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| The purpose of this worksheet is to aide investigators in developing a recruitment plan for the IRB. This worksheet is to be used as guidance on what needs to be included in the research protocol for recruitment. It does not need to be completed or retained. (Click box if “Yes”) | | | |
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| 1. Who will be asked to participate? | | | |
|  | **Do you know how many potential subjects are there?**  **If using Protected Health Information (PHI):** Consider using the Preparatory to Research Option under HIPAA to get aggregate numbers on potential subjects that could fit inclusion/exclusion criteria. When activities “preparatory to research” involve the use of PHI, IRB approval is required when activities in which an Investigator obtains and records individually identifiable health information (PHI) for purposes of planning a research proposal and/or identifying potential participants to aid in study recruitment. Investigator conducing preparatory to research activities are required to certify that: | | |
|  | | | Use or disclosure is sought solely to review PHI necessary to prepare the research protocol; |
|  | | | No PHI will be removed from the covered entity during the review; |
|  | | | The PHI the researcher seeks to use or access is necessary for research purposes; and |
|  | | | Access is limited only to the minimally necessary information needed for the purposes of preparing a research proposal. |
|  | **Any barriers to participating in research that may exclude populations from participating?**  Example: If participating requires computer access, economically disadvantaged may not have access to computers or tablets. If yes, be prepared to discuss with IRB these barriers and any steps you have taken to minimize barriers. | | |
|  | **Have you identified potential vulnerable populations?** | | |
|  | | | If yes, have you scientifically and ethically justified inclusion of the vulnerable population? |
|  | | | If excluding populations, have you scientifically and ethically justified excluding populations?  Example: Only enrolling men because the condition being studied only affects men. Example: Excluding Non-English speaking persons because tools used have not been validated in other languages. |
|  | | | Special resources required to enroll the vulnerable population? If yes, have you budgeted for these resources? Example: Money for translation of documents and time for interpreters for Non-English speaking persons. |
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| 1. Who will contact potential participants? | | | |
|  | IRB Approved: Have they completed research education requirements, COI disclosures, and been approved by the IRB to be on the study? | | |
|  | Training: Have been trained on the protocol to be able to answer potential subject’s questions? | | |
|  | Are there any non-university employees who will be contacting potential participants? | | |
|  | | | Are these non-university employees engaged in research? See [600.02 Checklist Engagement in Research Determination.](file:///C:\Users\llind\Desktop\Corrected%20IRB%20Internal%20Forms\600.02%20Checklist,%20Engagement%20in%20Research%20Determinations.docx) |
|  | | | If engaged, do they belong to an institution that holds an FWA?  Lookup FWA by typing institution name at <https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc> |
|  | | | Are they getting IRB approval at their home institution? |
|  | | | If engaged but not part of a FWA-institution, do you have a contract in place to cover their research activities? Contact irb@tamucc.edu for reliance contract. |
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| 1. How will the potential subjects be contacted? | | | |
|  | Will you need to use protected health information (PHI)? If No, skip these questions. | | |
|  | | | If yes, will you need to access PHI prior to approaching to consent the subject? If yes, submit a **partial HIPAA waiver** for pre-screening. |
|  | | | If yes, have you limited the pre-screening identifiers to the minimal amount in order to identify and contact persons to secure their informed consent? |
|  | Will you be using social medial to recruit? | | |
|  | | | Have you considered how potential subjects will interact with the social media platform? |
|  | | | Have you reviewed the social media for potential privacy issues?  Some social media platforms collect user information to be used for other purposes. This could adversely affect subject privacy or a notice of the site’s privacy practices should be provided to the subjects to inform them of this risk. |
|  | | | Have you considered disabling the comment functionality on the platform?  Individuals may unknowingly share personal information regarding their health or study participation on these sites, believing this information is only visible to a limited audience related to the study. In reality, the comment/post may be visible to all users of the social media platform. Allowing comments on the platform could have an adverse effect on subject privacy and potentially skew study data if other subjects can read one subject’s personal experience. |
|  | | | Submit social media copy to IRB for approval. |
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| 1. Advertisement Material Review (all must be checked in order to be compliant)  N/A   All draft recruitment materials will need to be submitted to the IRB and IRB-approved prior to use. | | | |
|  | | The application describes how the recruitment material will be used, i.e. distributed by mail, placed in patient areas, etc. | |
|  | | Information in the advertisement is accurate and consistent with the protocol and consent form. | |
|  | | **Advertisement to recruit research subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.** | |
| The name and address of the clinical investigator and/or research facility. | |
| The condition being studied and/or the purpose of the research. | |
| The time or other commitment(s) required of the subjects. | |
| The location of the research and the person or office to contact for further information. | |
| A clear statement that this is research and not treatment. | |
| A clear statement that participation is voluntary. | |
|  | | **Advertisement Content:** | |
| Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in consent or protocol. | |
| Does NOT promise “free treatment,” when the intent is only to say subjects will not be charged for taking part in the research. | |
| Does NOT include exculpatory language. | |
| Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type. | |
|  | | **For FDA-Regulated research, the advertisement content:**   N/A | |
| Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation. | |
| Does NOT make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device. | |
| Does NOT use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational. | |
| Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing. | |
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| 1. Will subjects be compensated for participating?  N/A | | | |
|  | | Amount of payment, proposed method, and timing of disbursement is not coercive or presents undue influence. | |
|  | | **All payments are described in the protocol including:** | |
| Amount | |
| Method | |
| Timing of disbursement | |
| To whom payment will be made (e.g., subject or parents if child subject) | |
|  | | Credit for payment accrues as the study progresses. | |
|  | | Payment is not contingent upon completing the entire study. | |
|  | | Plans have been made for distributing payments to participants: Is Payment, Reimbursement, Tangible Property properly designated?  Reimbursement is payment of the exact amount spent based upon subject providing receipt of cost associated with participation, i.e. presenting hotel room charge.  \*Mileage is considered payment when based upon map calculation of distance between two places.  \*Tangible property still requires that subject name, SSN, visit date, and address be recorded for tax purposes. | |
|  | | **The informed consent properly advises subjects of:** | |
| Payment method | |
| Maximum compensation to be paid | |
| Potential tax consequences | |
| Identifiers required to make payment: Social security number, name, visit date and address  These identifiers should also be listed in the HIPAA authorization section as identifiers collected for study purposes. | |
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