IRB Use Only
Protocol No. _____
Program(s) Review: _____
Date of Review: _____

Application for Protocol Review
OHIO DEPARTMENT OF HEALTH (ODH)
Institutional Review Board (IRB)

Instructions: Fill out the form below and include all of the additional materials as required for your request. If you will be requesting ODH data, contact the relevant ODH program to determine the guidelines for data release. Some ODH programs may offer guidelines to use in applying for data. The IRB requires the ODH program involved review requests prior to submission.

The IRB meets on the fourth Tuesday of each month except for November and December. The meeting for those two months is combined and held on the first Tuesday of December. To be considered for review, protocol must be received by the chair 14 calendar days prior to the scheduled meeting.

(1) Provide the following materials (*mandatory*):
   a. Completed application for protocol review
   b. A formal study proposal
   c. Completed Curriculum Vitae form for all persons who will have access to the data as part of the study
   d. Signed confidentiality agreements for all persons who will have access to data as part of the study

(2) Provide the following materials (*if applicable*):
   a. Your institution's IRB approval
   b. Consent forms
   c. Expedited Review – Initial Review form

All items are to be sent electronically to: odhirb@odh.ohio.gov

Questions may be directed to Pam Leimbach – pam.leimbach@odh.ohio.gov or Lisa Heinbach – lisa.heinbach@odh.ohio.gov

1. PROJECT TITLE
First Episode Psychosis Program Evaluation
CDC or HHS Federal Project Number (if any):

2. PRINCIPAL INVESTIGATOR (PI)			
Name (Last, First):	**Knudsen, Kraig**	Degree(s):	**PhD**
Title:	**Project Evaluator**		
Agency/Institution:	**Ohio Department of Mental Health and Addiction Services**		
If ODH, Bureau & Div.:			
Mailing Address: 30 East Broad Street, Columbus, OH 43215			

E-mail: kraig.knudsen@mha.ohio.gov	Fax:
Phone: 614-728-2527	Emergency phone:

3. ADDITIONAL CONTACT(S)			
Specify the additional contact person(s) (e.g., study or regulatory coordinator, research assistant, etc.) in case the PI is not available. If more than three, attach additional page with their information.			☐ N/A
Name (Last, First):	**Kraig Knudsen**	Phone:	**614-728-2527**
E-mail:	**Kraig.Knudsen@mha.ohio.gov**	Fax:	
Name (Last, First):		Phone:	
E-mail:		Fax:	
Name (Last, First):		Phone:	
E-mail:		Fax:	

4. CO-INVESTIGATORS & KEY PERSONNEL	
List any other staff who will be participating in this research. You will need to provide signed confidentiality agreements and CVs for each member of the team. Attach additional page if necessary.	☐ N/A
Name (Last, First):	
Name (Last, First):	
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Name (Last, First):	

5. ODH CONTACT(S)			
Please list any ODH staff members you are working with on this protocol.			☒ N/A
Name (Last, First):		Phone:	
E-mail:		Fax:	
Signature:			
Name (Last, First):		Phone:	
E-mail:		Fax:	
Signature:			

6. OTHER INSTITUTIONAL REVIEW BOARD APPROVALS
Check all that apply and provide applicable documentation. Attach additional page if necessary.
☐ Centers for Disease Control and Prevention

☐	Univ./Institution	Name:	Status:
☐	State IRB	Name:	Status:
☐	Other	Name:	Status:
☐	Other	Name:	Status:

7. EXPEDITED REVIEW

Are you requesting **Expedited Review**? The Federal Regulations establish two main criteria for an expedited review: 1. The research may not involve more than "minimal risk." "Minimal risk" means that "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 the performance of routine physical or psychological examinations or tests" (45 CFR 46.102(i) and 21 CFR 56.102(i)). 2. The entire research project must be consistent with one or more of the federally defined categories (see Expedited Review Form for complete list).	☐ Yes → Complete Expedited Review Form ☒ No

8. SUMMARY OF THE RESEARCH

Summarize the proposed research using ***non-technical*** language that can be readily understood by someone outside the discipline. Explain briefly the background, research design, years of data being examined and procedures to be used.

- **Please refer to the research protocol for a detailed description of the research and procedures.**

The First Episode Psychosis (FEP) Evaluation is part of the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Evaluation of the national First Episode Psychosis initiative. OhioMHAS is participating the local data collection and will be providing de-identified client level data to SAMHSA for analysis and dissemination.

This study proposes to help identify characteristics of the FEP participants involved in Ohio's mental health system and examine how they are being impacted by FEP services. The FEP Outcomes instruments will collect demographic and background information, and longitudinal data on clinical and functional outcomes, as well as service utilization.

The data that are collected from this study will help describe individual characteristics of participants served through the Substance Abuse and Mental Health Services Administration community block grant funded FEP initiative, and will include both descriptive information and changes in outcomes over time. Participating organizations will provide information on demographic data, clinical status, and participant characteristics. The goal is to collect data on every participant receiving services in the FEP program who are eligible to complete measures.

Research Design: This study uses a convenient sample pre-test post-test design to assess for change throughout the participant's time receiving services as a result of services.

9. RESEARCH OBJECTIVES

List the specific objectives of the research study.

The primary objective of this research is to evaluate the activities created to meet complex needs of persons experiencing their first episode of psychosis, specifically:

- Document the characteristics of the participants served by the program, the type and amount of services they receive.
- Document how these services are coordinated and the associated costs.
- Assess whether the program was implemented and the services were as experienced as intended as well as the geographic distribution of providers and clients
- Assess whether the persons served by the program experience improvement in clinical and functional outcomes, whether quality of life is improved, and whether improvements endure over time.

10. RESEARCH METHODS

a. Briefly describe the methods to be used in the research study. What is the nature of the measures or observations that will be made? Please provide a copy and a brief description of any questionnaires, tests or other instruments.

Each FEP program is coordinated by community mental health centers, and data will be collected by the clinicians as a part of their standard clinical practice. The evaluation pieces will be collected at baseline, 6 months, and 12 months or discharge if the client's treatment ends prior to either follow-up. Data will be collected from those participants served and who agree to participate in the evaluation.

The evaluation will utilize data from various descriptive, program, and outcomes data sources, including:

- *At Baseline*: gender, age, race, marital status, number of children, insurance type, approximate date of onset of psychosis, diagnosis.

- *Every six months while in treatment and at discharge*: services used, antipsychotic medication usage (type and dosage), employment and/or school attendance status, housing status, substance use (including tobacco and cigarettes), inpatient psychiatric hospitalizations, emergency room visits for psychiatric reasons, criminal justice involvement, the Colorado Symptom Index, the Social and Role Dysfunction in Psychosis and Schizophrenia scale, Lehman Quality of Life (1-item), suicide attempts in past 6 months, insight into illness. Instrument are attached.

Using the above indicators and instruments, organizations will interview participants and enter information in the FEPIS system. Some information, such as inpatient psychiatric hospitalizations, emergency room visits, suicide attempts may be gleaned from clinical charts.

b. Check all research activities that apply:

☐ Invasive Procedures	☐ Investigational Device or Apparatus	☐ New Drug, Vaccine or Diagnostic Test	☐ Existing Data

11. DURATION

Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

Data will be collected at baseline, 6 months, and 12 months or discharge if the client's treatment ends prior to either follow-up. Each occurrence of data collection should take no more than 23 minutes per interview.

12. SUBJECTS

Who will be the subjects of this study? How will they be solicited or contacted?

Target Respondents and Recruitment Protocol

To be included in this study, clients will need to:

- receive services at a community mental health center that offers First Episode Psychosis services;
- meet the local system's service program eligibility criteria for FEP services;
- be between age 14 and 30 years;
- have a mental health diagnosis;
- have a caregiver or guardian if the client is age 5 to 17 years old; and
- provide informed consent/assent, as appropriate based on client age.

Participants will be drawn from those programs to ensure the evaluation will be able to detect the impact of the FEP initiative on participant outcomes. An estimated number of approximately 600 respondents and staff with participate in this activity over the course of the evaluation.

13. OHIO DEPARTMENT OF HEALTH DATA

a. Are any data from ODH being requested?

☐ Yes

☒ No

IF YES → Specify variables (i.e. identifying information, years, fields, etc.)

b. How long will the data be kept and when will it be returned to ODH or destroyed? (Note: data must be returned to ODH, or certified that it has been appropriately destroyed, no later than a year after date of IRB

approval. Requests to keep the data longer than one year will require that an extension be requested from the IRB.)

14. NUMBER OF PARTICIPANTS

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

a.	Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval.	600

b. Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).

OhioMHAS' FEP program targets roughly 150 youth and young adults served per year, spread out among all of Ohio's counties. Each site currently provides services to approximately 12-25 individuals.

c.	Will your work with the participants take place at multiple locations?	☒ Yes → Indicate the total number of participants to be enrolled across all locations: ☐ No	600

15. PARTICIPANT POPULATION

a. If applicable, specify the age range of the individuals who are being included in the research/data request:

Age(s): **14 to 30**

b. Specify the participant population(s) or subject category/ (categories). Check all that apply:

☒	Adults	☐	Human In Vitro Fertilization
☐	Minors (< 12 years of age)	☐	Tissues
☒	Adolescents (12-17 years of age)	☐	Wards of the State or other Agency, Institution or Entity
☐	Pregnant women	☐	Prisoners
☐	Fetuses – Live or Dead	☐	Mentally Disabled Individuals
☐	Abortion	☐	Mentally Retarded Individuals

c. Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

Potential participants will include all youth receiving FEP treatment in funded FEP programs across Ohio. These individuals will all be between the ages of 14-30 and have been diagnosed with a mental health issue. Outcomes data specific to the treatment received is being collected, thus participants must have received services from the FEP program.

d. Will any participants be excluded based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status? ☒ Yes ☐ No

If Yes → Explain the criteria and reason(s) for each exclusion. ***Consider the study's scientific or scholarly aims and risks.***

Participants must meet the age and mental health criteria for inclusion in the FEP program.

The remaining question is for research involving direct contact with the participants. If you are using data only, please skip to Question 20.

e. Are any of the participants likely to be vulnerable to coercion or undue influence? ***Consider students, employees, terminally ill persons, or others who may have limited resources and/or autonomy.*** ☐ Yes ☒ No

If Yes → Describe additional safeguards to protect participants' rights and welfare. ***Consider strategies to ensure voluntary participation.***

16. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Provide evidence that you will be able to recruit the necessary number of participants to complete the study.

To date, the Ohio FEP program has enrolled approximately 200 individuals in the first two years of implementation. We anticipate an increase in enrollment across Ohio. Community mental health center sites should provide the necessary number of participants, while accounting for youth that may refuse to participate.

b. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

Treatment professionals at community mental health organizations in Ohio will identify potential participants. OhioMHAS currently funds the FEP treatment and support services that are offered to the population of interest in this evaluation. As such, contracts require that OhioMHAS conduct evaluation activities that will provide information for policy and program administrators related to the program's successes and areas of needed improvement.

c. List the names of investigator(s) and/or key personnel who will recruit participants and their qualifications.

This is an evaluation and participants will be individuals engaged in FEP treatment and support services. As such, recruitment will not occur in the traditional research manner. Those who explain the evaluation and ask for participation will be those treatment professionals who are also involved in gathering consent for treatment. Therefore, individuals will vary by program and setting, but all recruitment will be done by treatment professionals.

d. Describe the process that will be used to determine participant eligibility.

Enrollment in FEP services provided by community block grant funds in participating community mental health sites.

e. Describe the recruitment process; including the setting in which recruitment will take place. ***Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts).***

Recruitment will occur at enrollment, and the consent/assent forms will be presented to the participant and/or family/caregiver explaining the study and risks/benefits. It will take place at the local treatment provider at the time the youth is enrolled in the FEP program.

f. Explain how the process respects potential participants' privacy.

A client's decision to participate will not be disclosed to anyone else outside their parent/caregiver, including members of their treatment team. If a client is over the age of 18, their participation can be withheld from their parent/caregiver if they so choose.

17. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? ***Compensation plans should be pro-rated (not contingent upon study completion) and should consider participant withdrawals, as applicable.***

☐ Yes
☒ No

If Yes → Describe the incentive, including the amount and timing of all payments.

18. INFORMED CONSENT PROCESS

Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. ***Provide copies of documents.***

☒	Informed Consent – Form	☒	Assent – Form	☐ N/A
☐	Informed Consent – Verbal	☐	Assent – Verbal Script	
☐	Informed Consent – Addendum	☒	Parental Permission – Form	
☐	Translated Consent/Assent – Form(s)	☐	Parental Permission – Verbal Script	

b. List the names of investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives. ☐ N/A

Those who explain the evaluation and ask for participation will be treatment professionals. These same individuals will also gather consent for treatment. Therefore, individuals will vary by program and setting, but all consents (both to treatment and evaluation) will be done by treatment professionals.

c. Who will provide consent or permission (i.e. participant, legally authorized representative, parent and/or guardian)? ☐ N/A

Informed consent will be obtained using a consent form by the clinician, counselor, or other staff designated by the service provider who administers this tool. Informed consent will be obtained from youth age 18 and older. Informed assent will be obtained from participating older children and adolescents (age 11–17 years). For all children under the age of 18, although permission will be sought from the parents or caregivers, the child's assent decides whether the child will participate in the study or not. Written informed consent or assent will be obtained from children and families at the point of entry into services and before the collection of evaluation data. Programs are instructed to determine whether updates to consents are required at each data collection point, as the legal custody of a child may change, a child may become old enough to participate in a youth interview, a youth may become an emancipated minor or age up into adult status.

d. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation. ☐ N/A

At time of enrollment, participants/caregivers will be introduced to the study and given information regarding their rights, benefits of participation, and instructions on completing the required paperwork. They will be given up to a week to consider participation, at which time they will either sign the consent or decline participation.

e. Explain how the possibility of coercion or undue influence will be minimized in the consent process. ☐ N/A

Potential participants will be informed their participation will in no way affect the treatment or services they receive.

f. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension?
☐ Yes → ***Provide copies of these tools***
☒ No

g. Will any other consent forms be used (e.g., for third parties being questioned, marketing of products or services, etc.)?
☐ Yes → ***Provide copies of these forms***
☒ No

19. PRIVACY OF PARTICIPANTS

a. Describe the provisions to protect the privacy interests of the participants. ***Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants' expectations of privacy.***

All participants will have a unique ID assigned to them. This ID will be used rather than name. There may be data included that could lead to potential identification, however, such as date of birth, gender, ethnicity, services received, etc., given the small sample size per site.

b. Does the research require access to personally identifiable private information?
☒ Yes
☐ No

If Yes → Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

Information regarding mental health diagnoses, date of birth, assessment dates, and other information that could potential identify a client are included in the instruments.

20. CONFIDENTIALITY OF DATA

a. Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records. ***Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with Federal, State and Ohio Department of Health policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure location, or if electronically transmitted.***

Data will be collected locally using an online secure data portal housed at OhioMHAS that is encrypted and password protected.

b. Will any aspect of the data be made part of any permanent record that can be identified with the subject?

☐ Yes
☒ No

If Yes →Please describe

c. Will any data from files or archival data be used?

☐ Yes
☒ No

If Yes →Please describe

d. If no aspect of the data is to be made part of any permanent record, how will the data be destroyed?

Information in the FEPIS data portal will be destroyed once the study is complete (estimated 2020).

e. Describe how issues of small cell size will be addressed so that confidentiality is maintained. (Reference ODH small cell policy. See Disclosure Limitation Standard for full details.)

Data will be aggregated and completed for the entire state and not local community behavioral health providers.

f. Will a subject's participation (or lack of) in the study be made a part of any permanent record available to supervisors, teachers or employers?

☐ Yes
☒ No

If Yes →Please describe

g. Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected. ☐ N/A

Yes, data regarding mental health symptoms, behavior, alcohol/drug use, and mental health/substance abuse service receipt will be collected. The answers to these questions will be used to determine baseline status and to measure changes in these areas experienced after receiving FEP services. Since each program must keep data on participant status and service use, as well as treatment plan and other information, the data collection required for the evaluation is not introducing new, sensitive domains of inquiry, but is paralleling standard procedures in the field of community mental health.

h. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality (i.e. as per Ohio's mandatory reporting requirements). ☒ N/A

Instances in which a participant expresses current suicidality during the interview would result in mandatory reporting.

21. HIPAA RESEARCH AUTHORIZATION

Will individually identifiable data (Protected Health Information [PHI]) subject to the HIPAA Privacy Rule be accessed, used, or disclosed in the research study? ☒ Yes ☐ No

If Yes →Please describe

Yes, however, only aggregated information will be disseminated. We will be careful to avoid disseminating small numbers with demographic information that might be used to deduce the identity of individual respondents. All data will be destroyed within 3 years of the end of the project. The project will end in September 2020.

22. REASONABLY ANTICIPATED BENEFITS

a. List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. ***Compensation is not to be considered a benefit.***

While there are no direct benefits to being a part of this study, the services received may be a benefit and information collected through this study may help improve those services for persons experiencing their first episode of psychosis. In addition to information on participant clinical status and social function, other questions of a sensitive nature will be asked of participants. These include questions related to insight into illness. Experts in the field have consistently shown that a sign of recovery from mental illness is often one's own insight into their illness. Persons with various forms of mental illness often lack insight into their illness, making accepting and maintaining treatment more difficult. It is hoped that the new FEP program will assist in increasing illness insight. While the connection between insight and recovery is common clinical knowledge in mental health disorders such as depression and anxiety, there is inconsistent information on this construct for persons living with Schizophrenia. Indeed, many suggest that insight into illness may not be achievable for persons suffering the effects of psychosis or Schizophrenia.

b. List the potential benefits that society and/or others may expect as a result of this research study.

The data collected as a result of this study will help inform the FEP approach to serving participants who experience their first episode of psychosis. Research suggests that early intervention in psychosis is highly associated with a less severe disease course, and better clinical and functional outcomes later in life.

23. RISKS, HARMS, & DISCOMFORTS

a. Describe all reasonably expected or anticipated risks, harms, and/or discomforts that may apply to or result from the research. Discuss severity and likelihood of occurrence. ***Consider the range of risks, including physical, psychological, social, legal, and economic***. **All research carries some risk. "No Risk" is not an acceptable answer.**

The Evaluation requires collecting descriptive and outcome data from participants. Because this study concerns services to persons with serious emotional disturbances, it is necessary to ask questions that are potentially sensitive. However, only information that is central to the study is being sought. It is certainly possible that participants may experience discomfort answering questions regarding their mental health symptoms, exposure to trauma, and other sensitive topics. Participants can speak with their individual clinicians if they feel distressed from the questions. Participants can stop answering questions at any point, or not answer specific questions they feel are uncomfortable.

b. Describe how risks, harms, and/or discomforts will be minimized. ***If testing will be performed that might identify individuals with a previously unknown medical condition, address timing and method of testing; include how positive test results will be handled.***

Interviewers will be trained on the data collection process by the PI, including the procedures for introducing the interview, the confidentiality information, and the consent/assent/parental permission forms. Respondents will be informed that their participation is voluntary, and that they have the right to discontinue participation at any time without impacting services they receive, and of the risks and benefits of participation. They will also be informed they have the right to refuse to answer any question that may cause undue stress or discomfort.

24. MONITORING

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described above beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)? ☐ Yes ☒ No

If Yes → Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);

- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled); and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

None.

25. ASSESSMENT OF RISKS & BENEFITS

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

Some stress or discomfort to individual participants during the interview process is greatly outweighed by the potential improvements to the FEP treatment services this population receives.

26. PARTICIPANT COSTS/REIMBURSEMENTS

a. List any potential costs participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

None.

b. List any costs to participants that will be covered by the research study.

None.

27. ASSURANCE - PRINCIPAL INVESTIGATOR

I agree to follow all applicable federal regulations, guidance, state and local laws, and ODH policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators.

I verify that the information provided in this Initial Review of Human Subjects Research application is accurate and complete. I will initiate this research only after having received notification of final IRB approval.

Signature of Principal Investigator (Electronic Signatures are acceptable) _____ Date _____

Printed name of Principal Investigator _____

29. APPLICATION CONTENTS

Indicate the documents being submitted for this research project. Check all appropriate boxes. **Bold = Mandatory**

☐ **Initial Review of Human Subjects Research Application**

☒ **Research Protocol**

☒ **Signed Confidentiality Forms for all Persons Handling Data**

☒ **Curriculum Vitae form for all Persons Handling Data**

May also be required depending on your specific protocol

☐ Expedited Review – Initial Review Request

☒ Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s), including translated documents (question)

☒ Data Collection Form(s) for Investigator-Initiated Studies (question)

☒ Data Collection Form(s) involving protected health information

☐ Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question)

☐ Script(s) or Information Sheet(s), including Debriefing Materials (question)

☒ Instruments (e.g., questionnaires or surveys to be completed by participants) (question)

☐ Other Committee Approvals/Letters of Support (questions

☒ Other supporting documentation and/or materials