

## Social and Behavioral Research: Best Practices for Research Course References & Resources

---

**Tool/Resource:** List of selected references and resources related to the Social and Behavioral Research: Best Practices for Research course and research best practices

**Audience:** Study team members engaged in social and behavioral research studies

---

### RESOURCE REVISION HISTORY

VERSION No.	DATE	SUMMARY OF REVISIONS
V1.0	Sept2022	Original
V2.0	10Oct2022	Added copyright information to footer; corrected Module 9 link for Coursera course on Community Engagement in Research and Population Health
V3.0	10Oct2023	Updated copyright information in footer; updated version number in footer; added Module 2 to the table of contents

# Contents

---

General Resources .....	1
Module 1: Introduction .....	1
Module 2: Research Protocol .....	2
Module 3: Recruitment and Retention.....	2
Module 4: Informed Consent .....	3
Module 5: Privacy and Confidentiality.....	4
Module 6: Participant Safety and Adverse Event Reporting .....	5
Module 7: Quality Control and Assurance.....	6
Module 8: Research Misconduct .....	7
Module 9: Community and Stakeholder Engagement.....	7

## General Resources

Type	Description	URL
Work aids	NIDCR Clinical Researcher Toolkit & Educational Materials – a collection of templates and guidance documents organized by study design (e.g., Observational Studies, Interventional Studies) and study life cycle (e.g., Planning & Startup, Conduct & Operations and Close-out)	<a href="https://www.nidcr.nih.gov/research/human-subjects-research/toolkit-and-education-materials">https://www.nidcr.nih.gov/research/human-subjects-research/toolkit-and-education-materials</a>
Guidance	U.S. HHS 45 CFR 46 – a navigable presentation of the 2018 Common Rule	<a href="https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html</a>
Guidance	NIH Policy & Compliance – landing page for NIH policies including those governing human subjects research, scientific rigor and reproducibility and more	<a href="https://grants.nih.gov/policy/index.htm">https://grants.nih.gov/policy/index.htm</a>
Guidance	NIH Clinical Trial Definition – landing page for definitions, FAQs and decision tree for the 2014 definition of clinical trial	<a href="https://grants.nih.gov/policy/clinical-trials.htm">https://grants.nih.gov/policy/clinical-trials.htm</a>

GO TOP OF DOCUMENT

## Module 1: Introduction

Type	Description	URL
Journal article	The importance of Good Clinical Practice guidelines and its role in clinical trials – A. Vijayanathan (2008)	<a href="https://pubmed.ncbi.nlm.nih.gov/21614316/">https://pubmed.ncbi.nlm.nih.gov/21614316/</a>
Journal article	The International Conference on Harmonization Good Clinical Practice Guideline – J R Dixon Jr (1998)	<a href="https://pubmed.ncbi.nlm.nih.gov/10386329/">https://pubmed.ncbi.nlm.nih.gov/10386329/</a>
Journal article	Best practices in social and behavioral research: report from the Enhancing Clinical Research Professional's Training and Qualifications project – S L Murphy (2017)	<a href="https://pubmed.ncbi.nlm.nih.gov/28670483/">https://pubmed.ncbi.nlm.nih.gov/28670483/</a>

GO TOP OF DOCUMENT

### SELECTED REFERENCES & RESOURCES

(C) 2016 - 2023 The Regents of the University of Michigan. See full course acknowledgements under resources tab. All rights reserved.  
Social and Behavioral Research Best Practices for Clinical Research is licensed under the [Creative Commons Attribution 4.0 International \(CC BY 4.0\) License](https://creativecommons.org/licenses/by/4.0/).

## Module 2: Research Protocol

Type	Description	URL
Template	NIH Behavioral and Social Sciences Research Protocol Template – links to NIH protocol templates and writing tools; the Behavioral and Social Science Research (BSSR) Involving Humans template was developed to help behavioral and social science researchers draft study protocol documents	<a href="https://grants.nih.gov/policy/clinical-trials/protocol-template.htm">https://grants.nih.gov/policy/clinical-trials/protocol-template.htm</a>
Journal article & Work aid	Guidance for biostatisticians on their essential contributions to clinical and translational research protocol review – J D Ciolino (2021): includes a checklist and review guidance	<a href="https://pubmed.ncbi.nlm.nih.gov/34527300/">https://pubmed.ncbi.nlm.nih.gov/34527300/</a>
Guidance & Work aid	CONSORT (Consolidated Standards of Reporting Trials) Statements and Checklists for Non-Pharmacologic Treatment Interventions and Social & Psychological Interventions – links to CONSORT extensions for a variety of study designs	<a href="http://www.consort-statement.org/extensions">http://www.consort-statement.org/extensions</a>
Guidance & Work aid	STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) Checklists	<a href="https://www.strobe-statement.org/">https://www.strobe-statement.org/</a>
Journal article & Work aid	Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups – A Tong (2007)	<a href="https://pubmed.ncbi.nlm.nih.gov/17872937/">https://pubmed.ncbi.nlm.nih.gov/17872937/</a>

[GO TOP OF DOCUMENT](#)

## Module 3: Recruitment and Retention

Type	Description	URL
Guidance	The Use of Social Media in Recruitment to Research: A Guide for Investigators and IRBs	<a href="https://catalyst.harvard.edu/publications-documents/the-use-of-social-media-in-recruitment-to-research-a-guide-for-investigators-and-irbs/">https://catalyst.harvard.edu/publications-documents/the-use-of-social-media-in-recruitment-to-research-a-guide-for-investigators-and-irbs/</a>
Journal article	Using social media for health research: Methodological and ethical considerations for recruitment and intervention delivery – D Arigo (2018)	<a href="https://pubmed.ncbi.nlm.nih.gov/29942634/">https://pubmed.ncbi.nlm.nih.gov/29942634/</a>
Journal article	Using social media as a Research Recruitment Tool: Ethical Issues and Recommendations – L Galinas (2017)	<a href="https://pubmed.ncbi.nlm.nih.gov/28207365/">https://pubmed.ncbi.nlm.nih.gov/28207365/</a>

[GO TOP OF DOCUMENT](#)

### SELECTED REFERENCES & RESOURCES

(C) 2016 - 2023 The Regents of the University of Michigan. See full course acknowledgements under resources tab. All rights reserved.  
 Social and Behavioral Research Best Practices for Clinical Research is licensed under the [Creative Commons Attribution 4.0 International \(CC BY 4.0\) License](#).

## Module 4: Informed Consent

Type	Description	URL
Resources	NIH <i>Clear Communications</i> resource pages	<a href="https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication">https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication</a>
Resources	U.S. Government Plain Language resource pages	<a href="https://www.plainlanguage.gov/">https://www.plainlanguage.gov/</a>
Journal article	Simplification improves understanding of informed consent information in clinical trials regardless of health literacy level – E J Kim (2015)	<a href="https://pubmed.ncbi.nlm.nih.gov/25701156/">https://pubmed.ncbi.nlm.nih.gov/25701156/</a>
Journal article & Work aid	A new brief instrument for assessing decisional capacity for clinical research – D V Jeste (2007)	<a href="https://pubmed.ncbi.nlm.nih.gov/17679641/">https://pubmed.ncbi.nlm.nih.gov/17679641/</a>
Work aid	ARHQ Health Literacy Universal Precautions Toolkit, 2nd Edition – Use the Teach-Back Method: Tool #5	<a href="https://www.ahrq.gov/health-literacy/improve/precautions/tool5.html">https://www.ahrq.gov/health-literacy/improve/precautions/tool5.html</a>
Guidance	What is eConsent? – TransCelerate BioPharma, Inc.	<a href="https://www.transceleratebiopharmainc.com/assets/econsent-solutions/what-is-econsent/">https://www.transceleratebiopharmainc.com/assets/econsent-solutions/what-is-econsent/</a>
Guidance	Use of Electronic Informed Consent - Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors – U.S. HHS, OHRP, FDA, CDER, OGCP, CBER, CDRH (2016)	<a href="https://www.fda.gov/media/116850/download">https://www.fda.gov/media/116850/download</a>
Journal article	E-Consent-a guide to maintain recruitment in clinical trials during the COVID-19 pandemic – R Almeida-Magana (2022)	<a href="https://pubmed.ncbi.nlm.nih.gov/35550639/">https://pubmed.ncbi.nlm.nih.gov/35550639/</a>
Work aid	Informed Consent Checklist – SBR Best Practices for Research Course	
Work aid	Participant Conversations: Suggested open-ended questions to gauge understanding – SBR Best Practices for Research Course	
Work aid	Writing Informed Consent Documents and Materials – SBR Best Practices for Research Course	

[GO TOP OF DOCUMENT](#)

### SELECTED REFERENCES & RESOURCES

(C) 2016 - 2023 The Regents of the University of Michigan. See full course acknowledgements under resources tab. All rights reserved. Social and Behavioral Research Best Practices for Clinical Research is licensed under the [Creative Commons Attribution 4.0 International \(CC BY 4.0\) License](#).

## Module 5: Privacy and Confidentiality

Type	Description	URL
Guidance	NIH Certificates of Confidentiality	<a href="https://grants.nih.gov/policy/humansubjects/coc.htm">https://grants.nih.gov/policy/humansubjects/coc.htm</a>
Guidance	U.S. HHS Health Information Privacy (HIPAA)	<a href="https://www.hhs.gov/hipaa/index.html">https://www.hhs.gov/hipaa/index.html</a>
Journal article	Protecting Respondent Confidentiality in Qualitative Research – K Kaiser (2009)	<a href="https://pubmed.ncbi.nlm.nih.gov/19843971">https://pubmed.ncbi.nlm.nih.gov/19843971</a>
Journal article	Wearable Devices in Clinical Trials: Hype and Hypothesis – E S Izmailova (2018)	<a href="https://pubmed.ncbi.nlm.nih.gov/29205294">https://pubmed.ncbi.nlm.nih.gov/29205294</a>
Journal article	Research on Data Security and Privacy Protection of Wearable Equipment in Healthcare – D Jiang (2021)	<a href="https://pubmed.ncbi.nlm.nih.gov/3362840">https://pubmed.ncbi.nlm.nih.gov/3362840</a>
Journal article	Ethical Considerations of Wearable Technologies in Human Research – J Tu (2021)	<a href="https://pubmed.ncbi.nlm.nih.gov/33870653/">https://pubmed.ncbi.nlm.nih.gov/33870653/</a>
Journal article	Review of Wearable Devices and Data Collection Considerations for Connected Health – V Vijayan (2021)	<a href="https://pubmed.ncbi.nlm.nih.gov/34451032/">https://pubmed.ncbi.nlm.nih.gov/34451032/</a>

[GO TOP OF DOCUMENT](#)

### SELECTED REFERENCES & RESOURCES

(C) 2016 - 2023 The Regents of the University of Michigan. See full course acknowledgements under resources tab. All rights reserved. Social and Behavioral Research Best Practices for Clinical Research is licensed under the [Creative Commons Attribution 4.0 International \(CC BY 4.0\) License](#).

## Module 6: Participant Safety and Adverse Event Reporting

Type	Description	URL
Guidance	U.S. HHS Office of Research Protections – review the Regulations, Policy & Guidance tab for information on reviewing and reporting UaPs and AEs	<a href="https://www.hhs.gov/ohrp/index.html">https://www.hhs.gov/ohrp/index.html</a>
Journal article	The need for expanded monitoring of adverse events in behavioral health clinical trials – A L Peterson (2013)	<a href="https://pubmed.ncbi.nlm.nih.gov/23117077/">https://pubmed.ncbi.nlm.nih.gov/23117077/</a>
Journal article	Principles for defining adverse events in behavioral intervention research: lessons from a family-focused adolescent drug abuse trial – V E Horigian (2010)	<a href="https://pubmed.ncbi.nlm.nih.gov/20156957/">https://pubmed.ncbi.nlm.nih.gov/20156957/</a>
Journal article	Better reporting of harms in randomized trials: an extension of the CONSORT statement – J P A Ioannidis (2004)	<a href="https://pubmed.ncbi.nlm.nih.gov/15545678/">https://pubmed.ncbi.nlm.nih.gov/15545678/</a>
Journal article & Work aid	CONSORT-SPI 2018 Explanation and Elaboration: guidance for reporting social and psychological intervention trials – S Grant (2018): guidance and checklists	<a href="https://pubmed.ncbi.nlm.nih.gov/30060763/">https://pubmed.ncbi.nlm.nih.gov/30060763/</a>
Journal article & Work aid	The COMBINE SAFEE: a structured instrument for collecting adverse events adapted for clinical studies in the alcoholism field – B A Johnson (2005)	<a href="https://pubmed.ncbi.nlm.nih.gov/16223067/">https://pubmed.ncbi.nlm.nih.gov/16223067/</a>
Work aid	Participant Safety Adverse Event & Harms Querying – SBR Best Practices for Research Course	

[GO TOP OF DOCUMENT](#)

### SELECTED REFERENCES & RESOURCES

(C) 2016 - 2023 The Regents of the University of Michigan. See full course acknowledgements under resources tab. All rights reserved. Social and Behavioral Research Best Practices for Clinical Research is licensed under the [Creative Commons Attribution 4.0 International \(CC BY 4.0\) License](#).

## Module 7: Quality Control and Assurance

Type	Description	URL
Journal article	Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium – A J Bellg (2004)	<a href="https://pubmed.ncbi.nlm.nih.gov/15367063/">https://pubmed.ncbi.nlm.nih.gov/15367063/</a>
Journal article	Assessing intervention fidelity in a multi-level, multi-component, multi-site program: the Children's Healthy Living (CHL) program – J Butel (2015)	<a href="https://pubmed.ncbi.nlm.nih.gov/26622918/">https://pubmed.ncbi.nlm.nih.gov/26622918/</a>
Templates	Refer to General Resources, NIDCR Clinical Researcher Toolkit & Educational Materials – Interventional Studies for templates and guidance on Data Management Plans and Quality Management	JUMP TO GENERAL RESOURCES
Learning modules	U.S. HHS Office of Research Integrity Data Management	<a href="https://ori.hhs.gov/data-management">https://ori.hhs.gov/data-management</a>
Guidance	U.S. HHS Office of Research Integrity, Guidelines for Responsible Data Management in Scientific Research (2006)	<a href="https://ori.hhs.gov/education/products/clinicaltools/data.pdf">https://ori.hhs.gov/education/products/clinicaltools/data.pdf</a>
Journal article	Measurement error and reliability testing: application to rehabilitation - A E Bialocerkowski (2013)	<a href="https://www.magonlinelibrary.com/doi/abs/10.12968/ijtr.2008.15.10.31210">https://www.magonlinelibrary.com/doi/abs/10.12968/ijtr.2008.15.10.31210</a>
Journal article	Protocol deviation and violation – A Bhatt (2012)	<a href="https://pubmed.ncbi.nlm.nih.gov/23125964/">https://pubmed.ncbi.nlm.nih.gov/23125964/</a>
Journal article	Treatment fidelity in behavior change research: a case example – B Resnick (2005)	<a href="https://pubmed.ncbi.nlm.nih.gov/15778656/">https://pubmed.ncbi.nlm.nih.gov/15778656/</a>
Work aid	Study Self-Assessment for monitoring and auditing – SBR Best Practices for Research Course	

[GO TOP OF DOCUMENT](#)

### SELECTED REFERENCES & RESOURCES

(C) 2016 - 2023 The Regents of the University of Michigan. See full course acknowledgements under resources tab. All rights reserved. Social and Behavioral Research Best Practices for Clinical Research is licensed under the [Creative Commons Attribution 4.0 International \(CC BY 4.0\) License](#).



## Module 8: Research Misconduct

Type	Description	URL
Guidance	NIH Policy & Compliance – Research Integrity – scroll down to Research Misconduct section	<a href="https://grants.nih.gov/policy/research_integrity/index.htm">https://grants.nih.gov/policy/research_integrity/index.htm</a>
Guidance	American Psychological Association – Research Misconduct: includes links to federal policies and general resources	<a href="https://www.apa.org/research/responsible/misconduct">https://www.apa.org/research/responsible/misconduct</a>
Newspaper article	New York Times, <i>Harvard Finds Scientist Guilty of Misconduct</i> by Nicholas Wade (August 20, 2010)	<a href="https://www.nytimes.com/2010/08/21/education/21harvard.html">https://www.nytimes.com/2010/08/21/education/21harvard.html</a>

[GO TOP OF DOCUMENT](#)

## Module 9: Community and Stakeholder Engagement

Type	Description	URL
Journal article	Using community-based participatory research to address health disparities – N B Wallerstein (2006)	<a href="https://pubmed.ncbi.nlm.nih.gov/16760238/">https://pubmed.ncbi.nlm.nih.gov/16760238/</a>
Journal article	Defining Patient-Oriented Research for the Average Person (and Potential Research Partner) – D J Baumgardner (2019)	<a href="https://pubmed.ncbi.nlm.nih.gov/31414018/">https://pubmed.ncbi.nlm.nih.gov/31414018/</a>
Fact Sheet	Pan American Health Organization Community-based Participatory Research Factsheet	<a href="https://www.uml.edu/docs/cbpr%20factsheet_final_tcm18-176268.pdf">https://www.uml.edu/docs/cbpr%20factsheet_final_tcm18-176268.pdf</a>
Guidance	Canadian Institutes of Health – Strategy for Patient-Oriented Research - Patient Engagement Framework	<a href="https://cihr-irsc.gc.ca/e/48413.html">https://cihr-irsc.gc.ca/e/48413.html</a>
Learning module	Coursera – Faster Together, Enhancing the Recruitment of Minorities in Clinical Trials	<a href="https://www.coursera.org/learn/recruitment-minorities-clinical-trials">https://www.coursera.org/learn/recruitment-minorities-clinical-trials</a>
Learning module	Coursera – Community Engagement in Research and Population Health	<a href="https://www.coursera.org/learn/community-engagement-research-population-health">https://www.coursera.org/learn/community-engagement-research-population-health</a>
Work aid	University of California at Davis CTSA – Resources for Engaging Communities in Research	<a href="https://health.ucdavis.edu/ctsc/area/engagement/ourCommunitySponors.html">https://health.ucdavis.edu/ctsc/area/engagement/ourCommunitySponors.html</a>
Work aid	National Health Council – Patient Engagement Compensation and Contracting Toolbox	<a href="https://nationalhealthcouncil.org/patient-engagement-compensation-and-contracting/">https://nationalhealthcouncil.org/patient-engagement-compensation-and-contracting/</a>

### SELECTED REFERENCES & RESOURCES

(C) 2016 - 2023 The Regents of the University of Michigan. See full course acknowledgements under resources tab. All rights reserved. Social and Behavioral Research Best Practices for Clinical Research is licensed under the [Creative Commons Attribution 4.0 International \(CC BY 4.0\) License](#).

Type	Description	URL
Work aid	Patients Active in Research and Dialogues for an Improved Generation of Medicine (PARADIGM) Patient Engagement Toolbox	<a href="https://imi-paradigm.eu/petoolbox/">https://imi-paradigm.eu/petoolbox/</a>
Learning modules	University of Florida CTSA – Our Community, Our Health Townhall Series	<a href="https://www.ctsi.ufl.edu/community/our-communities-our-health-a-national-conversation/">https://www.ctsi.ufl.edu/community/our-communities-our-health-a-national-conversation/</a>
Learning module	University of Michigan – Community Engagement: Collaborating for Change MOOC	<a href="https://ginsberg.umich.edu/article/community-engagement-collaborating-change">https://ginsberg.umich.edu/article/community-engagement-collaborating-change</a>
Guidance	U.S. FDA – Patient Engagement in the Design and Conduct of Medical Device Clinical Studies	<a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies</a>
Journal article	PCORI – Effective Engagement Requires Trust and Being Trustworthy	<a href="https://www.pcori.org/engagement/engagement-literature/effective-engagement-requires-trust-and-being-trustworthy">https://www.pcori.org/engagement/engagement-literature/effective-engagement-requires-trust-and-being-trustworthy</a>
Learning Modules & Work aids	Detroit Community-Academic Urban Research Center – Community-based Participatory Research Tools	<a href="https://www.detroiturc.org/resources/detroit-urc-cbpr-tools">https://www.detroiturc.org/resources/detroit-urc-cbpr-tools</a>

GO TOP OF DOCUMENT

## SELECTED REFERENCES &amp; RESOURCES

(C) 2016 - 2023 The Regents of the University of Michigan. See full course acknowledgements under resources tab. All rights reserved.  
 Social and Behavioral Research Best Practices for Clinical Research is licensed under the [Creative Commons Attribution 4.0 International \(CC BY 4.0\) License](https://creativecommons.org/licenses/by/4.0/).