

Human Research Protection Guidance Frequently Asked Questions:

Community-Engaged Research (CEnR) and Community-Based Participatory Research (CBPR):

The University of Kentucky is committed to promoting community-engaged research (CEnR) and community-based participatory research (CBPR) and educating both researchers and institutional review board members on the unique ethical and regulatory challenges posed in this research. The Office of Research Integrity, Center for Clinical and Translational Science, investigators, and the Institutional Review Board members developed a list of frequently asked questions (FAQs) intended to assist researchers design and implement research in the community and facilitate Institutional Review Boards' review of CEnR/CBPR.

The FAQs were developed using [working definitions](#) for both community-engaged and community-based participatory research. Community-based participatory research is one type of community-engaged research and is conducted as an equal partnership between researchers and members of a community. CBPR is defined as an applied collaborative approach that enables community residents to more actively participate in the full spectrum of research (conception, design, conduct, analysis, interpretation, conclusions, and communication of results) with a goal of influencing change in community health, systems, programs or policies.

Frequently Asked Questions:

I. Contacts at the University of Kentucky Office of Research Integrity:

- Q: [Who are the preferred contacts at the University of Kentucky Office of Research Integrity \(ORI\) for general questions about human subjects protection in community-based participatory research?](#)
 - Q: [Who are the preferred contacts at the University of Kentucky Office of Research Integrity to help an investigator distinguish a person being a research subject versus being engaged as study personnel in community-engaged research or CBPR?](#)
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II. Submission of Application to the IRB:

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III. Modifications:

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- Q: [If a survey, questionnaire, or interview instrument has not been developed at the time of initial submission, may I still submit the application to the IRB?](#)
 - Q: [If a survey, questionnaire, or interview instrument has been approved by the IRB and modifications need to be made in the field, do I have to submit the changes to the IRB for approval?](#)
 - Q: [If I have a modification that needs a quick turnaround time, what can I do to speed up the turnaround time?](#)
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IV. Study Personnel:

- Q: [CBPR and other community-engaged research often involve the participation of local laypersons or community-based professionals as key partners in the research. What level of “engagement” in research qualifies them as study personnel?](#)
 - Q: [If the study personnel include laypeople or nonprofessionals, must the individuals complete the UK CITI mandatory human subjects protection training, or are there more appropriate alternatives?](#)
 - Q: [What are the rules or restrictions for voluntary faculty as key personnel or PI?](#)
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V. Multiple Institutions and IRBs:

- Q: [Are there any mechanisms for IRB review across two or more institutions that have IRBs, when one of them is UK?](#)
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VI. HIPAA:

- Q: [When proposing research that involves electronic health data, what criteria must be met for the data NOT to be considered protected health information \(PHI\) under HIPAA?](#)
 - Q: [When I want to access medical records in another facility, what agreements/notifications are necessary?](#)
 - Q: [What agreements between institutions would allow PHI data transfer to UK under HIPAA regulations?](#)
 - Q: [If another facility transmits PHI to UK, does that require 2 HIPAA forms?](#)
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VII. Data Retention and Ownership:

- Q: [How does the University of Kentucky treat data ownership for CEnR/CBPR protocols?](#)
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I. Contacts at the University of Kentucky Office of Research Integrity:

Q: Who are the preferred contacts at the University of Kentucky Office of Research Integrity (ORI) for general questions about human subjects protection in community-based participatory research?

A: Kasandra Lambert, M.A., M.P.H.
Quality Improvement Program Coordinator
kasandra.lambert@uky.edu
859-257-2910

Andrew Hedrick, MPA
Professional Associate, Nonmedical IRB #4 Full and Expedited Review
andrew.hedrick@uky.edu
859-257-1639

Q: Who are the preferred contacts at the University of Kentucky Office of Research Integrity to help an investigator distinguish a person being a research subject versus being engaged as study personnel in community-engaged research or CBPR?

A: Helene Lake-Bullock, PhD, JD
Director/Research Compliance Officer
helene.lake-bullock@uky.edu
859-257-9428

Jessica Williams
ORI Reliance Manager
jessica.williams@uky.edu
859-218-1501

Q: Who is the preferred contact at the University of Kentucky Office of Research Integrity for questions about HIPAA with respect to CBPR?

A: Joe Brown, MHS
Research Privacy Specialist (HIPAA)/Exempt Review
joe.brown@uky.edu
859-257-9084

II. Submission of Application to the IRB:

Q: What is the process and what are the criteria for deciding whether a community-engaged research proposal goes to the Medical IRB or Nonmedical IRB?

A: The Medical IRBs review research originating from the Colleges of Dentistry, Health Sciences, Medicine, Nursing, Pharmacy and Health Sciences, and Public Health. The Nonmedical IRB reviews research originating from the Colleges of Agriculture, Arts & Sciences, Business & Economics, Communications & Information Studies, Design, Education, Engineering, Fine Arts, Law, and Social Work.

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Please note that the Nonmedical IRB does not review studies that involve administration of drugs or studies that involve invasive medical procedures. (e.g. blood stick). Studies including those types of procedures should be submitted to the Medical IRB.

Q: Given the unique nature of Community- Engaged Research or Community-based Participatory Research, how can I be assured that the IRB reviewers have appropriate CEnR/CBPR expertise?

A: Before submitting to the IRB, if you have specific design issues that the IRB may not be familiar with, consult with ORI staff.

The ORI staff can identify a consultant with the appropriate expertise. Each IRB has an IRB member with experience with community-engaged research.

However, if after the IRB review you have concerns that the IRB did not have appropriate scientific expertise, you can appeal the IRB's decision and request that the study be sent to a consultant with community-engaged research expertise.

Q: Is it possible to use the Nonmedical Consent Form template instead of the Medical Consent form if the research is social-behavioral rather than clinical research in the community?

A: Yes. Use the Informed Consent template that is most appropriate for your subject population and your research. The templates include suggested language for providing various kinds of information. If the suggested language does not appear to be appropriate to your project or study population, replace it with language that expresses the information in a more appropriate manner.

Q: Are there any additional items or information that I need to include in my IRB application for community-based participatory research?

A: When submitting your initial application, there is a question on Form A (General Information Sheet) which asks you to indicate items that may apply to your research. One of the attributes is "community-based participatory research". Also, the Study Design section of Form B (Research Description) asks for the following additional information: *If you are conducting [community-based participatory research \(CBPR\)](#), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.*

III. Modifications:

Q: In CEnR/CBPR, it is often necessary to make changes to operational procedures in the field. Must the IRB approve every change prior to making these changes to the research in the field?

A: The Office for Human Research Protections has stated that any change from the current approved IRB application must receive prior IRB review and approval.

In preparing your initial application, include appropriate details to allow the IRB to apply the federal criteria for approval. However, when describing your operational procedures, your descriptions should be general enough to allow flexibility. Describe a range of procedures that may be employed. For example, when describing a meeting place for an interview, state a "mutually convenient place" instead of "Room 413 in

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Kinhead”. Please note: The IRB will make the final determination as to whether your research procedures meet the requirements for approval or may require revisions.

Q: If a survey, questionnaire, or interview instrument has not been developed at the time of initial submission, may I still submit the application to the IRB?

A: Yes. You can submit an application without a final instrument, but in the research description you must describe the nature of the survey, the procedures for developing the data collection instrument, and assurances that once the survey instrument is developed it will be submitted to the IRB for approval prior to implementation. Failure to do so is considered noncompliance.

Q: If a survey, questionnaire, or interview instrument has been approved by the IRB and modifications need to be made in the field, do I have to submit the changes to the IRB for approval?

A: It depends on how the original application was written and what was initially approved by the IRB. If the research protocol was written to include flexibility in the questions for subjects or as a semi-structured interview, then changes that do not alter the risk to subjects and stay within the approved parameters are permitted. The IRB understands there may be follow-up questions resulting from the answers provided by the subjects; in these situations, IRB approval is not needed as long as the questions stay within the key areas of the research. If a structured survey or instrument was approved at initial review, then any changes must be submitted to the IRB as a proposed modification to the research protocol.

Q: If I have a modification that needs a quick turnaround time, what can I do to speed up the turnaround time?

A: If you need a quick response, notify ORI staff when you submit the [modification form](#). Include a cover memo which explains the special circumstances for requesting a quick turnaround time. Although ORI attempts to facilitate urgent modification request as quickly as possible, there is no guarantee when the modification will be reviewed and approved. For example, if a request does not meet federal criteria for approval, revisions may be needed.

IV. Study Personnel:

Q: CBPR and other community-engaged research often involve the participation of local laypersons or community-based professionals as key partners in the research. What level of “engagement” in research qualifies them as study personnel?

A: At UK, there are two steps in defining engagement in research for individuals on a protocol. The first step is for the Principal Investigator in consultation with ORI to determine whether the individuals meet the UK definition for study personnel.

UK definition for study personnel: *A person listed as study personnel, in the IRB application, is an individual who is interacting and/or intervening with human subjects or handles personally identifiable data of a human subject.*

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The second step is to determine whether the activities that the individuals participate in constitute “engagement in the research.” In order to make the preliminary determination whether the person is “engaged”, the Principal Investigator in consultation with ORI uses the federal guidance.

Federal HHS Guidance on Engagement: *In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.*

The Principal Investigator should contact the following ORI staff for assistance:

Helene Lake-Bullock, PhD, JD
Research Compliance Officer
hlbullo@uky.edu
859-257-9428

Jessica Williams
ORI Reliance Manager
jessica.williams@uky.edu
859-218-1501

Q: If the study personnel include laypersons or nonprofessionals, must the individuals complete the UK CITI mandatory human subjects protection training, or are there more appropriate alternatives?

A: Traditional Human Subjects Protection training may not be appropriate for the study personnel who are laypersons in the community. There are a number of national programs available designed to educate nonscientific/nonprofessional community-based partners. Alternate education may apply to those individuals who are laypersons, not students or researchers.

Any alternative training plan must be submitted to the ORI for review. To propose use of a human subject protection (HSP) training for community partners that is different from the standard UK IRB approved training, send a proposal to Belinda Smith (belinda.smith@uky.edu) including:

1. Principal Investigator Name;
2. IRB Protocol # or Protocol Title if approval pending;
3. A brief description of who the community partners are and their role in the research (should be non-UK or UK personnel working solely in a community position geographically separate from UK such as a county extension agent);
4. Justification for using an alternate training method;
5. A description of the training including how it will be administered (e.g., classroom, telemed, etc.); and
6. Type of knowledge assessment (exam, mock practice);
7. Method to notify ORI of names, email, and documentation of training completion (e.g., dated attendance sheet, dated certificate).

The preferred contact at ORI for proposed alternate education is:

Belinda Smith, MS, RD, CCRC
Research Education Specialist
belinda.smith@uky.edu
859-323-2446

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The following human subject training options were developed to meet the needs of community engaged partners or field workers. Curriculum materials may be used and tailored to fit the needs of the specific community population and protocol.

Title/Description	Link to download or request materials	Audience
CIRTification: Community Involvement in Research (CIRT) Training developed by the University of Illinois at Chicago	http://www.ccts.uic.edu/content/cirtification	<ul style="list-style-type: none"> Community Partners
Harvard Catalyst Community-Engaged Research (CEnR) Human Subject Training for Community Partners available upon request. Includes and invites contribution of case studies applicable for CEnR	https://catalyst.harvard.edu/programs/regulatory/cenr.html	Versions for: <ul style="list-style-type: none"> Community Partners Researchers IRB Members
Research Ethics Training Curriculum for Community Representatives (RETC-CR)	http://www.fhi360.org/resource/research-ethics-training-curriculum-retc-second-edition	<ul style="list-style-type: none"> Researchers or Community Partners
Johns Hopkins University Human Subjects Research Ethics Field Training Guide – training document available multiple language translations	http://www.jhsph.edu/offices-and-services/institutional-review-board/training/field-training-guides-for-data-collectors/	<ul style="list-style-type: none"> Community Partners
Community-Campus Partnerships for Health: Evidence-based comprehensive curriculum intended as a tool for community-institutional partnerships that are using CBPR approach to improving health.	https://ccph.memberclicks.net/cbprcurriculum	<ul style="list-style-type: none"> Researchers
University of Michigan Institute for Clinical and Health Research – Ethical Protections in Community-Engaged Research – appropriate for classroom delivery; includes hands-on activities and adult learning strategies.	Available for Non-Profit use with licensing agreement at https://secure.nouvant.com/umich/technology/4768/license/466	<ul style="list-style-type: none"> Community Partners

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Title/Description	Link to download or request materials	Audience
CITI Community Engaged (CEnR) Modules – provide an introduction to CEnR, CBPR, and outlines ethical issues and practical considerations particular to the design, review, and conduct of CEnR.	Available on UK's CITI program under the IRB/Optional Courses menu	<ul style="list-style-type: none"> • Researchers, IRB Members, or others interested in CEnR

Q: What are the rules or restrictions for voluntary faculty as key personnel or PI?

A: Voluntary faculty can be key personnel, but several factors must be taken into consideration on a case-by-case basis including data ownership, HIPAA, and ownership of the results of the research, if applicable. An Individual Investigator Agreement may be required. Voluntary faculty and other faculty who are not UK-paid employees may not act as the PI in a research study. For assistance, contact the following ORI staff:

Jessica Williams
 ORI Reliance Manager
jessica.williams@uky.edu
 859-218-1501

V. Multiple Institutions and IRBs:

Q: Are there any mechanisms for IRB review across two or more institutions that have IRBs, when one of them is UK?

A: Yes. Under federal regulations and consistent with UK policy, there are mechanisms available to establish protocol-specific inter-institutional agreements, which requires approval by the University of Kentucky Vice President for Research. UK may enter into an agreement with an individual or an institution. There are standard agreement templates for an [Individual Investigator Agreement](#) and an [IRB Authorization Agreement](#) available on the [ORI website](#). For more information, see the Office of Research Integrity's Standard Operating Procedures for Off-Site Research (*under revision*). Requests should be submitted to:

Jessica Williams
 ORI Reliance Manager
jessica.williams@uky.edu
 859-218-1501

Q: What are the recommended steps for obtaining approval from multiple IRB's?

A: As a UK employee, begin by contacting the ORI:

Jessica Williams
 ORI Reliance Manager
jessica.williams@uky.edu
 859-218-1501

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The next steps depend on a number of different variables including: funding source, whether activities are [FDA-regulated](#), the roles of the employees at each institution, and whether the institution is “engaged” under the federal guidance.

Federal HHS Guidance on Engagement: *In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.*

These factors will help determine what type of agreement ([Individual Investigator Agreement](#) or [Institutional Agreement](#)), if any, is needed. There are standard agreement templates available on the [ORI website](#). For more information, see the Office of Research Integrity’s Standard Operating Procedures for Off-Site Research (*under revision*).

Q: How is it determined which Institution’s IRB covers research in the community?

A: There are several criteria used to determine which IRB covers research in the community including the federal guidance on engagement, the primary grant recipient, whether the institutions have an IRB, and the policy and procedures of the institutions involved in research. For further clarification, contact the ORI:

Jessica Williams
ORI Reliance Manager
jessica.williams@uky.edu
859-218-1501

Q: Must all modifications requested by a local IRB be approved by the UK IRB?

A: It depends on the agreement between institutions that outlines each IRB’s responsibilities. If UK is the IRB of record, then all modifications must be approved by the UK IRB. For more information, see the Office of Research Integrity’s Standard Operating Procedures for Off-Site Research (*under revision*).

Q: Is it permissible to have more than one version of the consent document?

A: Yes. UK may enter into an agreement with an institution which outlines each IRB’s responsibilities. The terms of the outlined agreement may include that each IRB reviews and approves the consent document for the local site. If UK is the IRB of record, then UK’s IRB typically reviews one consent form and any changes to the consent document must be approved by the UK IRB. For more information, see the Office of Research Integrity’s Standard Operating Procedures for Off-Site Research (*under revision*).

Q: If a local IRB request changes, can they only apply to that site?

A: Yes. UK may enter into an agreement with an institution which outlines each IRB’s responsibilities. The terms of the outlined agreement may include that each IRB may request changes for the local site. For more information, see the Office of Research Integrity’s Standard Operating Procedures for Off-Site Research (*under revision*).

**Human Research Protection Guidance Frequently Asked Questions:
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VI. HIPAA:

Q: When proposing research that involves electronic health data, what criteria must be met for the data NOT to be considered protected health information (PHI) under HIPAA?

A: The HIPAA Rules only apply to covered entities and business associates. If an entity does not meet the definition of a covered entity or business associate ([45 CFR 160.103](#)), it does not have to comply with the HIPAA Rules. The Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)". The data cannot contain any of the [18 HIPAA identifiers](#). Age, Race and Gender in addition to data is permissible. If data from deceased individuals are used in research, then IRB review is not required. However, HIPAA may still apply. If there are any HIPAA-related questions on deceased individuals, contact University of Kentucky Corporate Compliance: <https://ukhealthcare.uky.edu/staff/corporate-compliance>.

Q: When I want to access medical records in another facility, what agreements/notifications are necessary?

A: You must contact the other facility to determine if it is a covered entity and abide by their HIPAA requirements. The forms/agreements for release of information will depend on the nature of the research and the institution's interpretation of HIPAA. You can contact the facility's Medical Record Department for assistance. The Medical Record Department will tell you which forms are necessary for the release of information. If the Medical Records Department cannot assist you, then contact the facility's Privacy Officer for further assistance.

Accessing medical records in another facility may or may not involve a Business Associate Agreement. Contact the University of Kentucky Corporate Compliance for questions regarding Business Associate Agreements: <https://ukhealthcare.uky.edu/staff/corporate-compliance>.

Q: What agreements between institutions would allow PHI data transfer to UK under HIPAA regulations?

A: Data transfer is permissible through a HIPAA Authorization or a HIPAA Waiver in some cases, but in other cases may require a business associate agreement (BAA). Contact the University of Kentucky Corporate Compliance for questions regarding Business Associate Agreements: <https://ukhealthcare.uky.edu/staff/corporate-compliance>.

Q: If another facility transmits PHI to UK, does that require 2 HIPAA forms?

A: It could. If another facility transmits PHI to UK, it would be released by the other facility to UK according to that facility's HIPAA regulations, if applicable. If it is then entered into medical records here at UK, UK HIPAA regulations would apply.

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VII. Data Retention and Ownership:

Q: How does the University of Kentucky treat data ownership for CEnR/CBPR protocols?

A: The University of Kentucky applies the same data ownership policy with CEnR/CBPR research as it would with any other research.

The UK Data Retention and Ownership Policy: *Research data are created at the University of Kentucky by faculty, staff, students, post-doctoral fellows, scholars, and visiting scientists in the course of their scholarly activities and in conducting sponsored activities funded by external agencies. The University of Kentucky owns data resulting from scholarly activities, sponsored activities, or works produced in certain University units whose specific mission includes the production of works for instructional, public service or administrative use. The University may choose not to claim ownership rights if there is a specific condition to the contrary in the sponsored project's grant, contract, or cooperative agreement or if the activity is considered to be the unrestricted property of the author as defined in the University of Kentucky [Administrative Regulations 7:6](#), IV.A, which defines traditional products of scholarly activity.*

However, in many CBPR-focused projects, the data or study outcomes are generally viewed as “owned” by the communities in which they dwelled or originated. The investigator should work with university legal counsel and the community to clearly establish use and access rights as a part of the protocol prior to the initiation of the research.

Human Research Protection Guidance Frequently Asked Questions:

Community-Engaged Research (CEnR) and Community-Based Participatory Research (CBPR):

The following are working definitions used to develop the Community-Based Participatory Research Frequently Asked Questions:

Community-Engaged Research

Community-engaged research (CEnR) is a broad term, representing a continuum of approaches that involve the community in the research process from research that incorporates only a few elements of community engagement and minimal collaboration to research in which community organizations and researchers are equal partners throughout the process.

In community-engaged research, researchers and community agencies or groups form a partnership. Communities and researchers may collaborate in many different ways, including defining the problem, planning the research, making decisions about elements of intervention implementation, and sharing the presentation of the research results. The extent of the collaboration, when it occurs in the research process, and the relationships among researchers and community organizations may be very different from project to project.

Community-Based Participatory Research

Community-based Participatory Research, or CBPR, is one type of community-engaged research and is conducted as an equal partnership between researchers and members of a community. CBPR is defined as an applied collaborative approach that enables community residents to more actively participate in the full spectrum of research (from conception – design – conduct – analysis – interpretation – conclusions – communication of results) with a goal of influencing change in community health, systems, programs or policies.

The Continuum of Research

The table below provides a comparison of approaches along the research continuum; however, many projects involve a variety of techniques, making the distinction between “types” of research more difficult.

	Traditional	Community-Engaged	CBPR
Research Objective	Based on epidemiologic data & funding priorities	Community input in identifying locally relevant issues	Full participation of community in identifying issues of greatest importance
Study Design	Design based entirely on scientific rigor and feasibility	Researchers work with community to ensure study design is culturally acceptable	Community intimately involved with study design
Recruitment & Retention	Based on scientific issues & “best guesses” regarding how to best reach community members	Researchers consult with community representatives on recruitment & retention strategies	Community representatives provide guidance on recruitment & retention strategies and aid in recruitment
Instrument Design	Instruments adopted/adapted from other studies. Tested chiefly w/ psychometric analytic methods.	Instruments adopted from other studies & tested/adapted to fit local populations	Instruments developed with community input and tested in similar populations

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Data Collection	Conducted by academic researchers or individuals w/no connection to the community	Community members involved in some aspects of data collection	Conducted by members of the community, to the extent possible based on available skill sets. Focus on capacity building.
Analysis & Interpretation	Academic researchers own the data, conduct analysis & interpret the findings	Academic researchers share results of analysis with community members for comments & interpretation	Data is shared; community members & academic researchers work together to interpret results
Dissemination	Results published in peer-reviewed academic	Results disseminated in community venues as well	Community members assist academic researchers to identify appropriate venues to disseminate results (public mtgs, radio, etc.) in a timely manner & community members involved in dissemination. Results also published in peer-reviewed journals.

Practicing Community-Engaged Research:

<https://www.citiprogram.org/citidocuments/Duke%20Med/Practicing/comm-engaged-research-4.pdf>

Community-Based Participatory Research: <https://www.nimhd.nih.gov/programs/extramural/community-based-participatory.html>

*The project described was supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, UL1TR000117. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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