Clinical Trial/Gene Therapy Psychosocial Template

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Adult Psychosocial Assessment Template

Research and/or Gene Therapy

This template is an outline of recommended psychosocial assessment considerations for clinical trial participation and/or evaluation of psychosocial impact of gene therapy trial participation. This document is subject to change at the clinical expertise of the clinical social worker administering the tool in compliance with the NASW Code of Ethics and the health care institutions policies and procedures.
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Summary

Clinical Trial and/or Gene Therapy Psychosocial Assessment Template

**History & Need:** The engagement of clinical trials, and that of gene therapy has opened the blood disorder community to an expansion of care options through clinical trials. As part of the multidisciplinary care team in the federally funded hemophilia treatment centers, clinical social workers provide expertise to evaluate psychosocial barriers to care, supports, and socioeconomic impact.

**Purpose:** This Clinical Trial Psychosocial Template will provide standardized tools for clinical social workers to assist with evaluating psychosocial needs for patients considering Clinical Trials and/or Gene Therapy Clinical Trials.

**Use of tool:**
This template can be used in full or partial form at the discretion of the clinical social worker and their institution.

It is recommended fully licensed clinical social workers following the NASW Standards for Social Work Practice in Health Care assess patients considering clinical trials in the inheritable blood disorder community due to the complexity of psychosocial impact socially, emotionally, physically, mentally, and financially. Mental health clinicians of equal licenser and expertise are also appropriate pending the institution’s composition of the multidisciplinary team.

National Association of Social Workers (NASW) Standards for Social Work Practice in Health Care Settings ensure fully licensed social workers follow the ethical standards of providing clinical care, and ensure competences for care spanning from clinical assessment and quality improvement through cultural and linguistic competencies.
**Interview Specifics**

Date of interview: ____________  Gene Therapy  Research Trial
Interviewer: ____________  Interviewee: ____________
Study Name: ____________ Pharma Co: ____________
Study Phase: ____________ Duration of Study: ____________

Has the patient been medically cleared to participate in this study/Gene Therapy?
(Otherwise healthy; diabetes, history of cancer, heart disease, glaucoma, high blood pressure, etc.)
No  Yes  Document in record  Document pending

*This MSW Psychosocial assessment will assess for biopsychosocial barriers and resource needs.*

**Demographic Information**

Patient Name: ___________________________  Date of Birth: ____________
Medical Record #: ___________________________  Age: ____________
Race: ___________________________  Gender: ____________
Diagnosis: ___________________________  Diagnosis date: ____________
Primary Physician: ___________________________  PCP Location: ____________
Hematologist: ___________________________
HTC: ___________________________
Patient Primary Language: Spoken: ____________  Written: ____________
Interpreter Needed: Yes  No  Language: ____________

**Household Composition**

Adult: Patient Married: ____________  Partner/ Spouse: ___________________________
Authorized consent to speak with spouse: ____Yes  ____ No  Children: ___________________________
Is there guardianship in place? ___________________________
Advanced Directive on file: ____Yes  ____ No  Healthcare Power of Attorney: ____Yes  ____ No
Follow up Needed? Explain: ___________________________

**Education & Development**

Highest level of education: ___________________________  Occupation: ___________________________
Currently enrolled in school: ___________________________  Interested in further education: ________
Self identified learning: ___________________________
Days missed from work and/or school: ___________________________
Barriers to communication: ___________________________
Other: ___________________________
Medical History

Other illnesses and diagnoses _____________________________________________________________

Status: ____________________________________________________________________________

Compliance with current treatment plan for BDO: (based on categories from SIPAT page 2-of 17):

<table>
<thead>
<tr>
<th>Good (mostly)</th>
<th>Moderate (partially)</th>
<th>Limited (no consistency with dosing)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Comments: __________________________________________________________________________

Compliance with treatment plan for other illnesses:

<table>
<thead>
<tr>
<th>Good (mostly)</th>
<th>Moderate (partially)</th>
<th>Limited (no consistency with dosing)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Comments: __________________________________________________________________________

ADL/IADL/Mobility status/ use of DME: __________________________________________________________________________

Potential impact of Gene Therapy/Research/Clinical trial on current compliance and developmental status: _____________________________________________________________

Patient/Family Support/Resources

Patient/Family identifies the following as their primary support: (List info after checked section, and level of engagement and support)

☐ Immediate Family ____________________________________________________________

☐ Extended Family __________________________________________________________

☐ Partner _________________________________________________________________

☐ Friends _________________________________________________________________

☐ Mental Health Agency _______________________________________________________

☐ Disease Specific Agency ____________________________________________________

☐ Faith Community __________________________________________________________

☐ Social Organization ________________________________________________________

☐ Other (ex. Pain Specialist/etc.) ____________________________________________

☐ Safety Assessment: (Evaluation of potential abuse, neglect, exploitation, sex trafficking).

____________________________________________________________________________

Financial Resources

☐ Full-time Employment

☐ Part-time Employment

☐ Self Employed

☐ SSI/SSDI

☐ Child Support

☐ Public Assistance

☐ Patient Assistance Programs: _________________________________________________

Other Resources: (specify) ________________________________________________________

Social Security Disability Insurance (SSDI): Is the patient on disability? __Yes____No
Certified Disability Diagnosis: ________________________________

Will Gene Therapy/Research process or outcomes impact disability status or requirements? __Yes  
No

Explain:

**Financial Resources continued:**

Income:

- ☐ Meets usual expenses
- ☐ Exceeds usual expenses
- ☐ Doesn’t cover expenses

Notes:

______________________________________________________________________________

______________________________________________________________________________

Primary Health Insurance Provider:

Secondary Health Insurance Provider:

Dental Insurance: __________________________ Vision Insurance: __________________________

If unintended expenses occur that are not covered by the Gene Therapy/Research Trial, will  
financial assistance be needed?

- ☐ Depends on the amount  
- ☐ Assistance is appreciated but not needed
- ☐ Yes

- ☐ No

- ☐ Specifically anticipated need __________

- ☐ Notes/Concerns: ________________

**Transportation**

Distance to treatment center from home: ________________________________

Method of transportation:

- ☐ Public Transit
- ☐ Personal Vehicle
- ☐ Family/Friends
- ☐ Non-profit organization
- ☐ Medicaid
- ☐ Other: __________________________

Barriers for reliable transportation to medical care: ________________________________

**Lodging**

Review of facility rules and regulations with guests staying with patients in acute care.

If lodging arrangements are needed during Gene Therapy/Research, what type does the patient request:

- ☐ Local Residence
- ☐ Ronald McDonald House

- ☐ Hospitality House Program
- ☐ Motel/Hotel

Other: ____________________________________________________________________________
## Coping/Social

**Coping/Social: If confirmed factors, add expounding information**

<table>
<thead>
<tr>
<th>Noted formal Clinical Mental Health diagnosis and treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of mental health issues/medications</td>
</tr>
<tr>
<td>History of in-patient/out-patient treatment or hospitalization</td>
</tr>
<tr>
<td>History of drug use</td>
</tr>
<tr>
<td>History of alcohol use</td>
</tr>
<tr>
<td>History of marijuana use (medical or recreational)</td>
</tr>
<tr>
<td>History of domestic violence</td>
</tr>
<tr>
<td>Abuse, neglect, or exploitation issues</td>
</tr>
<tr>
<td>Legal Issues and/or history (probation/parole)</td>
</tr>
<tr>
<td>Alternative medications/holistic medications</td>
</tr>
<tr>
<td>History of opioid use</td>
</tr>
<tr>
<td>Caregiving responsibilities</td>
</tr>
<tr>
<td>Fear of medical care (needles, enclosed spaces, etc.)</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

**Notes:**
**Coping/Social Risk Assessment**

- no apparent risk factors
- have minimal issues but able to participate
- have issues that need to be resolved before successful participation

**Clinical Impressions**

**CLINICAL IMPRESSIONS (adaptation from The Valerie Fund Assessment Tool)**

<table>
<thead>
<tr>
<th>(Check all that apply)</th>
<th>Patient</th>
<th>Parent</th>
<th>Parent</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual Emotional Responses:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate &amp; normal range of emotions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gets appropriately upset, yet reasonable</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Emotional but manageable, can calm</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Disruptive/extreme expression of emotions</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Withdraws/shuts down emotionally</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Understanding of Research/Gene Therapy</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Adequate understanding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seeks information appropriately</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Passive, asks few questions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor or distorted comprehension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrealistic expectations</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Interactions with Treatment Team:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooperative, appreciative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriately assertive</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guarded, quiet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has difficulty participating or asserting self</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Compliant; passive aggressive, not engaged</td>
<td></td>
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<tr>
<td>Dissatisfied with team/process/care</td>
<td></td>
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<tr>
<td>Other:</td>
<td></td>
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</tr>
</tbody>
</table>

**Ability to Cope/Function:**

<table>
<thead>
<tr>
<th></th>
<th>Patient</th>
<th>Parent</th>
<th>Parent</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capable of participating in plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates ability to follow instructions</td>
<td></td>
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<tr>
<td>Adequate functioning, though limited/slow</td>
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</tr>
<tr>
<td>Capable of participating with guidance</td>
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<tr>
<td>Needs constant redirection &amp; focus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has difficulty following instructions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Is parent/child interaction appropriate? ____NA (adult patient) ____Yes ____NO ____Unknown
Explain (bond appropriate/caring or emotional inhibiting interactions/poor boundaries)


Does mental, physical, emotional state appear to be appropriate for GT/research? ____Yes ____No
Explain, include potential barriers or concerns


Research Trial/Gene Therapy

☐ Reasons for participating in trial/research
(Check all that apply)
☐ I’m not sure why I signed up
☐ Take an active role in my healthcare
☐ To receive medical care without insurance
☐ Improved quality of life
☐ Financial compensation
☐ Access to new medications & supplies
☐ Increased access to treatment team
☐ To help advance science in area of BDO

☐ To participate in building trust and decreasing fear about clinical trials
☐ Better outcomes for future generations
☐ Access without co-pays & deductible
☐ Increased knowledge of my disorder
☐ Trial medications work better
☐ Ability to opt out, withdraw consent
☐ Other, please explain

Consider asking about goals for outcomes, anticipated expectations around outcomes, use teach back method to assess literacy

Level of comfort with existing? knowledge of this trial and participation

☐ Very comfortable and able to move forward with the knowledge that I have
☐ Mostly comfortable with what I know but have a few more questions
☐ Slightly anxious about moving forward and have several questions for my treatment team
☐ Somewhat fearful and anxious and would like to temporarily postpone participation until I get more information and “feel better” about moving forward
☐ I realize that I do not want to move forward and would like to withdraw consent

Education on Gene Therapy Treatment (source www.hemophilia.org) Are you aware in addition to being a male over the age of 18 there are other important eligibility requirements that must be met:

☐ Currently, women & children under 18 are not able to participate in Gene Therapy
☐ Responses to gene therapy varies from person to person
☐ Different gene therapy patients may have different factor level results
☐ At this time it is unknown how long the effects of gene therapy will last
☐ Your need for factor after gene therapy will be assessed & monitored by your medical team
☐ You may be required to be on steroid medications for an extended period to make sure you tolerate therapy
☐ Right now, if gene therapy doesn’t work it can only be done once
☐ Gene therapy can’t be reversed or stopped
☐ There are risks associated with gene therapy
☐ Once you have gene therapy you will need to be monitored for several years after the therapy.
Educational Materials

Note to Care Team: NHF has extensive educational materials on clinical trails, gene therapy and more. Visit their website at www.hemophilia.org for more information or call NHF’s Information Resource Center (HANDI) at 800-424-2634, extension 2 or via email at: handi@hemophilia.org

Plan of Intervention

Customary and supportive interventions will be provided throughout the research/gene therapy process for all participants based on the identified needs Consider language for formatting recommendations of written recommendation for both options

<table>
<thead>
<tr>
<th>Provided</th>
<th>Is needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Targeted supportive counseling</td>
<td></td>
</tr>
<tr>
<td>Educational materials on research/gene therapy</td>
<td></td>
</tr>
<tr>
<td>Ongoing assessment (monitor progress in identified areas)</td>
<td></td>
</tr>
<tr>
<td>Crisis intervention counseling</td>
<td></td>
</tr>
<tr>
<td>Cognitive behavioral interventions</td>
<td></td>
</tr>
<tr>
<td>Referral for psychiatric evaluation</td>
<td></td>
</tr>
<tr>
<td>Assistance with practical/financial concerns</td>
<td></td>
</tr>
<tr>
<td>Counseling/Interventions with/for family members</td>
<td></td>
</tr>
<tr>
<td>Referral to community agencies, support groups</td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td></td>
</tr>
</tbody>
</table>

Notes:

Impression of Commitment to Care Plan: Level of understanding through teach back of required engagement and commitment to clinical trial participation

Knowledge & understanding of _______Gene Therapy _______Clinical Research Study

- **Good Understanding:** Patient/support system have a reasonable and clear understanding of commitment, action steps, requirements and potential outcomes of participation
- **Moderate Understanding:** Patient/support system need a minimal amount of education, information or literature for a reasonable and clear understanding of commitment, action steps, requirements and potential outcomes of participation
- **Poor Understanding:** Patient/support system unable to retain, process or transfer learning necessary to follow through with the commitment, action steps or requirements of participation.
Psychosocial Recommendation

☐ Recommend proceeding with Gene Therapy/Research
☐ Recommend proceeding with Gene Therapy/Research with concerns/interventions
  (Explain)__________________________________________________________________________

☐ Do not recommend proceeding with Gene Therapy/Research (Explain)
  (Explain)__________________________________________________________________________

Related Documents Tools:

(May vary with institutions and region)
☐ Gene Therapy and/or Clinical Trial Educational Document
☐ Communication/Behavioral Agreement
☐ Unbiased/Unbranded Educational Materials
☐ DPOA/Advanced Directive/Power of Attorney
☐ Guardianship documents
☐ Electronic Communication Consent
☐ Employer Disclosure
☐ School Disclosure