National Institutes of Health
Office of Extramural Research

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/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

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

- **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 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/humansubjects.htm

- **NIH Decision Tool: Am I Doing Human Subjects Research?**
  https://grants.nih.gov/policy/humansubjects/hs-decision.htm

- **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

- **NIH Training & Resources- Human Subjects website**
  https://grants.nih.gov/policy/humansubjects/research/training-and-resources.htm

- **NIH Certificate of Confidentiality website**
  https://grants.nih.gov/policy/humansubjects/coc.htm

- **NIH Single IRB for Multi-Site or Cooperative Research website**
  https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm

- **Podcast: Am I Doing Human Subjects Research? Part 1**
  https://grants.nih.gov/podcasts/All_About_Grants/episodes/Human-Subjects-Part-1.mp3

- **Podcast: Human Subjects Protection and Monitoring Plans Part 2**
  https://grants.nih.gov/podcasts/All_About_Grants/episodes/HSR-Protection-and-Monitoring-Plans-Part2.mp3

- **Podcast: Human Subjects Research Post-Award Part 3**
  https://grants.nih.gov/podcasts/All_About_Grants/episodes/HSR-Part-3-Post-Award-Final.mp3

- **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

- **NIH Continued Extension of Certain Flexibilities for Prospective Basic Experimental Studies With Human Participants** https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-205.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 ClinicalTrials** 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

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Tools

- **NIH Definition of a Clinical Trial** https://grants.nih.gov/policy/clinical-trials/definition.htm

- **NIH Clinical Trials Requirements for Grants and Contracts website** https://grants.nih.gov/policy/clinical-trials.htm

- **NIH Decision Tool: Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical Trial?** https://grants.nih.gov/ct-decision/index.htm

- **NIH Clinical Trial FAQs:** https://grants.nih.gov/policy/clinical-trials/faq-list.htm

- **Podcast: Understanding the Definition of a Clinical Trial and What that Means for You** https://grants.nih.gov/podcasts/All_About_Grants/episodes/Understanding_the_Definition_of_a_Clinical_Trial_and_what_that_means_for_you.mp3

- **NIH Clinical Trial-Specific Funding Opportunities website** https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm

- **Frequently Asked Questions (FAQs) Clinical Trial-specific FOAs**

  https://grants.nih.gov/faqs#/clinical-trial-specific-foas.htm

- **NIH Clinical Trial-Specific Review Criteria website** https://grants.nih.gov/policy/clinical-trials/review-criteria.htm

- **NIH Basic Experimental Studies Involving Humans (BESH) website** https://grants.nih.gov/policy/clinical-trials/besh.htm

- **NIH Chart Comparison of Funding Opportunity Announcement 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 in ClinicalTrials.gov website** https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

- **NIH ClinicalTrials.gov website, How to Register Your Study** https://clinicaltrials.gov/ct2/manage-recs/how-register

- **NIH ClinicalTrials.gov website, How to Submit Your Results** https://clinicaltrials.gov/ct2/manage-recs/how-report

- **NIH Good Clinical Practice Training website** https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

- **NIH Posting Clinical Trial Informed Consent Forms website** https://grants.nih.gov/policy/clinical-trials/informedconsent.htm

- **Podcast: Basic Experimental Studies with Humans (BESH)** https://grants.nih.gov/podcasts/All_About_Grants/episodes/Podcast-BESH.mp3

- **NIH Understanding the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information website** https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm

- **NIH Guidance: Valid Analysis Reporting in ClinicalTrials.gov for Applicable NIH-Defined Phase III Clinical Trials website** 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/clinical-trials/protocol-template.htm

- **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 Subjectsin Clinical Research (2018)** 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 Subjectsin Clinical Research (2001)** https://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html and https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm

- **NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants inResearch 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/grants/funding/women_min/women_min.htm

- **NIH Inclusion Across the Lifespan website** https://grants.nih.gov/policy/inclusion/lifespan.htm

- **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 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/lHYrdlPfKVo

- **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/

- **Podcast: Inclusion Across the Lifespan Policy**
  http://grants.nih.gov/podcasts/All_About_Grants/episodes/Podcas-Inclusion-Across-the- Lifespan.mp3

📄 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 AskedQuestions (FAQs) Regarding Proposed Human Fetal Tissues Research**
  https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-137.html

Tools and Resources

- **NIH Examples Informed Consent Language Certificates of Confidentiality**
  https://grants.nih.gov/policy/humansubjects/coc/helpful-resources/suggested-consent.htm

- **NIH Human Subjects System (HSS) Help and Tutorials** https://era.nih.gov/help-tutorials/hss

- **NIH Video overview of Human Subjects and Clinical Trials form:**
  https://www.youtube.com/watch?v=FNgOHqmk0rY

- **Podcast: Certificates of Confidentiality Basics**
  https://grants.nih.gov/podcasts/All_About_Grants/episodes/Certificates-of-Confidentiality.mp3