

## Summary of Next Steps for ATHN Affiliates

October 23, 2009

Programs	HTC Actions	Patient Actions	Legal/Regulatory Basis
<b>ATHN Affiliate</b>	ATHN Affiliate Agreement	n/a	Commitment to work together
<b>WebTracker</b> <ul style="list-style-type: none"> <li>▪ Clinical patient management tool</li> </ul>	DUBAA	n/a	Business associate component authorizes ATHN to provide support for the infrastructure used by the HTC
<b>ATHNdataset</b> <ul style="list-style-type: none"> <li>▪ Limited data set stripped of the 16 patient identifiers</li> </ul>	DUBAA	Patient Authorization	Creation and data sharing of a limited data set governed by HIPAA Privacy Rule; Viewed as IRB exempt research; Patient authorization is not required by law, but required by ATHN to support openness and transparency
<b>ATHNready</b> <ul style="list-style-type: none"> <li>▪ Emergency preparedness service delivered by the HTC</li> </ul>	Available within WebTracker	No authorization needed	ATHN Privacy Policy (in development)
<b>Research Study Protocols</b> <ul style="list-style-type: none"> <li>▪ Projects that go beyond analysis of the ATHN dataset</li> </ul>	IRB approval needed	Patient Consent required	Protection of Human Subjects: 45 CFR 46  Food and Drug Administration Regulations: 21 CFR Parts 11, 50, 56
<b>ATHNadvoy</b> <ul style="list-style-type: none"> <li>▪ Infusion and bleed log delivered by the HTC</li> <li>▪ Stewardship of ATHN</li> </ul>	Current users: Must authorize transfer from Baxter to ATHN to continue use and access by its patients. Non-users: No action	Current users: Must authorize transfer of current data to the stewardship of ATHN for continuity of service. Non-users: No action	Baxter's agreement with Advoy users. Time limited transition. Transition details at <a href="http://www.advoy.com/transition">www.advoy.com/transition</a>

