtained and/or photographs or videos taken are solely from the student researcher (self samples). Student will be asked to share any safety precautions.

ADDITIONAL HUMAN TISSUE RULES

Projects utilizing human/vertebrate animal established cell lines or tissue cultures must include documentation regarding the source of the cells/tissues, even if project is exempt from IRB approval. If obtained from a commercially available collection (e.g., ATCC) the catalog number is required. If obtained from a private/non-commercial source (public or private laboratory, museum, etc.), documentation from the supplier must be uploaded in the application. This includes samples from blood banks.

INSTITUTIONAL REVIEW BOARD & RISK ASSESSMENT

An Institutional Review Board (IRB) is an independent committee that evaluates the potential physical and/or psychological risk of research involving human participants. All proposed human research must be reviewed and approved by an IRB before experimentation begins unless deemed exempt in the above section. This includes any surveys or questionnaires to be used. Projects completed at a federally registered research institution should use their IRB (university, hospital, etc). If a project is conducted at school or home, then a school-level IRB is likely acceptable. Consider the location of the research subject, and what type of institution is granting access to them when deciding on the type of IRB approval needed. If unsure, email sts@societyforscience.org for clarification.

The Regeneron STS online application will ask students whose research required IRB review to upload a blank copy of informed consent (if required) and a completed copy of the IRB approval form. Students should also complete a risk assessment.

To avoid conflicts of interest, no member of any IRB may be personally related to the student researcher. Teachers and advisors who oversee a specific project must not serve on the IRB reviewing that project. An improperly constituted IRB invalidates the approval of a project. IRBs must secure additional alternate members to ensure the eligibility of the projects being reviewed. Paperwork approved by an IRB is only considered valid if it contains original signatures from members of the IRB; this documentation demonstrates that appropriate approval was obtained.

Types of IRBs

FEDERALLY REGISTERED RESEARCH INSTITUTION IRB

IRBs exist at federally registered institutions (e.g., universities, medical centers, NIH, correctional facilities). The IRB must initially review and approve all proposed research conducted at, or sponsored by, that institution.

SCHOOL-LEVEL IRBs

Projects conducted at home or school may gain approval through a school-level IRB. Any high school can form their own IRB. Instructions available on page **38**; **consult your science teacher or local science fair for help.** For projects completed at the high school or home environment, school-level IRBs must consist of a minimum of three members. A school-level IRB must include:

- a. a science teacher not involved with project(s) being reviewed,
- b. a school administrator (preferably a principal or vice principal) and
- c. one of the following who is knowledgeable and capable of evaluating the physical and/or psychological risk involved in a given study: a physician, psychiatrist, physician's assistant, registered nurse, psychologist, or licensed social worker who is not involved with the project being reviewed.

RISK ASSESSMENT

Once a study population is chosen, the student researcher must assess any potential physical and/or psychological risks. In evaluating risk, students and IRBs must follow the federal definition of minimal risk: no more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in DAILY LIFE or during performance of routine physical or psychological examinations or tests. The risk assessment should also address how stressful situations will be handled and impacts addressed after experimentation.

A sample informed consent document/parental permission/assent that students may use is available in Appendix 11 but students may also use ISEF forms or forms from their own institutions.

The following risk groups require additional safeguards because they may be vulnerable to coercion or undue influence:

- 1. Any member of a group that is naturally at-risk (e.g., pregnant women, individuals with diseases such as cancer, asthma, diabetes, cardiac disorders, psychiatric disorders, dyslexia, AIDS, etc.).
- Special vulnerable groups that are covered by federal regulations (e.g. children/ minors, prisoners, pregnant women, intellectually disabled persons, or economically or educationally disadvantaged persons).

The following are examples of activities that contain more than minimal risk:

- 1. PHYSICAL
 - a. Exercise other than ordinarily encountered in daily life by that participant.
 - b. Ingestion of any substance or exposure to any potentially hazardous materials.
- 2. PSYCHOLOGICAL
 - a. Any activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress. For example, answering questions related to personal experiences such as sexual, physical or child abuse, divorce and/ or psychological well-being (e.g. depression, anxiety, suicide) is considered more than minimal risk. Additionally, research activities that involve exposing participants to stimuli or experimental conditions that could potentially result in emotional stress must also be considered more than minimal risk. Examples include violent or distressing video images, distressing written materials or activities that could potentially result in feelings of depression, anxiety, or low self-esteem in participants.
 - b. Any activity that could potentially result in negative consequences for the participant due to invasion of privacy or breach of confidentiality. When research activities involve collection of personal information (e.g. history of abuse, drug use, opinions, fingerprints) or health-related data (genetic material, blood, tissue) the researcher must consider risks related to invasion of privacy and possible breach of confidentiality. Ways to reduce these risks include collecting data anonymously or developing data collection procedures that make it impossible to link any identifying information (e.g. participant's name) with their responses or data.

INFORMED CONSENT

Human participant research/data collection may begin only after the participants have been provided complete information about the risks and benefits associated with participation in the research. This allows the participant to make an independent, educated decision about whether to participate. Informed consent is an ongoing process, not a single event that ends with a signature on a page. It must not involve coercion or deception. Adults give their CONSENT. Research participants under 18 years of age and/or individuals not able to give consent (e.g. developmentally disabled individuals) give their ASSENT, and the parents/ guardians give their PERMISSION.

Documentation of informed consent/parental permission/assent is required when:

- 1. The IRB determines that a research study involves physical or psychological activities with more than minimal risk;
- The IRB determines that the project could potentially result in emotional stress to a research participant;
- 3. The IRB determines that the research participants belong to a risk group.

ADDITIONAL RESOURCES

Additional resources are available regarding human participant research guidelines. On this website, the Office for Human Research Protections details national guidelines from which Regeneron STS rules are derived and provides the recommended online training prior to planning any human participant study, for students, new high school IRBs, and new IRB members: <u>https://www.hhs.gov/ohrp/irbs-and-assurances.html</u>. Bioethics resources are at: <u>https://bioethics.nih.gov/clinical/irb.shtml</u>.

QUESTIONS? Email sts@societyforscience.org or check out our rules webinar, available at societyforscience.org/regeneron-sts



"I applied to Regeneron STS to share the product of my research and all the hard work I have put into it. This competition allowed me to present the culmination of my scientific work and my personal motivations for it, creating a holistic view of my research. My advice to future applicants would be to persevere, remember what drives you, and prioritize the journey as you complete your research rather than the end result. The research process is highly valuable and strengthens many skills; make sure you appreciate it every step of the way. Be sure to be genuine in your application, and highlight the attributes that push you to your research. You can do it!"

KAMISI ADETUNJI, REGENERON STS FINALIST 2023

VERTEBRATE ANIMAL AND TISSUE RULES FOR RESEARCH

Projects involving experimentation with live, non-human vertebrate animals are permitted under restricted/limited conditions, as are projects involving non-human vertebrate tissue. Review the rules below. In most cases, even if a project is exempt from demonstrating proof of preapprovals, you will be asked to upload documentation confirming this exempt status. DO NOT BEGIN RESEARCH until proper permissions are obtained.

Live, non-human vertebrate animals are defined as any live mammalian embryo or fetus, bird or reptile eggs within three days (72 hours) of hatching, and all other vertebrates at hatching or birth. Exception: Because of their delayed cognitive neural development, zebrafish embryos are not considered vertebrate animals until 7 days (168 hours) post-fertilization.

All studies involving vertebrate animals must be conducted at a Regulated Research Institution and be reviewed and approved before experimentation begins by an Institutional Animal Care and Use Committee, known as an IACUC.

NON-HUMAN VERTEBRATE ANIMAL RESEARCH RULES

All projects involving live, non-human vertebrate animals must adhere to the following rules:

- 1. Projects involving experimental procedures conducted on vertebrate animals <u>must be</u> <u>conducted in a Regulated Research Institution with documentation of IACUC pre-approval</u> and must be restricted to the following:
 - a. the student's only physical contact with live animal(s) is restricted to supervised handling and husbandry procedures that meet IACUC standards at Regulated Research Institutions (see Animal Husbandry rules on next page), which conform to federal regulations protecting animal well-being and researcher safety; AND
 - b. the student works with non-living material (e.g. tissue, blood) that has been supplied to them by the supervising scientist from the scientist's or lab's existing study; AND
 - c. the animal(s) is/are not sacrificed solely or primarily for the student's project; AND
 - d. the project the student designs and implements begins with non-living material that is a by-product of another study. (No procedures, invasive or otherwise, were conducted on live vertebrate animals prior to euthanasia for the sake of the studentdesigned project).
 - e. the student was not involved in the collection of data, directly or indirectly (through media or video) where the research involved invasive or intrusive experimentation that causes more than momentary pain or distress to the vertebrate animal(s).
- Projects involving animals in their natural environment may be conducted in the field or other site with documentation of IACUC approval, proper permissions or licenses and must be restricted to the following:
 - a. the study is observational or behavioral AND
 - b. the study is non-invasive and non-intrusive AND
 - c. the study does not affect an animal's health or well-being by causing stress, discomfort or pain AND
 - d. the student has no direct contact with the animal.
- 3. Projects that only involve the observation of animals in their natural environments, where no experimental or behavioral procedures are conducted AND in which the study does not affect the animal's health or well-being by causing stress or discomfort do not require prior review and approval, as long as the student researcher has not manipulated the environment in any way.

Examples of manipulating the environment include, but are not limited to: changing conditions of the natural habitat, adding or changing food source, placing an object or other stimulus for the animal to react to within the environment, etc.

NON-HUMAN VERTEBRATE ANIMAL CELL LINES AND TISSUES

- 4. Projects utilizing vertebrate animal established cell lines or tissue cultures must include documentation regarding the source of the cells/tissues.
 - a. If obtained from a commercially available collection (e.g., ATCC) the catalog number is required. If catalog number is unavailable, student can provide a receipt and/or letter from mentor regarding the origin of the items.
 - b. If obtained from a private/non-commercial source (public or private laboratory, museum, etc.), documentation from the supplier must be uploaded in the application, including IACUC approvals for the original study.
 - c. If obtained from mentor's study or another lab's study, upload original study's IACUC approval OR reference to the original study's publication.
- 5. Projects utilizing only data or images are exempt from IACUC pre-approval ONLY if the originating study is published in a peer-reviewed journal or the data is available in a publicly-available database. In this case, the student must provide a reference to the original study OR link to the database.
- 6. If the data or images were obtained from another scientist (mentor or not a mentor) or source AND the research is not yet published (not publicly available), then IACUC approval of the original study must be provided by the Regeneron STS entrant.

In cases 1, 2, 4 and 6 described above, documentation of IACUC approval, proper permissions, and licenses must be provided with the application.

RULES FOR ANIMAL HUSBANDRY

Student researchers may ONLY handle live vertebrate animals under mentor supervision and to support basic husbandry procedures.

Basic husbandry is defined as regular care of research animals. Husbandry tasks include but are not limited to: providing food and water, cleaning enclosures, health monitoring, maintenance of equipment and other daily care tasks. Husbandry does NOT include administering experimental procedures.

Below is a list of recommended resources defining basic husbandry procedures for different types of vertebrate animals.

ANIMAL CARE AND USE

1. Laboratory Animals, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research http://dels.nas.edu/ilar

2. Guide for the Care and Use of Laboratory Animals, 8th Edition (2011) http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf www.nap.edu/catalog.php?record_id=12910

3. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide) Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) www.aaalac.org/ www.aaalac.org/about/Ag_Guide_3rd_ed.pdf

 Guidelines for the Use of Fish in Research (2004), American Fisheries Society. www.fisheries.org www.fisheries.org/afs/docs/policy_16.pdf

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS AND HAZARDOUS MATERIALS

Potentially Hazardous Biological Agents (PHBAs) include microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi and parasites) and recombinant DNA technologies. Hazardous materials include hazardous chemicals, devices and radiation.

It is the responsibility of the student and all of the adults involved in a PHBA-related research project to conduct and document a risk assessment to define the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The risk assessment determines a biosafety level which in turn determines if the project can proceed, and if so, the laboratory facilities, equipment, training, and supervision required.

- Research involving PHBAs is permitted when conducted at a RRI or a certified BSL-2 laboratory, or a BSL-1 laboratory at a high school depending on the classification of the biological agents used (see next page for more details). Research must be closely supervised and should follow all Institutional Biosafety Committee (IBC) requirements as applicable (understanding that most high schools will not have an IBC).
 - a. Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms, is prohibited in a home environment. This includes the use of *E. coli* k-12, studies involving fermentation of baker's and brewer's yeast, algae-eating bacteria, soil microbes, mold growth, slime molds and edible mushrooms. These studies are permitted in a school lab and require a Risk Assessment form, but cannot be conducted in a home environment.
 - b. Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions, if not stored in a home environment as of June 2020:
 - i. If experimentation occurred in the home environment prior to 2020, this research is eligible for STS as long as all conditions of rule 1b are met. Student must provide documentation to demonstrate the dates of experimentation.
 - ii. Organism is cultured in a plastic petri dish (or other standard non-breakable container) and sealed.
 - iii. Experiment involves only procedures in which the petri dish remains sealed throughout the experiment (e.g., counting presence of organisms or colonies).
 - iv. The sealed petri dish is disposed of via autoclaving or disinfection under the supervision of the mentor/supervising scientist/Pl.
 - v. If a culture container with unknown microorganisms is opened for any purpose, (except for disinfection for disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory precautions.
 - c. Research involving human or vertebrate animal tissues/blood/breast milk/other bodily fluids from established cell lines or freshly collected are considered PHBA studies and student researcher should complete a Risk Assessment form before working with these materials.
- 2. Research involving Hazardous Materials is permitted when the research meets the following requirements:
 - a. Student researcher has completed a risk assessment process, and a supervising adult can verify that student identified potential risks prior to experimentation, and followed proper safety precautions and disposal methods.
 - b. Project remains within local, state and federal laws. Hazardous chemicals, devices and radiation carry significant legal and safety regulations and should be approved via the risk assessment by a supervising adult in advance of experimentation.
- 3. Risk Assessment

- a. Students who worked with PHBAs and Hazardous Materials will be asked to upload a Risk Assessment Form in the online application. The Risk Assessment Form is available in Appendix 9.
- b. Hazardous Materials
 - i. Chemicals should be assessed for toxicity, reactivity, flammability and corrosiveness. The type and amount of exposure to a chemical must be considered in the risk assessment. Student researcher must refer to the Materials Safety Data Sheets provided by the vendor (SDS) to ensure proper safety precautions are taken. A risk assessment must include proper disposal methods for the chemicals used in an experiment.
 - ii. Devices including potentially hazardous/dangerous equipment or other devices, in or outside a laboratory setting that require a moderate to high level of expertise to ensure their safe usage (high vacuum equipment, heated oil baths, NMR equipment, high-temperature ovens, etc). It is recommended that all student designed inventions also have documentation of a risk assessment.
 - iii. A risk assessment must be conducted when a student's project involves radiation beyond that normally encountered in everyday life. Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (NW), radiofrequency (RF) and extremely low frequency (ELF).

CLASSIFICATION OF BIOLOGICAL AGENTS

RISK GROUPS

Biological agents, plant or animal, are classified according to biosafety level risk groups. These classifications presume ordinary circumstances in the research laboratory, or growth of agents in small volumes for diagnostic and experimental purposes.

BSL-1 risk group contains biological agents that pose low risk to personnel and the environment. These agents are highly unlikely to cause disease in healthy laboratory workers, animals or plants. The agents require Biosafety Level 1 containment. Examples of BSL-1 organisms are: Agrobacterium tumifaciens, Micrococcus leuteus, Neurospora crassa, Bacillus subtilis, non-pathogenic strains of E.coli..

BSL-2 risk group contains biological agents that pose moderate risk to personnel and the environment. If exposure occurs in a laboratory situation, the risk of spread is limited and it rarely would cause infection that would lead to serious disease. Effective treatment and preventive measures are available in the event that an infection occurs. The agents require Biosafety Level 2 containment. Examples of BSL-2 organisms are: Mycobacterium, Streptococcus pneumonia, Salmonella choleraesuis.

BSL-3 risk group contains biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences. Projects in the BSL-3 group are prohibited.

BSL-4 risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. Projects in the BSL-4 group are prohibited.

LEVELS OF BIOLOGICAL CONTAINMENT

There are four levels of biological containment (Biosafety Level 1–4). Each level has guidelines for laboratory facilities, safety equipment and laboratory practices and techniques. This type of research is not permitted in a home environment.

BSL-1 containment is normally found in water-testing laboratories, in high schools, and in colleges teaching introductory microbiology classes. Work is done on an open bench or in an appropriate biosafety hood. Standard microbiological practices are used when working

in the laboratory. Decontamination can be achieved by treating with chemical disinfectants or by steam autoclaving. Lab coats and gloves are required. The laboratory work is supervised by an individual with general training in microbiology or a related science.

BSL-2 containment is designed to maximize safety when working with agents of moderate risk to humans and the environment. Access to the laboratory is restricted. Biological safety cabinets (Class 2, type A, BSC) must be available. An autoclave should be readily available for decontaminating waste materials. Lab coats and gloves are required; eye protection and face shields must also be worn as needed. The laboratory work must be supervised by a scientist who understands the risk associated with working with the agents involved.

BSL-3 containment is required for infectious agents that may cause serious or potentially lethal diseases as a result of exposure by inhalation. Projects in the BSL-3 group are prohibited.

BSL-4 containment is required for dangerous/exotic agents that pose high risk of lifethreatening disease. Projects in the BSL-4 group are prohibited.

APPENDIX 1: CATEGORIES

Entrants must select one category from the list below; this will determine the expertise of the initial review only. Scholars and finalists are selected without regard to the category, and winners may not be selected proportionally across categories. Consultation with teachers or mentors is encouraged to determine the best category for each entry.

During the review process, evaluators are able to request additional expertise from readers in other categories or suggest category reassignment as appropriate for the project.

ANIMAL SCIENCES: Study of animals – ornithology, ichthyology, herpetology, entomology, animal ecology, paleontology, cellular physiology, circadian rhythms, animal husbandry, cytology, histology, animal physiology, invertebrate neurophysiology, studies of invertebrates, etc.

BEHAVIORAL AND SOCIAL SCIENCES:

Human and animal behavior, social and community relationships – psychology, sociology, anthropology, archaeology, ethology, ethnology, linguistics, learning, perception, urban problems, public opinion surveys, educational testing, etc.

BIOCHEMISTRY: Chemistry of life processes – mechanisms of molecular biology and genetics, enzymes, photosynthesis, blood chemistry, protein chemistry, food chemistry, hormones, etc. Studies involve understanding life and cellular processes specifically at the molecular level.

BIOENGINEERING: Engineering principles applied to biology or medicine, such as bodily aids or replacements, medical/diagnostic devices, and drugs or other therapies using engineering to address a biological problem.

CELLULAR AND MOLECULAR BIOLOGY: Wide ranging field that studies cellular structure, function, biomolecule trafficking, signal transduction, genetic information flow, and cellular replication.

CHEMISTRY: Study of nature and composition of matter and laws governing it – physical chemistry, organic chemistry (other than biochemistry), inorganic chemistry, plastics, fuels, pesticides, metallurgy, soil chemistry, etc.

COMPUTATIONAL BIOLOGY AND BIOINFORMATICS: Studies that primarily focus on the discipline and techniques of computer science and mathematics as they relate to biological systems. This includes the development and application of data-analytical and theoretical methods, mathematical modeling and computational simulation techniques to the study of biological, behavioral, and social systems.

COMPUTER SCIENCE: Study and development of computer hardware, software engineering, internet networking and communications, graphics (including human interface), simulations/virtual reality or computational science (including data structures, encryption, coding and information theory), etc.

EARTH AND PLANETARY SCIENCE:

Geology, mineralogy, physiography, cryosphere, ocean sciences, geomagnetism, hydrology, meteorology, climatology, speleology, seismology, tectonics, volcanology, and planetary science, etc.

ENGINEERING: Technology; projects that directly apply scientific principles to manufacturing and practical uses – civil, mechanical, aeronautical, chemical, and electrical engineering; electronic, sound, automotive, marine, heating and refrigeration, transportation, environmental engineering, etc.

ENVIRONMENTAL SCIENCE: Study of ecology, sustainability, climate, and human impacts, including pollution from air, water or land sources and their control or remediation, etc.

GENOMICS: DNA microarray and deep sequencing studies; phylogenetic analysis of DNA or other biomolecules; analysis of human or other genomes, molecular evolution, etc.

MATERIALS SCIENCE: The structure, engineering properties, processing, and innovative uses of metals/alloys, polymers, ceramics, glasses, electronic materials, biomedical materials, composites, and other innovative materials at scales ranging from the atomic to the macroscopic, etc.

MATHEMATICS: Development of formal logical systems or various numerical and algebraic computations, and the application of these principles – calculus, geometry, abstract algebra, number theory, statistics, complex analysis, probability, etc.

MEDICINE AND HEALTH: Study of diseases and health of humans and animals – pharmacology, physiology, pathology, ophthalmology, oncology, cardiology, nephrology, endocrinology, pediatrics, dermatology, allergies, speech and hearing, nutrition, dentistry, etc.

NEUROSCIENCE: Studies of the neural basis of cognitive processes, including learning and memory, language and thought, perception, attention, and affect. It investigates the human brain, from the functional organization of large scale cerebral systems to microscopic neurochemical processes.

PHYSICS: Theories, principles, and laws governing energy and the effect of energy on matter – solid state, optics, acoustics, particle, nuclear, atomic, plasma, superconductivity, fluid and gas dynamics, thermodynamics, magnetism, quantum mechanics, biophysics, etc.

PLANT SCIENCES: Study of plant life – agriculture, agronomy, horticulture, forestry, plant taxonomy, plant physiology, plant pathology, plant genetics, hydroponics, algae, etc.

SPACE SCIENCE: Study of celestial bodies, their positions, motions, nature and evolution – astronomy, astrometry, celestial mechanics, etc.

APPENDIX 2: RESEARCH REPORT GUIDELINES

REGENERON SCIENCE TALENT SEARCH 2024

All Regeneron STS entrants will submit a written Research Report detailing original, independent research. The Research Report is evidence of research ability, scientific originality, and creative thinking. It is an opportunity to demonstrate competence in planning and completing a project in science, mathematics, or engineering. Students must have completed an independent scientific investigation and have results to report. **Research proposals, investigations not yet completed, literature reviews, and essays are not eligible for this competition. Students may not submit additional research after the application deadline.**

- 1. Each entrant may submit only one entry and Research Report on one topic.
- 2. The Research Report must be 20 pages or less. This includes all photos, tables, graphs, charts, drawings, maps, codes and appendices. There is no page minimum. Pages of content beyond page 20 (excluding the pages mentioned below) will not be read or considered.
 - a. Include a title page as the first page, abstract as the second page, and a bibliography at the end of the Research Report. The title page, abstract, and bibliography do not count toward the 20-page limit.
 - b. Within the 20-page limit, we recommend including a short introduction describing the background and purpose of the work, an experimental design section including methods and results, and concluding discussion of results and implications. We do not require a specific format/order, and you may format in the standards of your scientific discipline.
 - c. List your name and project title (required) on the title page. It is also permitted to list your lab and mentor names. Do not put any e-mail addresses or phone numbers on your title page.
 - d. Appendices count toward the 20-page limit. Some students choose to include all images, charts, data, etc. within the paper, while others place them in appendices. Both options are acceptable.
 - e. Bibliographic references should be submitted for all sources and images consulted with internal citations (not in 20-page limit). All images should include citations.
- 3. The Research Report format should adhere to these basic requirements:
 - a. Choose a font that is legible and appropriate for a research paper. Research Reports found to use smaller than recommended font or margin size in order to increase word count may be disqualified. The font size should appear on the page at least as large as Times New Roman 11pt font. Captions may be smaller if legible.
 - b. Use 1.5 line spacing and 1" margins on all sides. Do not use multiple columns.
 - c. Number the pages of your research report in the bottom right corner, starting after the Abstract.
 - d. Do not include any photographs of people, especially yourself, unless scientifically necessary and with proper consent.
 - e. Students may not provide links within the Research Report or application of any sort, except within bibliographic references or where specifically requested in the application.
 - f. PDF files that are 5MB or smaller are the only format accepted in the online system.
 - g. Please name your file "LASTNAME.FIRSTNAME.ZIPCODE."
 - h. After uploading the report in the application system, download your application pdf to be certain all symbols are still present and correct.

- 4. Students may submit published work, as long as all other formatting guidelines are similar (do not use very small font) and adhere to Regeneron STS rules. It is not recommended that students submit published research papers if they are not the sole or first author. While we realize science is collaborative, publishing research of the lab makes it difficult to assess student work from lab work. In the case of published group research, acknowledge the published paper, and submit your own paper here that highlights your actual contributions to the larger research project.
- 5. If it is widely accepted to write scientific journal articles in your specific subject area using first person plural "we" then it is acceptable for a student to use the first person "I" in place of "we" in their Regeneron STS research report. This will help to clarify what was done independently vs. with support. If this is not widely accepted in your subject area, the passive voice should still be used.
- 6. Do not include library research or a history of literature beyond the short introduction, detailed explanations of experiments and procedures of other researchers that preceded the project, lengthy autobiographical information or personal history.
- Do not upload statistics or a sample of your survey here for Behavioral and Social Sciences projects. A sample survey must be uploaded along with the IRB approval in the Rules Wizard task.

ENTRANTS ARE ENCOURAGED TO SEEK EVERY POSSIBLE RESOURCE: Books, journals, experts in the field, adult advisors. Refer to research journals in your subject area for examples of report formats to guide your own format. Regeneron STS recognizes the independent research of student investigators. Work submitted by the student scientist should be of their own design and execution, and presented in their own words. Frequently Regeneron STS applicants do research within the context of the laboratory and/or in collaboration with others outside of a laboratory in which they work or that is related to that of those with whom they are working. This is expected, since science is a cumulative process, each finding built on previous ones. However, full disclosure of any research or person that has influenced the applicant's work is required.

Furthermore, the research report must accurately reflect the work of only the student researcher. While students may seek review of their content and presentation of the research report, both the content and writing should be the work of the applicant. Adults reviewing research reports should suggest areas for improvement, but not provide the student with replacement text or rewrite any portion of the entry.



"Regeneron STS is a truly life-changing experience that will connect you with amazing students with various backgrounds and aspirations. It will change your way of thinking and make you more curious about the world around you. Getting to present your work is a fantastic opportunity and the opportunities you will have to speak to professionals across a variety of fields will be very illuminating."

VIVIAN WU, REGENERON STS FINALIST 2023

APPENDIX 3: TYPES OF RECOMMENDATIONS

Applicants must request the following recommendations, all to be submitted by the designated adults by the application deadline (**November 8, 2023 at 8:00 pm ET**). Recommendations are confidential and will not be shared with student entrants. All recommendations and transcripts must be shared in the Regeneron STS application portal. Students should ask each recommender for their preferred email for recommendations, so that requests by multiple students do not span multiple email accounts.

- Educator Recommendation (up to 2)
 - O Educator Recommendation should be completed online by the person with the most knowledge of the student in an academic setting and of their scientific potential. Students may choose a teacher from any year of high school, a non-science teacher, and if they choose to submit two of this type of recommendation, may select a coach or other type of advisor as the second Educator Recommender.
- Project Recommendation (up to 2)
 - Project Recommendation should be completed online by the person closest to the student's research. The head of a lab should only complete this if they worked with the student closely.
 - Project Recommenders might be asked to provide information and documentation about projects involving humans and vertebrate animals.
- High School Report
 - O Talk to or email your guidance counselor and let them know that you will be emailing them with instructions from our online system regarding your high school transcript. The form should be completed online by a counselor or administrator. Official high school transcripts must be uploaded in this section. Counselors must upload transcripts in the high school report as PDFs. Mailed, hard copies are not accepted. Current semester grades are not needed.
 - Counselors are now asked to complete a series of school profile questions just once for all of their entrants, rather than for each entrant. We hope this will save time. Counselors only need to do this once, then upload each transcript.
 - O Students who would like to submit a second transcript from a college course may now submit these on their own via the online application.

Students are encouraged to request recommendations early in the application process through the online system. Recommenders receive an email invitation and are prompted to create a password to complete and submit forms online. Students are responsible for the timely receipt of transcripts and recommendations. Students and recommenders are encouraged to visit the application website for FAQs that include troubleshooting tips and more in-depth answers to common questions about the recommendation process.

To preview the Recommendation Forms, see Appendices 4-6.

All recommendations are due on the student application deadline – **Wednesday, November 8, 2023 at 8:00 pm ET**. No exceptions can be made.

APPENDIX 4: EDUCATOR RECOMMENDATION

INSTRUCTIONAL DOCUMENT REGENERON SCIENCE TALENT SEARCH 2024

INFORMATION FOR STUDENTS

Who should complete the Educator Recommendation?

 A high school teacher who has worked with you in a classroom setting during any year of high school. Preference should be given to science, engineering and/or math educators.

When is the Educator Recommendation due?

• The deadline for your Recommender to submit this form is Wednesday, November 8, 2023 at 8:00 pm Eastern Time. This deadline is now the same date and time as the student application deadline. We will be unable to accept materials, including recommendations, after this deadline.

How do I request my Educator Recommendation?

- Talk to or email your recommenders to ask them if they would be willing to complete
 a recommendation on your behalf. Let them know that they should anticipate an
 automated email from our online system the sender name will be "Regeneron
 Science Talent Search." Then request your Educator Recommendation through the
 online application system.
- We recommend that you request your recommendations the day you open your application to allow your recommenders plenty of time.
- It is your responsibility to remind your recommenders to submit their recommendations before the deadline. We cannot accept any portions of the application, including recommendations, after the application deadline.

How many Educator Recommendations should I request?

- Consider requesting multiple Educator Recommendations only if you believe each educator has something unique to say about your abilities. We encourage you to ask another supportive adult, like a coach or boss, to provide a recommendation as well.
- If you are a homeschool student and your parent is your only educator and completes an Educator Recommendation, we recommend that you request a second Educator Recommendation from a non-relative who knows you in an academic setting, even if not in the traditional classroom sense.

Other things to know about the Educator Recommendation:

- The Society does not accept PDF letters of recommendations. Recommenders are required to answer a few short responses within the online form.
- Recommendations are confidential; entrants waive their rights to see content shared by recommenders.
- Exact questions and word limits stated on the next page may vary slightly in the online application.

EDUCATOR RECOMMENDATION PREVIEW

- 1. Do you have a familial relationship with the student? Such a relationship is not disallowed under Regeneron STS rules, however it is important that it be disclosed. If so, please describe the relationship.
- 2. Have any of your former students entered and/or won awards in the Science Talent Search?
 - a. Yes, my students have entered STS
 - b. Yes, my students have won awards at the scholar or finalist level in STS
 - c. No, none of my students have ever entered STS
 - d. Unsure
- 3. Describe the culture of science research at your high school. Do you teach or lead a research class or club? Is the group selective? If this context impacts your ranking of this student in the questions below, please explain here. (150 words max)
- 4. How long have you known this student and in what capacity? How does this student compare to students you currently teach and also to those you have known during your teaching career? (150 words max)
- 5. Please describe your personal observation (if any) of the student's character and integrity, leadership among their peers or in your community, and any challenges they have overcome. Use specific examples, if possible, and do not include activities you have not witnessed. Entrants are able to provide a full extracurricular list in their portion of the application. What makes you believe in their potential as a future leader in science, technology, engineering and mathematics? What makes this student stand out amongst their peers? (200 words max)
- 6. What level of mentorship and guidance have you provided the student with the STS application process and/or the research project? Please explain your level of knowledge (if any) regarding the submitted research project and/or any other research projects conducted by this student during their high school career. (It's ok if you really don't know or were not involved in the project itself! We are just curious about the levels of support the student received). Can you attest that the application and research project submitted in this application properly reflect the student's contribution? (200 word max)
- 7. Please rank this student compared to others you have supported in the past. Rankings are NOT used to cull applicants. Please be honest in your assessment, as this helps us compare your own students to one another, and others in your community. Regeneron STS seeks to identify future leaders in STEM. Rank in the following categories: Independence, Creativity, Problem-Solving Abilities & Leadership Potential Top 1% Top 5% Top 10% Top 25% Top 50% Other
- 8. or anything we should know about this student in general? (150 words max)

ETHICS AGREEMENT

I certify that I have presented the full truth regarding the student researcher's experience in my classroom and have not presented false information. I understand that mentors of Regeneron STS entrants may not benefit financially based on the overall placement of entrants in the competition.

TROUBLESHOOTING ISSUES

Should your Recommender experience any issues with our online process, please encourage them to review the Recommender FAQ on the application website and to email sts@societyforscience.org with any other concerns. Once you request a recommendation from them through the online system, the Recommender should receive an email with instructions. Occasionally these messages are caught in junk mail or strict school email filters, or a recommender could receive requests from multiple students under different email addresses, causing confusion. We are happy to investigate any issues.

APPENDIX 5: PROJECT RECOMMENDATION

INSTRUCTIONAL DOCUMENT REGENERON SCIENCE TALENT SEARCH 2024

INFORMATION FOR STUDENTS

Who should complete the Project Recommendation?

- The person who is most familiar with the research and the work you did on a daily basis. In many cases that is a graduate student in a lab rather than the head of the lab.
- If your parent/guardian or any relative is the person closest to your research and completes your Project Recommendation, we recommend requesting an additional Project Recommendation from someone who has experience with you in a lab or research setting, making it clear that they did not mentor this particular research.
- If there is no adult who provided guidance to you, please have a parent or teacher complete this recommendation, stating that is the case.
- If you worked tangentially with a scientific advisor (did not work in their lab, but sought their advisement), this person should complete the recommendation form to share their level of involvement.

When is the Project Recommendation due?

• The deadline for your Recommender to submit this form is Wednesday, November 8, 2023 at 8:00 pm Eastern Time. This deadline is the same date and time as the student application deadline. We will be unable to accept materials, including recommendations, after this deadline.

How do I request my Project Recommendation?

- Talk to or email your recommenders to ask them if they would be willing to complete
 a recommendation on your behalf. Let them know that they should anticipate an
 automated email from our online system the sender name will be "Regeneron
 Science Talent Search." Then request your Project Recommendation through the
 online application system.
- We recommend that you request your recommendations the day you open your application to allow your recommenders plenty of time.
- It is your responsibility to remind your recommenders to submit their recommendations before the deadline. We cannot accept any portions of the application, including recommendations, after the application deadline.

How many Project Recommendations should I request?

- Each applicant must request one Project Recommendation, but may request up to two.
- If you worked closely with more than one mentor, you may request one additional Project Recommendation.

Other things to know about the Project Recommendation:

- The Society no longer accepts PDF letters of recommendations. Recommenders are now required to answer specific questions within the online form. You and your mentors are required to disclose any familial or personal relationships.
- Exact questions and word limits stated on the next page may vary slightly in the online application.
- You, and your mentor, are required to disclose any known or perceived conflicts of interest. This means, if your parent/guardian/relative/neighbor/long-time family friend/etc. is writing your recommendation, you must tell us about this pre-existing relationship. This also includes any employer/employee or mentor relationships between your parents/guardians and your mentor, real or perceived.

PROJECT RECOMMENDATION PREVIEW

The online form will lead recommenders through a series of questions about the student's research to determine what type of approvals and paperwork were needed, and will ask mentors to upload or verify specific information on a case-by-case basis.

PROJECT QUESTIONS

- 1. Do you, or does anyone in your lab, have a familial, long-term or pre-existing relationship to the student? Please acknowledge any type of employer, mentor, donor and/or family, connections between you, members of your lab and the student and their family. Such a relationship is not disallowed under Regeneron STS rules, however it is important that it be disclosed. Examples include: parent of entrant mentored the recommender; mentor is a graduate student in a parental figure's lab; recommender is employed by the same university department as the entrant's parent; parent is the mentor; mentor is the entrant's neighbor, etc. If so, please describe the relationship.
- 2. Were you paid for your services as a mentor to this student, and/or did you work with this student through a program that charges tuition or fees? This type of program and mentoring relationship is permitted but must be disclosed. High school teachers who supported mentees directly through classroom or school club activities, and were not separately compensated, should select "no". If yes, describe and explain the fees/tuition.
- 3. Briefly explain how the student became known to you. (75 words max) (e.g. personal relationship, summer program, high school partnership, direct communication from student, required or elective high school course)
- 4. Please describe the nature of your involvement with the student's research. (150 words max) What role did you serve for the student? What type of guidance did you provide? Did you meet in person or in a virtual setting?
- 5. How did the student get the idea for the project? (200 words max) Was the project assigned; picked from a list of possible research topics; result from discussion with a scientist; arise from work in which the student was engaged; suggested by student?
- 6. What was the duration and intensity of the student's research experience at your institution?
 - a. Number of weeks, months or years
 - b. Approx. start and end dates
- 7. Provide a brief description of your laboratory/research environment and what the student's role was within this group. (150 words max) size, # of scientists/students and their research levels (post-doc, doctoral, undergrad, high school)
- 8. If there were other high school students in your research group please name them and explain in detail the difference between this student's work and the work of other high school students in your group.
 - a. Are there other high school students in your research group?
 - b. Have you mentored any other students who are entering Regeneron STS this year?
 - c. If so, list their names.
 - d. Name any students who performed research that was similar to this student (this year or in a previous year) and explain how this student's work was different and independent from others.
- 9. For what aspects of the research can you give credit to the student as being their own unique contribution: Procedural Design, Data Collection, Data Analysis, Drawing Conclusions (200 words each)
- 10. Students may submit published research to Regeneron STS (this is not required), though it is often difficult to determine student contribution to published paper when the student is not the sole or primary author. To your knowledge, how much of the paper that the student is submitting to Regeneron STS is their own contribution, vs. that of your lab group or larger research project? (200 words max)

- 11. What did the student do that showed creativity and ingenuity? Based on your knowledge of the student, please provide examples of how this student demonstrates potential as a scientist. Were they creative in their science, or creative for a high school student? What is your impression of their knowledge of experimental design, construction or use of equipment, evaluation of data, etc.? (250 words max)
- 12. Would you hire this student again in the future to work in your lab? Why or why not? In 5 to 10 years, do you believe this student could have a career as a working scientist, engineer or mathematician? How do they rank against other students you have worked with in the past? (200 words max)
- 13. Is there anything else you would like to share about how the COVID-19 pandemic has impacted your lab and/or this particular student? (250 words max)
- 14. Does the student have permission to share this research project with the Regeneron Science Talent Search? If selected as a finalist (top 40) or scholar (top 300), our science writers will compose short summaries of the research project to share with the public. The student might be interviewed in the media. Through these processes, results might be shared. The Society for Science does not share student applications, which includes the full research report, with the public or the sponsoring organization.
- 15. Is there anything else we should know about this student? (100 words max)

ETHICS AGREEMENT

I certify that I have presented the full truth regarding the student researcher's experience in my classroom and have not presented false information. I understand that mentors of Regeneron STS entrants may not benefit financially based on the overall placement of entrants in the competition.

TROUBLESHOOTING ISSUES

Should your Recommender experience any issues with our online process, please encourage them to review the Recommender FAQ on the applicatioin website and to email sts@societyforscience.org with any other concerns. Once you request a recommendation from them through the online system, the Recommender should receive an email with instructions. Occasionally these messages are caught in junk mail or strict school email filters, or a recommender could receive requests from multiple students under different email addresses, causing confusion. We are happy to investigate any issues.

APPENDIX 6: HIGH SCHOOL REPORT

INSTRUCTIONAL DOCUMENT REGENERON SCIENCE TALENT SEARCH 2024

INFORMATION FOR STUDENTS

Who should complete the High School Report?

• Your school counselor or other school official who is able and allowed to provide the information requested (your transcript).

When is the High School Report due?

• The deadline for your counselor to submit the High School Report is Wednesday, November 8, 2023 at 8:00 pm Eastern Time.

How do I request my High School Report?

- Talk to or email your counselors to ask them if they would be willing to submit this
 report on your behalf. Let them know that they should anticipate an automated
 email from our online system the sender name will be "Regeneron Science Talent
 Search." Then request your High School Report recommendation through the online
 application system.
- We recommend that you request your recommendations the day you open your application to allow your recommenders plenty of time.
- It is your responsibility to remind your recommenders to submit their recommendations before the deadline. We cannot accept any portions of the application, including recommendations, after the application deadline.

How many High School Reports should I request?

 One. Only one counselor can upload a transcript on your behalf. The official high school transcript must come from this High School Report. Applicants who have additional transcripts from college coursework may submit them within the application, but this is not required.

Other things to know about the High School Report?

- The Society no longer accepts hard copy transcripts; your counselor will need to upload your transcript through the online system.
- Should you have other types of transcripts from a community college or summer course, students need to request these transcripts and upload themselves in the app. They can only request one high school report. First quarter grades are not necessary. Please request transcripts early in the process through the High School Report recommendation from your guidance counselor.
- Letters of recommendation from the counselor are not required, unless the student requests an educator recommendation from the counselor. There is no letter of recommendation associated with the high school report.
- Exact questions and word limits stated on the next page may vary slightly in the online application.

HIGH SCHOOL REPORT PREVIEW

Entrants must request that their school counselor or an administrator complete this form in the online recommendation system.

- 1. What is the graduation rate of your school from entering students to graduation?
- 2. Approximately what percentage of your graduates attend four-year colleges?
- 3. Is this school classified as Title I?
- 4. How many students at your school receive free or reduced lunch?
- 5. Is your school in a military-impacted district?
- 6. Regeneron STS is a competition for students in their final year of high school. Will this student graduate from high school in December 2023 or Spring 2024?
- 7. Is there anything else you would like to share about this student's transcript, official name vs. chosen name, the impact of COVID-19 pandemic on your school and/or this student, or how this student is learning of the submission of this report? (200 words max)
- 8. Upload Student Transcript
- 9. Upload School Profile

Note about Standardized Test Scores: Student applicants to the Regeneron Science Talent Search are now permitted to upload their own test scores within the application. In prior years, this information was submitted with the High School Report.

TROUBLESHOOTING ISSUES

Should your Recommender experience any issues with our online process, please encourage them to review the Recommender FAQ on the application website and to email **sts@societyforscience.org** with any other concerns. Once you request a recommendation from them through the online system, the Recommender should receive an email with instructions.

Occasionally these messages are caught in junk mail or strict school email filters, or a recommender could receive requests from multiple students under different email addresses, causing confusion. We are happy to investigate any issues.

APPENDIX 7: DOCUMENTATION AND PAPERWORK

The check list below is intended to give you an idea of the types of paperwork you might be asked to provide in the online application when you complete Task 3. You should read the Human, Vertebrate Animal Rules, and PHBA section for more information about what types of projects are allowed, and to determine whether or not your project is exempt from the requirements outlined below. As you fill out the required forms, be sure to carefully answer all questions, provide correct documentation, and make sure that your paperwork is correctly signed and dated. We will also collect similar information from your Project Recommenders.

HUMAN PARTICIPANT RESEARCH

This includes engineering projects, invention and software tested on humans and projects involving surveys and observational studies)

- · Research Plan with Risk Assessment
- Evidence of IRB Approval (obtained before experimentation) by a properly constituted IRB
- · Blank Copy of the Informed Consent/Assent/Permission Form (if applicable)
- · Blank Copy of Survey Instrument (if applicable)

Note: Projects involving data that is preexisting or publicly available are likely exempt from IRB pre-approval, but might be asked to share information about data sources. Behavioral observations of unrestricted public settings that meet all requirements outlined in the rules are also exempt from pre-approval. Entrants should read Human Participant Rules section to clarify exemptions.

HUMAN AND VERTEBRATE ANIMAL TISSUE STUDIES

- Evidence of IRB Approval (human) and/or IACUC Approval (animal)
- Students may provide IRB and IACUC Approvals for original studies that produced the cell lines used in their STS project or provide reference to the original studies' publication
- · Documentation of the source of the cells/tissues.
- If obtained from a commercially available collection (e.g., ATCC) the catalog number is required.
- If obtained from a private/non-commercial source (public or private laboratory, museum, etc.), documentation from the supplier must be uploaded in the application.

Note: Projects involving publicly available pre-existing tissue samples are exempt from preapproval, but student will still be asked to share information about origin of cells/tissues.

VERTEBRATE ANIMAL STUDIES

- Evidence of IACUC approval of experimental procedures performed by supervising scientist
- · Describe student designed study that begins with non-living material
- For observational or behavioral research involving animals in their natural environment, provide documentation of IACUC approval
- Studies that only involve the observation animals in their natural environment do not require IACUC approval

Note: Projects involving ONLY observations in unaltered animal habitats are exempt from pre-approval, but will still be asked to provide information about the animal population observed, and possibly permits.

PHBAS AND HAZARDOUS MATERIALS

Risk Assessment Form

APPENDIX 8: GUIDE TO CREATING SCHOOL-LEVEL INSTITUTIONAL REVIEW BOARDS

Human research often requires pre-approval by an Institutional Review Board. Students who are interested in pursuing human participant research in a high school setting may share this guide with their science teacher or mentor. Prior to any recruitment or interaction with human participants, the research plan must be reviewed and approved by an IRB. This document outlines the steps required to form an Institutional Review Board at the high school level, and how a high school can create their own IRB process to approve student projects.

Note: If research is conducted at a federally regulated research institution (e.g., university, medical center, NIH, correctional institution, etc.), the research plan must be reviewed and approved by that institution's IRB and proper documentation must be provided.

INSTITUTIONAL REVIEW BOARD

An Institutional Review Board (IRB) is an independent committee that, according to federal regulations (45-CFR46), evaluates the potential physical and/or psychological risk of research involving human participants. <u>All proposed human research must be reviewed</u> and approved by an IRB before experimentation begins. This includes any surveys or questionnaires to be used. Projects completed at a federally registered research institution should use their IRB (university, etc). If a project is conducted at school or home, then a school-level IRB is acceptable.

HOW TO FORM A SCHOOL-LEVEL IRB

- 1. Projects conducted at home or school may gain approval through a school-level IRB. Any high school can form their own IRB. For projects completed at the high school or home environment, school-level IRBs must consist of a minimum of three members. A school-level IRB must include:
 - a. an educator not involved with project(s) being reviewed,
 - b. a school administrator (preferably a principal or vice principal), and
 - c. one of the following who is not involved with the project being reviewed and is knowledgeable and capable of evaluating the physical risk in a given study:
 a physician, psychiatrist, physician's assistant, registered nurse, psychologist, or licensed social worker.
- 2. No member of any IRB may be personally related to the student researcher. Teachers and advisors who oversee a specific project must not serve on the IRB reviewing that project. An improperly constituted IRB invalidates the approval of a project. IRBs must secure additional alternate members to ensure the eligibility of the projects being reviewed.

RESPONSIBILITIES OF THE SCHOOL-LEVEL IRB

- 1. The IRB should carefully review the Regeneron STS Rules for Human Participant Research to determine what is permissible. Note that the rules adjust annually.
- 2. The IRB should develop an approval form based on the sample IRB Approval Form and Sample Informed Consent Forms in this rules book. Schools may use these forms or adapt them to include additional rules and restrictions; a local IRB must adhere to all STS rules, but may be more strict.
- 3. The IRB should share the forms and process with high school teachers and students, set appropriate deadlines for submitting forms to the IRB, and make a plan to review approval forms on a schedule that fits the school's academic research program calendar.

- 4. High School-Level IRBs should require that students:
 - a. Follow the Regeneron STS official rules.
 - b. Draft a research plan that includes a description of research participants, recruitment procedures, research methodology, assessment of risks and benefits of the research, procedures for minimizing physical, psychological and privacy risks to participants and procedures for obtaining informed consent.
 - c. Complete an IRB Approval Form (available in Appendix 10) and submit to the IRB prior to starting research.
- 5. The research plan must be reviewed and approved by the IRB prior to the start of experimentation. After initial IRB approval, a student with any proposed changes to the research plan must repeat the approval process before experimentation/data collection resumes.
- 6. The IRB should maintain a record of approved student project proposals.
- 7. The IRB should complete the IRB Approval Form (Appendix 10) submitted by the student with their assessment of risk, required consent process, supervision and approval with checkmarks in the appropriate places and via dated signatures. Without the form completed with checkboxes and signatures, the documentation is not valid. The IRB should provide the student with a copy of this signed documentation.

IRB REVIEW CHECKLIST FOR STUDENT PROJECTS

- It is the responsibility of the members of the IRB to thoroughly review the Research Plan and collectively decide whether to approve the project, request revisions to the methodology/require more oversight (e.g., Qualified Scientist) to reduce risk to participants, or to determine that the project is not appropriate for student research. Members of the IRB will collaboratively make the following determinations which are documented on IRB Approval Form:
 - whether the study contains no more than minimal risk or more than minimal risk (see definitions below) to potential participants. The IRB will consider characteristics of the study population, the specific risks associated with the research activity and local norms when making a risk level determination.
 - · whether a qualified scientist is required
 - Finally, whether the study is a) approved as it is written, b) must be revised or c) is not appropriate for a student research project (due to level of risk to the student researcher and/or participants). The IRB will sign IRB Approval form only if the project is approved.
- 2. It is the responsibility of the members of the IRB to thoroughly review the student's Research Plan and collectively decide the following pertaining to risk: If the study contains no more than minimal risk to potential participants AND risk level determination associated with the research activity and local norms and the characteristics (e.g., age, health status, vulnerability to coercion) of the study population; Resource to help determine risk: https://sspcdn.blob.core.windows.net/files/Documents/ SEP/ISEF/Resources/Risk-Assessment-Guide.pdf
- Research participants must voluntarily give informed consent/assent, and in cases where the research participant is a minor, parental permission may be required. The IRB determines whether written documentation of consent/assent/permission is necessary.
- 4. Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs), without written consent (Public Health Service Act, 42, USC 241 (d)).
- 5. If a student-designed invention, program, concept, etc. is product tested by human participants, other than the student researcher, the project must be reviewed and approved by an IRB as described above before the product testing takes place.

Note that some studies involving human data or human tissue samples are not considered human participant projects and are exempt from IRB review and approval. See official rules.

APPENDIX 9: RISK ASSESSMENT FORM FOR RESEARCH INVOLVING PHBAS AND HAZARDOUS MATERIALS

To be completed by the Student Researcher(s) in collaboration with Designated Supervisor/Qualified Scientist: (All questions must be answered; additional page(s) may be attached.)

- 1. Identify and assess the risks and hazards involved in this project:
- 2. Subjects
 - a. list all hazardous chemicals, activities, or devices that will be used
 - b. identify microorganisms exempt from pre-approval (see Potentially Hazardous Biological Agent rules)
- 3. Describe the safety precautions and procedures that will be used to reduce the risks.
- 4. Describe the disposal procedures that will be used (when applicable)
- 5. List the source(s) of safety information.

To be completed and signed by the Designated Supervisor (or Qualified Scientist, when applicable):

I agree with the risk assessment and safety precautions and procedures described above. I certify that I have reviewed the Research Plan and will provide direct supervision.

Designated Supervisor's Printed Name	Signature	Date of Review (mm/dd/yy)
Position & Institution		Phone or small contract information
Position & Institution		Phone or email contact information

Experience/Training as relates to the student's area of research

APPENDIX 10: REGENERON STS INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL FORM

Required for all research involving human participants. (Institutional Form or Regeneron ISEF form may be substituted.)

Student's Name:	Title	e of Project:
Adult Sponsor:	Con	tact Phone/Email:
 I have submitted my Research Pla privacy issues, informed consent I have attached any surveys or qu I have attached an informed cons Yes	an which addresses re procedures and a risk estionnaires I will be u ent that I would use if ng with a Qualified Sci	required by the IRB.
Name:	Deg	ree:
Email Address/Phone Number.		
Experience/Training as it relates to the	iis project:	
ITEMS IN THIS BOX MUST BE COMPLETE	D TO BE VALID	
requested revisions.	s and is NOT approved the following condition Minimal Risk Yes minor participants: No red for minor subjects:	d at this time. IRB will attach document indicating concerns and/or ons below: (All 5 must be answered) More than Minimal Risk No Not applicable (No minors in this study) Not applicable (No minors in this study)
	onflict of interest). None of	may be the adult sponsor, designated supervisor, qualified scientist or re- of these individuals may personally oversee the student research project. ove IRB determinations.
Medical or Mental Health Professional (a psy- physician's assistant, or registered nurse)	chologist, psychiatrist, m	nedical doctor, licensed social worker, licensed clinical professional counselor,
Printed Name		Degree/Professional License
Signature		Date of Approval
School Administrator		
Printed Name		Degree
Signature		Date of Approval
Educator (not involved with the pro	vject)	
Printed Name		Degree

Date of Approval

Regeneron Science Talent Search 2024

Signature

APPENDIX 11: SAMPLE INFORMED CONSENT FORM

INSTRUCTIONS TO THE STUDENT RESEARCHER:

- An informed consent/assent/permission form like the version below should be developed in consultation with the student researcher's Project Mentor, Designated Supervisor or Qualified Scientist. This consent form is used to provide information to the research participant (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission. When written documentation is required, the researcher keeps the original, signed form.
- Students may use this sample form below or may copy ALL elements of it into a new document.
- If the form is serving to document parental permission, a blank copy of any survey or questionnaire must be attached when shared with parents/guardians.
- Student researcher must upload a copy of the consent form shared with research participants, and a blank copy of any surveys used, in their Regeneron STS application.

STUDENT RESEARCHER:

TITLE OF PROJECT:

I am asking for your voluntary participation in my science research project. Please read the following information about the proje	ct.
If you would like to participate, please sign in the appropriate box below.	

PURPOSE OF THE PROJECT:

F YOU PARTICIPATE, YOU WILL BE ASKED TO:
TIME REQUIRED FOR PARTICIPATION:
RISKS:
BENEFITS:
IOW CONFIDENTIALITY WILL BE MAINTAINED:
f you have any questions about this study, feel free to contact:
Adult Sponsor: Phone/email:
VOLUNTARY PARTICIPATION:
Participation in this study is completely voluntary. If you decide not to participate there will not be any negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.
By signing this form I am attesting that I have read and understand the information above and I freely give my consent/ assent to participate or permission for my child to participate.

ADULT INFORMED CONSENT OR MINOR ASSENT	Date Reviewed & Signed:
Printed Name of Research Subject:	Signature:
Parent/Guardian Printed Name:	Signature:

APPENDIX 12: COMMON REASONS PROJECTS FAIL TO QUALIFY

The list below includes reasons students failed to qualify in 2023; however, the reasons entrants may fail to qualify are not limited to only these examples. After applications are submitted each year, a team of PhD scientists reviews each entry and performs an extensive rules check. When a Regeneron STS entry "fails to qualify," the student is not eligible for awards. Entrants should also explore Task 3 of the application, and can email any questions to **sts@societyforscience.org**.

Human Research

- Student fails to obtain IRB approval before testing an invention, software or product, or conducting a survey.
- Human data was not properly deidentified before being shared with student, OR mentor or paperwork fail to corroborate student claims of deidentification.
- Student fails to upload a blank copy of survey used on human participants (if survey used in project).
- Student fails to upload a blank copy of informed consent document used on human participants, or does not share evidence of collecting informed consent (if informed consent required by IRB).
- Student fails to upload IRB documentation or proof of publication from mentor's originating study.
- IRB is improperly constituted (school IRBs are permitted, but teachers who oversee a project must not be part of the school IRB as this is a conflict of interest. Parents/ guardians must not be members of IRBs governing their own students' projects.)
- · IRB paperwork not signed or checkboxes of IRB decision not checked.
- · Dates on paperwork do not align with dates of student data collection.
- · Student project diagnoses or treats medical conditions.

Non-Human Vertebrate Animal Research

- The source of vertebrate animal/human cell lines or tissues are not properly documented.
- Vertebrate animal/human established cell lines or tissue cultures were obtained from a commercial source and neither student nor project recommender provided a catalog number; or if obtained from a non-commercial source there is no documentation from supplier.
- Vertebrate animal sacrificed solely for student study.
- Student study involved pain or stress to vertebrate animals.
- Vertebrate animal's habitat and/or food was altered without IACUC approvals (in order for a study to be considered observational, no factors can be altered in animal's habitat).
- Student fails to upload IACUC documentation or proof of publication from mentor's originating study.
- Student performs vertebrate animal research in a home environment.
- · IACUC paperwork not provided.
- Dates on paperwork do not align with dates of student data collection.

PHBAs

- Student performs PHBA research in a home setting after June 2020.
- Student cultures microorganisms in a home environment.

Other

- Student's research report fails plagiarism screening.
- Student fails to disclose personal relationships in the mentorship of their project, or other conflict of interest.
- Student or mentor fails to disclose payment for services.
- Student is not in their final year of high school.
- · Student submits high school team project as individual work.
- · Student does not meet residence or citizenship eligibility requirements.
- Student adheres to University requirements that are less strict than Regeneron STS requirements.
- Research Report exceeds 20 page limit, or attempts to deceive the spirit of the page limit.

APPENDIX 13: ALUMNI HONORS

NOBEL PRIZE

STS YEAR	NAME
1944	Ben R. Mottelson
1946	Gerald Edelman
1947	Leon Cooper
1947	Martin Karplus
1949	Walter Gilbert
1950	Sheldon Glashow
1952	John Hall
1955	Roald Hoffmann
1958	Kip Thorne
1964	Paul Modrich
1967	Frank Wilczek
1968	Roger Tsien
1968	Alvin Roth

HONOR, YEAR

Physics, 1975 Physiology or Medicine, 1972 Physics, 1972 Chemistry, 2013 Chemistry, 1980 Physics, 2005 Chemistry, 1981 Physics, 2017 Chemistry, 2015 Physics, 2004 Chemistry, 2008 Economics, 2012

FIELDS MEDAL

1950	Paul J. Cohen	1966
1953	David B. Mumford	1974

NATIONAL MEDAL OF SCIENCE

1948	Ronald Breslow	1991
1950	Paul Cohen	1967
1950	Daniel Kleppner	2006
1953	Leo Kadanoff	1999
1953	David Mumford	2009
1954	Lubert Stryer	2006
1955	Roald Hoffmann	1983
1956	Leroy Hood	2011
1956	Donald Knuth	1979
1957	Richard Zare	1983
1961	Robert Axelrod	2012

NATIONAL MEDAL OF TECHNOLOGY

1952	Carver Mead	2002
1954	Marcian E. "Ted" Hoff	2010
1957	George Carruthers	2011
1961	Mary Shaw	2012
1965	Raymond C. Kurzweil	1999
1985	Fredrick Brooks	1949

MACARTHUR FELLOWSHIP

1948	Dishard C. Dorm	1002
	Richard S. Berry	1983
1953	David Mumford	1987
1953	Alar Toomre	1984
1958	Jane Richardson	1985
1958	John Schwarz	1987
1960	Arthur Winfree	1984
1961	Robert Axelrod	1987
1962	Michael Silverstein	1982
1964	Amory Lovins	1993
1967	Frank Wilczek	1982
1972	Robert Coleman	1987
1974	Eric Lander	1987
1978	David Spergel	2001
1982	Peter Miller	1998
1984	Daniel Schrag	2000

STS YEAR	NAME	HONOR, YEAR
1989	Jon Kleinberg	2005
1989	Vamsi Mootha	2004
1999	Maneesh Agrawala	2009
1996	Jacob Lurie	2014
1997	Nadarajan Chetty	2012
1997	William Thies	2016
2001	Monika Schleier-Smith	2020

ALBERT LASKER BASIC MEDICAL RESEARCH AWARD

1949	Walter Gilbert	1979
1956	Leroy Hood	1987
1976	Ron Vale	2012

NATIONAL ACADEMY OF ENGINEERING

Willaim Agnew	1965	Raymond Kurzeil
Eberhardt Rechtin	1974	Edward Frank
Anthony Kurtz	1974	llan Kroo
George Turin	1974	F. Tom Leighton
Alan J. Goldman	1975	John Langford, III
Edwin Chandross	1977	Grant Stokes
John A. Armstrong	1978	Mark Drela
Leroy Hood	1979	Ann Lee
Donald Knuth	1979	James Bellingham
Charles Thacker	1986	Lisa Su
Bailey Diffie	1989	Andrew Jackson
Michael Lesk	1989	Jon Kleinberg
James Baker	1949	Fredrick Brooks
Robert Sproull		
	Eberhardt Rechtin Anthony Kurtz George Turin Alan J. Goldman Edwin Chandross John A. Armstrong Leroy Hood Donald Knuth Charles Thacker Bailey Diffie Michael Lesk James Baker	Eberhardt Rechtin1974Anthony Kurtz1974George Turin1974Alan J. Goldman1975Edwin Chandross1977John A. Armstrong1978Leroy Hood1979Donald Knuth1979Charles Thacker1986Bailey Diffie1989Michael Lesk1989James Baker1949

NATIONAL ACADEMY OF SCIENCES

1948	Ronald Breslow	1966
1945	Kenneth Wiberg	1967
1947	Martin Karplus	1967
1950	Paul J. Cohen	1967
1945	Andrew Streitwieser	1969
1946	Gerald Edelman	1969
1945	Michael Tinkham	1970
1944	Roald Hoffmann	1972
1944	Ben Mottelson	1973
1952	James Bjorken	1973
1958	Kip Thorne	1973
1957	Stephen L. Adler	1975
1947	Leon N. Cooper	1975
1956	Donald Knuth	1975
1953	David Mumford	1975
1947	Gary Felsenfeld	1976
1949	Walter Gilbert	1976
1957	Richard Zare	1976
1956	Richard Lindzen	1977
1950	Sheldon Glashow	1977
1958	Carl Wunsch	1978
1953	Leo Kadanoff	1978
1948	Paul Martin	1979
1948	Stephen Berry	1980
1945	George Clark	1980
1944	James Serrin	1980
1948	Richard S. Berry	1980
1952	Gordon Baym	1982
1958	Bertrand Halperin	1982

STS YEAR	NAME	HONOR, YEAR	STS YEAR	NAME	HONOR, YEAR
1956	Leroy Hood	1982	1989	Jon Kleinberg	2011
1950	Saul Sternberg	1982	1965	James McCammon	2011
1953	Alar Toomre	1983	1968	Joseph Harris	2011
1943	Murray Rosenblatt	1984	1972	James Demmel	2011
1952	Howard Berg	1984	1977	William Bialek	2012
1954	Lubert Stryer	1984	1956	James Bardeen	2012
1952	John Hall	1984	1968	Alvin Roth	2013
1952	Paul Richards	1985	1961	Mark Cane	2013
1956	Mary-Dell Chilton	1985	1989	Vamsi Mootha	2014
1954 1949	Eric Davidson Richard Dickerson	1985 1985	1971 1972	John Preskill Eric D'Asaro	2014 2014
1949	Robert Solovay	1985	1972	Alfred Goldberg	2014
1950	Daniel Kleppner	1986	1976	Nancy Andrews	2015
1951	Shlomo Sternberg	1986	1982	Noam Elkies	2010
1961	Robert Axelrod	1986	1967	Mary Hatten	2017
1954	Donald Crothers	1987	1997	Nadarajan Chetty	2018
1959	Harvey Lodish	1987	1963	Sarah Roberts Elgin	2018
1960	John Mather	1988	1960	Jack Griffith	2018
1950	Dana Scott	1988	2000	Feng Zhang	2018
1952	Carver Mead	1989	1971	Arlene Sharpe	2018
1949	Philip Hanawalt	1989	1986	Dalton Conley	2018
1945	Andrew Sessler	1990	1962	Barry Simon	2019
1947	Walter Kamb	1990	1970	Rosina Bierbaum	2019
1967	Frank Wilczek	1990	1970	Roger Falcone	2019
1958	Jane Richardson	1991	1968	David Knipe David R. Liu	2021
1960 1960	Melvin Hochster Alexandra Navrotsky	1992 1993	1990 1969	Gordon Freeman	2021 2022
1964	Paul Modrich	1993	1909	Joel Moore	2022
1956	Eric Adelberger	1994	1551	50er 1000re	2022
1968	Corey Goodman	1995			
1956	William Happer	1996			
1974	Eric Lander	1997			
1974	F. Tom Leighton	2008			
1958	John Schwarz	1997			
1960	Charles Bennett	1997			
1956	James Tumlinson	1997			
1961	Michael Gimbrone	1997			
1970	Paul Steinhardt	1998			
1953 1968	Charles Gross Roger Tsien	1998			
1958	William Bardeen	1998 1999			
1946	Douglas Lilly	1999			
1970	Douglas Rees	2000			
1944	Robert Kraichnan	2000			
1965	Kenneth Ribet	2000			
1949	Frederick Brooks	2001			
1967	Jeffrey Lagarias	2001			
1969	Robert Cava	2001			
1976	Ronald Vale	2001			
1962	Dennis Carson	2003			
1963	James Vaupel	2004			
1976	George Yancopoulos	2004			
1962 1961	Paul Chaikin Wayne Hubbell	2004 2005			
1964	Edward Solomon	2005			
1969	Jeffrey Ravetch	2005			
1978	David Spergel	2000			
1970	Wayne Yokoyama	2007			
1954	Allen Goldman	2007			
1980	Lisa Randall	2008			
1974	Frank Leighton	2008			
1961	Michael Botchan	2008			
1972	Michael Greenberg	2008			
1959	Allan Gibbard	2009			



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About Regeneron

Regeneron is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for nearly 35 years by physician-scientists, Regeneron's unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all of which were homegrown in Regeneron's laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, infectious diseases and rare diseases.

Regeneron's long-standing commitment to corporate responsibility is crucial to achieving our mission of delivering vital medicines to patients. We leverage the unique knowledge and expertise within our company to focus on three goals: improving the lives of people with serious diseases, fostering a culture of integrity and excellence and building sustainable communities. Our most significant philanthropic commitments focus on fostering future scientific leaders through STEM education outreach and equity, including the Regeneron Science Talent Search and Regeneron International Science and Engineering Fair. Regeneron is proud to be included on the Dow Jones Sustainability World Index, the Civic 50 list of the most "community-minded" companies in the United States and *Newsweek* America's Most Responsible Companies.

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