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WVU Flex Model

In an effort to streamline human subject research submissions and reduce burden on investigators and staff at West Virginia University (“WVU”), the WVU Institutional Review Board (IRB) is implementing a new submission and review process for certain IRB submissions. This new submission type, called the WVU Flex Model is intended to be a shorter, expeditious submission in the electronic system.

To implement this model, WVU has chosen to limit the application of the federal regulations (Common Rule) for the protection of human subjects to federally-funded or federally-regulated research. Although, in general, studies that qualify under the Flex Model are not covered by the federal regulations, they must still operate within the bounds of the ethical guidelines found in the Belmont Report. Therefore, research eligible for review under the Flex Model will continue to be afforded equal consideration in regards to ensuring the protections of human subject research participants.

Only research which is not federally funded and is no more than minimal risk is eligible for consideration using the Flex Model. If a research protocol, originally approved using the Flex Model, receives federal funding or incurs a change in the risk level, it is the responsibility of the Principal Investigator (PI) to notify the IRB.

Flex Model Eligibility

Although non-federally funded research may not be covered under the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report. This section will outline the inclusion and exclusion criteria to this model.

Application of this procedure will be at the discretion of the WVU IRB.

Excluded Components

The WVU Flex Model excludes research applications that include any of the following elements:

1. Research with federal funding
   - Per 45 CFR 46.101(a), any research that receives federal funding is regulated by the Common Rule.

2. Research supported, in full or in part, by WV Clinical & Translational Science Institute (CTSI), WV IDeA Network of Biomedical Research Excellence (WV-INBRE), Center of Biomedical Research Excellence (CoBRE) or other programs supported by federal funding.
   - WVCTSI receives funding via federal agencies; funds awarded to researchers from WVCTSI are considered to be federal, thus excluding research from the Flex Model.

3. Research involving Food and Drug Administration (FDA) regulated elements
   - Research which would otherwise be approvable under Expedited Category 1 (45 CFR 46.110) are not eligible for the Flex Model. This includes:
     - Research on drugs for which an investigational new drug application is not required; or
- Research on medical devices for which an investigational device exemption is not required or the medical device is approved for marketing and used in accordance with its approved label.

b. Research requiring an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application(s).

4. Sensitive topics in research
   a. Research in which any of the following are included, but not limited to, is not eligible for consideration under the Flex Model:
      i. Research studying suicide and/or suicide ideation; or
      ii. Research studying traumatic life events that may evoke powerful emotion or induce mood changes in participants; or
      iii. Research involving identifiable results of drug misuse and abuse, criminal history, and/or other behaviors which may put the participant at risk unless the risk of inadvertent disclosure is no more than minimal.

5. Receipt of a Certificate of Confidentiality
   a. Applying for or obtaining a Certificate of Confidentiality implies that there is a risk to participants should their identity be disclosed outside of the research and is therefore excluded from review under the Flex Model.
   b. A Certificate of Confidentiality is awarded by the NIH.

6. Interactions with prisoners
   a. Research targeting prisoner populations is not eligible for review under the Flex Model.
   b. WVU IRB will NOT consider persons in transitional custody whose liberty is restricted such as half-way houses, electronic monitoring, probation, or house arrest, to meet the federal definition of prisoner. For those individuals, the criteria at 45 CFR 46.111 offer sufficient protection for their level of vulnerability.

**Included Components**
The Flex Model includes research applications with following elements:

1. Research involving tissues and samples collected under standard of care procedures
   a. Research which would otherwise be permitted and approved under Expedited Categories 2 and 3 (45 CFR 46.110) are eligible for review using the Flex Application.
      i. This includes the prospective collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings, saliva, urine, or cheek swabs.
      ii. Blood samples from healthy, non-pregnant adults who weigh at least 110 pounds may not exceed 550ml in an 8-week period and collection may not occur more frequently than twice per week.
iii. Blood samples from other adults and children, may not exceed the lesser of 50ml or 3ml/kg in an 8-week period and collection may not occur more frequently than twice per week.

b. The tissue or sample extraction or collection would be conducted regardless of the research (as the Standard of Care). Only identifiable samples collected for this standard of care procedure are permitted to be used.

i. An example of this would be a standard of care tooth extraction.

ii. If an additional sample or volume is needed in addition to the standard of care, the research does not qualify for consideration under the Flex Model.

2. Review of data that have been collected, or will be collected, solely for non-research purposes

   a. Research which would otherwise be permitted under Exempt Category 4 (45 CFR 46.101(b)(4) or Expedited Category 5 (45 CFR 46.110) are eligible for review using the Flex Application.

   b. The recording of Personally Identifiable Information (PII) and Protected Health Information (PHI) are both permissible and eligible for the Flex Application.

      i. Application for Waivers of HIPAA requirements must be included in the Flex Application submitted for review and, if appropriate, approved by the IRB Chair or designated reviewer.

   c. Research is permitted to be either retrospective or prospective.

      i. Note that with prospective studies, the participant should be consented to participate in the research or meet with the conditions to waive informed consent, as applicable.

3. Deception

   a. Any research in which participants are intentionally deceived as to the true purpose of the study must have an adequate de-briefing and opt-out plan. If there is no de-briefing or opt-out plan, the protocol is ineligible for flex.

4. Research involving minimal risk intervention (45 CFR 46 Expedited Categories 6 & 7)

   a. Participants are asked to complete minimal risk behavioral interventions that are brief, harmless, painless, and not physically and/or emotionally invasive or offensive.

      i. Examples include having subjects play an online game or having them solve puzzles under varying noise conditions.

   b. The information obtained and recorded should not risk damaging the subject criminally, financially, their employability, educational advancement, or reputation.

**Special Considerations**

To qualify for Flex Model review, the research must provide cultural and age appropriate sensitivity to qualify and make provisions to account for the protected populations including, but not limited to, those listed below:
Protected Populations

Pregnant Adults
Pregnant adult women may be included as participants under the Flex Model as long as the investigational procedures do not expose the fetus or mother to more than minimal risk.

Consent must be sought and obtained from the participant, using the Flex Consent Form.

Children
Participants under the age of 18 years old are permitted to be included in research subject to the Flex Model. The research should not involve more than minimal risk and any tasks should be limited to benign interventions.

Unless waived, parental consent and child assent must be sought and obtained, using the Flex Consent Form.

Other Protected Populations
Studies that target tribal members, military personnel, wards of the state, or cognitively impaired individuals are not permitted under the Flex Model.

Genetic Testing
Under no circumstances is genetic testing permitted in research submitted or previously approved under the Flex Model.

Collaborative Research
Research collaborations which would need an Interinstitutional Authorization Agreement (IAA) are not permitted under the Flex Model.

Research collaborations, where an Interinstitutional Authorization Agreement (IAA) would be applicable, and the WVU IRB is asked to be the IRB of record, are not eligible for review under the Flex Model.

Flexibility Determination
In order to obtain approval under the Flex Model, investigators must submit the following via the electronic system:

1. A completed Flex Application
2. Recruitment materials
3. Flex Consent Form
4. Surveys, questionnaires, and data collection instruments
5. Letter(s) of Permission from each non-WVU site

An IRB Chair (or designee) reviews all requests for research submitted under the Flex Model and determines whether or not the application meets the criteria for inclusion. The IRB Chair may designate an IRB member(s) or qualified administrator(s) to review requests for consideration under the Flex Model submitted to the IRB. The Chair selects designees who are qualified to review this
category of submission based on their expertise of the application content and knowledge of regulations pertaining to research.

If there is not a designated reviewer to consider requests, the IRB Chair reviews the requests. Reviewers involved in issuing a determination cannot be involved with the research. To document the reviewer’s determination of the request, he/she approves the Flex Application.

The reviewer holds the right to require additional protections for subjects, or require that the application be submitted or reviewed by other means. Any determinations made by the reviewer or administrative staff will be communicated with the Principal Investigator via the electronic system.

Informing Participants

A Waiver of Documentation of Informed Consent will automatically be applied to all qualified Flex Applications; however, reviewers retain the right to require signatures from participants and the investigator conducting the consent procedure. Investigators should customize the Flex Consent Form Template for their proposed study. This form should be presented to the participant, either physically or via electronic communications (i.e. online survey) prior to the participant beginning research related activities.

Signed Flex Consent forms are required for all research approved under the Flex Model that target either pregnant adult women or children under 18 years of age.

Required elements that must be included on the Flex Consent Form include:

1. Statement that the activity is research
2. The purpose of the study, in lay terms
3. Risk(s) to the participant
4. Benefit(s) to the participant
5. Alternatives to participating in the research
6. Statement that participation is voluntary
7. Statement that participant may withdraw at any time
8. Principal Investigator contact information

Waiver of Informed Consent

The IRB may waive the requirement to obtain informed consent provided that the proposed research meets requirements set forth in 45 CFR 46.116 (d).

CITI Training

CITI training courses are required for the approval of a Flex Application; however, the abbreviated Biomedical Research Investigator or Social and Behavioral Research Investigator course is permitted to meet this requirement under Flex provisions in the conduct of Humans Subjects Research.

While the abbreviated course meets with the requirements under the Flex Model, the full Biomedical or Social and Behavioral Research Investigator training course is strongly recommended. By completing the non-abbreviated course to meet the training requirements, investigators and other study personnel will not be delayed in starting research should their project become ineligible under the Flex Model.

Non-Eligible Flex Applications

In the event that an application is deemed not appropriate for review and approval under the WVU Flex Model, the investigator will be contacted using the electronic system.
Post Approval Submissions

Both amendment and renewal submissions for protocols approved under the Flex Model will undergo the same review procedures as stated under the Flexibility Determination section above.

Amendments to Flex Applications

As previously stated, if any change or modification that increases risk to participants are anticipated to a protocol originally approved using the Flex Model, an amendment must be submitted for review and approval prior to implementing the change. If the research is awarded federal funding, or funding from CTSI, an amendment must be submitted indicating this change.

Amendment submissions that continue to qualify for the Flex Model do not change the approval period of a protocol.

Amendments No Longer Eligible for the Flex Model

Protocols that are no longer eligible for approval under the Flex Model because of an amendment must be filed under regular protocol approval procedures. This will require submitting a protocol in the electronic system and completion of new sections in the application questionnaire. Researchers and personnel are also required to meet the applicable CITI requirements.

Continuing Review of Flex Applications

Each protocol approved by the WVU IRB as being eligible for the Flex Model will be granted a five (5) year approval period. In order to extend the research approval period beyond this initial five (5) year approval period, a Continuing Review/Renewal application must be submitted for review and approval by the WVU IRB.

Reporting Requirements

All Flex Applications approved by the WVU IRB are subject to the reporting requirements as outlined in Sections 8, 9 and 10 of the HRPP Standard Operating Procedures.