

Resources: Human Subjects Protections, Inclusion, and Clinical Trials



Regulations

- **HHS Regulations Protection of Human Subjects 45 CFR 46, Subparts A-E**
<https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46>



Human Subjects Protections

Policies and Notices

- **NIH Policy Required Education in the Protection of Human Research Participants**
<https://grants.nih.gov/grants/guide/notice-files/not-od-00-039.html> and
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html>
- **NIH Notice for the End of Common Rule Single IRB Exceptions After the COVID-19 Public Health Emergency Expiration** <https://grants.nih.gov/grants/guide/notice-files/not-od-23-097.html>
- **Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research**
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>
- **NIH Reminder of Guidance on Requirement for NIH Single Institutional Review Board (IRB) Plan**
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-174.html>
- **NIH Policy for Issuing Certificates of Confidentiality** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

Tools and Trainings

- **NIH Human Subjects Research website** <https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects>
- **NIH Decision Tool: Am I Doing Human Subjects Research?** <https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/hs-decision>
- **NIH Human Subjects Research Infographic** <https://grants.nih.gov/sites/default/files/human-subjects-research-infographic.pdf>
- **NIH Exempt Human Subjects Research Infographic**
https://grants.nih.gov/sites/default/files/exemption_infographic_v8_508c_1-15-2020.pdf

- **NIH Research Involving Private Information or Biospecimens Flowchart**
<https://grants.nih.gov/grants/policy/hs/private-information-biospecimens-flowchart.pdf>
- **Single IRB (sIRB) Requirement Determination Workflow**
<https://grants.nih.gov/sites/default/files/sIRB-Determination-workflow.pdf>
- **NIH Training & Resources- Human Subjects website** <https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/training-and-resources>
- **NIH Certificates of Confidentiality website** <https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc>
- **NIH Single IRB for Multi-Site or Cooperative Research website** <https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/single-irb-policy-multi-site-research>
- **Podcast: Am I Doing Human Subjects Research? Part 1** <https://grants.nih.gov/news-events/podcasts?episode=930>
- **Podcast: Human Subjects Protection and Monitoring Plans Part 2** <https://grants.nih.gov/news-events/podcasts?episode=1020>
- **Podcast: Human Subjects Research Post-Award Part 3** <https://grants.nih.gov/news-events/podcasts?episode=923>
- **OHRP Human Subject Regulations Decision Charts: 2018 Requirements**
<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html>
- **OHRP Exempt Research Determination FAQs** <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html>
- **OHRP Human Research Protection Training** <https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html>
- **OHRP Guidance Document: Engagement of Institutions in Human Subjects Research**
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>



Clinical Trials

Policies and Notices

- **NIH Policy on Funding Opportunity Announcements (FOA) for Clinical Trials**
<https://grants.nih.gov/grants/guide/notice-files/not-od-16-147.html>
- **Continued Extension of Certain Flexibilities for Prospective Basic Experimental Studies With Human Participants** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-118.html>
- **NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information**
<https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html>

- **NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials** <https://grants.nih.gov/grants/guide/notice-files/not-od-16-148.html>
- **NIH Policy for Data and Safety Monitoring** <https://grants.nih.gov/grants/guide/notice-files/not98-084.html>
- **NIH Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials** <https://grants.nih.gov/grants/guide/notice-files/not-od-00-038.html>

Tools

- **NIH Definition of a Clinical Trial** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition>
- **NIH Clinical Trial Requirements for Grants and Contracts website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials>
- **NIH Decision Tool: Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical Trial?** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/ct-decision>
- **NIH Clinical Trial FAQs:** <https://grants.nih.gov/faqs#/clinical-trial-definition.htm>
- **Podcast: Understanding the Definition of a Clinical Trial and What that Means for You** <https://grants.nih.gov/news-events/podcasts?episode=911>
- **Podcast: Clinical Trials Reporting Requirements – Our Shared Commitment** <https://grants.nih.gov/news-events/podcasts?episode=951>
- **Podcast: What Researchers and Recipients Should Know about ClinicalTrials.gov** <https://grants.nih.gov/news-events/podcasts?episode=984>
- **NIH Clinical Trial-Specific Funding Opportunities website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/specific-funding-opportunities>
- **NIH Clinical Trial-Specific Review Criteria website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/review-criteria>
- **NIH Basic Experimental Studies Involving Humans (BESH) website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/besh>
- **NIH Chart: Comparison of Funding Opportunity Types by Clinical Trial Allowability** <https://grants.nih.gov/grants/Comparison-of-FOA-Types-Clinical-Trials.pdf>
- **NIH Requirements for Registering & Reporting NIH-funded Clinical Trials on ClinicalTrials.gov website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/reporting>
- **NIH ClinicalTrials.gov website: How to Register Your Study** <https://clinicaltrials.gov/submit-studies/prs-help/how-register-study>
- **NIH ClinicalTrials.gov website: How to Submit Your Results** <https://clinicaltrials.gov/submit-studies/prs-help/how-submit-results>

- **NIH Good Clinical Practice (GCP) Training website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/good-clinical-training>
- **NIH Posting Clinical Trial Informed Consent Forms website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/informedconsent>
- **Podcast: Basic Experimental Studies with Humans (BESH)** <https://grants.nih.gov/news-events/podcasts?episode=966>
- **Understanding the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/reporting/nih-policy>
- **NIH Guidance: Valid Analysis Reporting in ClinicalTrials.gov for Applicable NIH-Defined Phase III Clinical Trials**
https://grants.nih.gov/sites/default/files/Valid%20analysis%20CTgov%20guidance%20final_508c.pdf
- **NIH Matchmaker website** <https://reporter.nih.gov/matchmaker>
- **NIH Protocol Templates for Clinical Trials website** <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/protocol-template>
- **NIH e-Protocol Writing Tool website** <https://e-protocol.od.nih.gov/#/home>



Inclusion

Policies and Notices

- **Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (2017)** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html>
- **Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (2001)** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html> and <https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities/guideline>
- **NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>
- **NIH Policy- Inclusion of Children in Clinical Research: Change in NIH Definition** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html>

Tools

- **NIH Inclusion of Women and Minorities website** <https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities>
- **NIH Inclusion Across the Lifespan website** <https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/lifespan>
- **NIH Decision Tree: Applying the Inclusion of Women and Minorities Policy** https://grants.nih.gov/sites/default/files/Decision%20tree-%20Sex-gender%20race-ethnicity_508final%204-12-18.pdf
- **NIH Infographic: Guidance for Applying the Inclusion Across the Lifespan Policy** <https://grants.nih.gov/sites/default/files/IAL%20policy%20infographic%20rev%204-23-19%20508c.pdf>
- **NIH Inclusion Across the Lifespan Case Studies** <https://grants.nih.gov/sites/default/files/IAL-Case-studies-for-Extramural-community.pdf>
- **NIH Tip Sheet: Using the Participant-level Data Template** <https://grants.nih.gov/sites/default/files/Participant-level%20data%20template%20tip%20sheet.pdf>
- **NIH Video: Entering Inclusion Data Using the Participant Level Data Template** <https://youtu.be/IHYrdlPfkVo>
- **Open Mike Blog: the Inclusion Across the Lifespan Policy** <https://nexus.od.nih.gov/all/2018/11/13/understanding-age-in-the-nih-portfolio-implementation-of-the-nih-inclusion-across-the-lifespan-policy/>
- **Open Mike Blog: Reminders, Updates, and Some Data for Participant Inclusion** <https://nexus.od.nih.gov/all/2024/05/21/reminders-updates-and-some-data-for-participant-inclusion/>
- **Podcast: Inclusion Across the Lifespan Policy** <https://grants.nih.gov/news-events/podcasts?episode=909>



General Information

NIH Policies and Notices

- **NIH Notice: Update on Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-111.html>
- **NIH Notice: Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-137.html>

Tools and Resources

- **NIH Example Informed Consent Language: Certificates of Confidentiality**
<https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc/suggested-consent>
- **NIH Human Subjects System (HSS) Help and Tutorials** <https://era.nih.gov/help-tutorials/hss>
- **NIH Video: Overview of the Human Subjects and Clinical Trials Form**
<https://www.youtube.com/watch?v=FNgOHqmk0rY>
- **Podcast: Certificates of Confidentiality Basics** <https://grants.nih.gov/news-events/podcasts?episode=995>