Study Title (Protocol Number)

Participant Recruitment, Retention and Adherence Plan Template

[Required components of the plan are in bold non-italicized font. *Suggested approaches and strategies and study-dependent components od the plan are in italicized font.***]**

I. **Pre-initiation phase**

A. Determine protocol staff assignments and document assignments

1. *Assign dedicated recruitment coordinator*
2. *Assign alternate recruiters*
3. *Determine site PI role*
    a) *Determine involvement (e.g., meet with every participant? consent every participant? see participant at every visit? etc.)*
    b) *Assure PI availability to coordinator*
    c) *Give appropriate decision-making authority to coordinator*
    d) *Monitor recruitment*
    e) *Meet w/ protocol staff regularly*
4. *Plan consistent site staff and trial contacts for patients (e.g., coordinator, PI, receptionist)*

B. Evaluate protocol design with respect to "recruitability"

1. *Evaluate feasibility of sample size*
    a) *Consider availability of target population considering demographics*
    b) *Consider availability of target population considering eligibility criteria*
2. *Consider protocol design effects on recruitment*
    a) *Possible effects of placebo*
    b) *Possible effects of participant access to study drug if it is FDA-approved*
    c) *Possible effects of potential toxicity*
    d) *Possible effects of complicated entry criteria and burdensome protocol procedures*
3. *Calculate availability of eligible participants based on*
    a) *Consult with potential participants - consider feasibility study/survey*
    b) *Review patient lists within each practice*
    c) *Review the literature*
    d) *Calculate*
        (1) *Number of <u>eligible</u> participants at each site*
        (2) *Estimate number of eligible enrolled participants/ total eligible participants*
    e) *Estimate accrual time (participants/month)*
4. *Consider protocol modifications (if recruitment goal is unrealistic)*
        (1) *Consider broadening eligibility criteria*
        (2) *Consider simplifying protocol*
        (3) *Consider decreasing sample size*
        (4) *Consider extending recruitment period*

C. Identify referral sources

1. *Contact referral bases*
    a) *Advocates*
    b) *Retirement communities*
    c) *Senior centers*
    d) *YMCAs, JCCs, etc*
    e) *Health clubs*

f) MD referrals
g) Churches
h) Community centers
i) Corporate strategies (i.e., enlist endorsement and cooperation from local industry to promote enrollment)
j) Alliances with disease specific organizations
(1) Patient advocacy groups
(2) Support groups
(3) Charitable organizations

2. Cultivate working relationship with non-oncology specialists (e.g., GI, surgery, pulmonologists, ENT, gyn)
3. Survey potential referral doctors, get letter of commitment if possible
4. Re-evaluate sample size

D. Determine and document metrics for evaluation of recruitment and retention performance

1. Plan for quick recognition of lagging enrollment
***a)* Create and document recruitment timeline with milestones and evaluation points**
b) Plan to monitor and document task completion for timeliness
(1) Regulatory requirements
(2) Weekly meetings
(3) Meeting minutes

2. Plan to evaluate and document strategies: outcomes
a) Plan to track number of participants enrolled in a defined time period as a result of each strategy
b) Create screening log forms with attribution to specific strategy and reasons for ineligibility, or non-enrollment
c) Plan to calculate cost of enrollment per participant
d) Plan to maintain and monitor screening/enrollment logs
e) Plan survey of participants' opinions re: strengths and weaknesses of strategies

3. Plan to track participant withdrawals and reasons for withdrawal

E. Train staff

1. Educate all participating staff re: protocol (after protocol is approved)
2. Develop and distribute protocol pocket cards
3. Provide Frequently Asked Questions document
4. Train support staff
a) Smooth clinic flow and hospitality
b) Procedural requirements (e.g., fasting)
c) Prepare procedures for when protocol is violated
5. Prepare script of protocol explanation

F. Promote comfortable and pleasant clinic environment/experience

1. Supply driving directions to schedulers
2. Coordinate well-organized clinic flow
3. Assure user-friendly test scheduling, drug dispensing, etc
4. Negotiate (if possible, insist upon) flexible appointment times (i.e., more than one day per week)
5. Plan to allow ample time for participants with the clinical trial staff

6. Schedule periodic meetings between the clinic coordinator and the protocol staff meetings

G. Ensure adequate budget

1. Adequately compensate staff
2. Consider recruiter's transportation to community, meetings
3. Consider participant compensation
4. Cover recruitment, retention and adherence tools (e.g., newsletter, mailings, protocol pocket cards, participant visit calendars, etc.)

H. Determine recruitment and retention strategies based on evaluation of protocol, target population, clinic, referral sources

1. Contact and inform referral sources
2. Advertisements
a) Newspaper
b) TV
c) Radio
d) Internet
e) Direct mailings
3. Public relations
a) Investigator interviews
b) Patient education
(1) Investigator or coordinator educational sessions to relevant community
(2) FAQ documents
4. Recruiters/study staff support
a) Newsletter for study sites/ consortium
b) Teleconferences for study sites/consortium
c) Recognition of high recruiters (within consortium or study site)
d) Frequent contact with participating site coordinators

5. Minority recruitment strategies

a) Perform cultural assessment of local community
b) Consider centralized minority coordinator
c) Consider matched ethnicity recruitment coordinator
d) Have translator available
e) Minority community liaison
f) Meet with minority community leaders
g) Go to community
(1) Meetings
(2) Churches

II. **Active recruitment phase**

A. Implement strategies as determined during pre-initiation phase of plan

B. Assess eligibility of individual potential participants

1. Begin supportive relationship with patient
2. Consider poor adherence and retention potential
a) Exclude participants unlikely to comply and stay on study – unless you can provide compensatory support and follow-up
(1) Known history of non-compliance/adherence
(2) Socially unstable
(3) Expressed difficulty with and numerous objections to protocol requirements

(4) *Cavalier attitude toward protocol*
(5) *Verbalized minimization of cancer risk*
(6) *Verbalized "active drug only"*

C. *Explore participant's objections to enrollment*
   1. *Clarify any misconceptions*
   2. *Offer to resolve manageable logistical problems*
   3. *Consider multiple objections as red flag indicating possible retention/compliance problems*

D. *Involve participant's social network in decision-making*

E. Continuously evaluate strategies as planned during pre-initiation phase of plan
   1. *Monitor and document task completion for timeliness*
      a) *Regulatory requirements*
      b) *Weekly meetings*
      c) *Meeting minutes*
   2. *Evaluate and document strategies: outcomes*
      a) *Track number of participants enrolled in a defined time period as a result of each strategy*
      b) *Maintain screening/enrollment log forms with attribution to specific strategy and reasons for ineligibility, or non-enrollment*
      c) *Calculate cost of enrollment per participant*
      d) *Survey of participants' opinions re: strengths and weaknesses of strategies*
   3. *Track participant withdrawals and reasons for withdrawal*
   4. *Rapidly implement modified or alternative plans if recruitment is lagging*

III. **Retention and adherence phase – Be proactive**

A. *Maintain communication with referring physicians re; participant progress*

B. *Establish and maintain rapport among staff during follow-up*
   1. *Newsletter*
   2. *All-site teleconferences*
   3. *Buddy system among coordinators*
   4. *Adequate staff compensation*
   5. *Staff recognition/awards*
   6. *Clinic non-protocol staff recognition*

C. *Establish and maintain rapport and communication with participants*
   1. *Identify and track attrition red flags*
      a) *Adverse effects*
      b) *Missed appointments*
      c) *Frequent appointment time changes*
      d) *Major personal or family events*
      e) *Health deterioration*
      f) *Loss of support system*
      g) *Do not promise support that cannot be maintained*
   2. *Adverse effects (AEs)*
      a) *Inform patients as to what to expect*
      b) *Have prepared AE management protocol*
   3. *Maintain current contact info*
   4. *Enlist support of participant's social network*

    a) *Transportation*
    b) *Encouragement*
    c) *Agent compliance*
5. *Consider establishing a support group*
6. *Provide remuneration as budgets permit*
    a) *Parking*
    b) *Time lost from work*
    c) *Transportation*
    d) *Child care*
7. *Ensure pleasant clinic visits*
    a) *Limit waiting room time*
    b) *Coordinate assessments (e.g., Blood work, imaging, etc.) with visits*
    c) *Provide refreshments*
    d) *Flexible scheduling*
    e) *Toll-free numbers*
8. *Ensure consistent staff contact person and access to PI*
9. *Establish schedule for contact with patient*
10. *Consider retention tools*
    a) *Calendars*
    b) *Newsletter*
    c) *Appointment reminder cards and calls*
    d) *Anniversary cards*
    e) *Certificates of appreciation and appreciation*
    f) *Tee-shirts, mugs, magnets*
    g) *Buddy system*
    h) *Support groups*